DEPARTMENT OF HEALTH & HUMAN SERVICES 9 Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

PR 37
(74FR17794)

June 1, 2009

Ms. Merri Horn
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555

RE: Public Comments on the Part 37 Preliminary Draft Language
(Background Investigation and Access Control Program only)

Dear Ms. Horn,

In response to the Request for Comments by the Nuclear Regulatory Commission on the draft language of 10 CFR 37, Physical Protection of Byproduct Material, the National Institutes of Health (NIH) wishes to submit the following comments on behalf of the approximately 650 individuals who access and use category 1 quantities of radioactive material at the NIH:

1. The NIH is relieved from the access authorization program for many individuals through the allowance of 37.41(k), since all NIH badge-holders are subjected to a U.S. government criminal history record check pursuant to a federal HSPD-12 compliance program involving fingerprinting and an FBI identification and criminal history records check as a condition of their campus access. Unescorted access to category 1 quantities of radioactive material is not granted unless that check has been favorably adjudicated within the last five years.

2. In a recent dialogue with NRC headquarters' staff, it became apparent that the exact wording of 37.41(k) has fostered the expectation that compliance with this relief provision is contingent upon *completion* of (among other examples) a National Agency Check. However, this is not the case; a National Agency Check entails much more than the stated requirement of fingerprinting and an FBI identification and criminal history records check. To require a full completion of a National Agency Check disregards the eligibility of an individual to be designated "trustworthy and reliable" (T&R) after the initial steps of the National Agency Check are completed and adjudicated. In the NIH experience of the last several years, T&R eligibility can be met through fingerprinting and an FBI identification and criminal history records check with a turn-around on the order of weeks, whereas completion of the National Agency Check (of which the fingerprinting and FBI identification and criminal history records check is only a part) entails a turn-around on the order of a half-year or more. A regulatory interpretation that requires the *completion* of a National Agency Check represents a significant hardship to a research population who is often only employed on a short-term basis. Visiting, post-baccalaureate and post-doctoral fellows comprise a large percentage of irradiator users, and are expected to work on projects independently. Escorted access to irradiators is a severe hardship for this population, who often work late hours and require repeat experiments; an inability to approve these individuals as T&R immediately after they have met all stated requirements will cause an unnecessary delay in their research and will slow the pace of biomedical research.

3. The NIH finds the arbitrary deadline of 60 days for the collection of investigatory information as stated in 37.23(a) to be untenable. The NIH T&R determination includes the

Template = SECY-067 DS 10

Office of Personnel Management (OPM) requirement that all background investigation data be submitted within 120 days of the fingerprinting and FBI identification and criminal history records check. Even then, many individuals find it difficult to complete the requirements in that timeframe, especially if they are foreign nationals or have a significant history of residences, employment, and/or educational institutions. The NIH and OPM review process itself can often exceed 120 days; this results in the need for the individual to repeat the fingerprinting and FBI identification and criminal history records check, causing an interruption to the individual's work and an extra cost to the government. While the NIH can understand the need to only consider recent investigatory information to be valid for purposes of a T&R determination, limiting such information to 60 days is believed to be impractical, for no just cause.

4. The draft wording of 37.25(a) states the minimum requirements for the components of a background investigation. Included here are several requirements not previously stated in the Orders for Increased Controls; namely, verification of military history and a credit history evaluation. The NIH questions whether there is added value to a background investigation by including these criteria. We note that at least in the instance of a credit history evaluation, the requirements of 37.25 would not be met by completion of a National Agency Check. A higher order OPM investigation (National Agency Check and Inquiries plus Credit) at the public trust level would be required, which necessitates added processing time and added cost. Yet the relief from 37.25 and 37.31 is understood to be met by completion of a National Agency Check.

5. The requirement of 37.25(a)(5) does not specifically state U.S. military history; for foreign nationals who disclose military history, it appears that the requirement would include the need to verify such information regardless of country.

6. No allowance has been given to the transmission of fingerprints to the FBI by an agency outside of the NRC. A fully-accredited fingerprint collection program exists at the NIH in support of its HSPD-12 compliance, and approval for the NIH to utilize this method of fingerprint collection and FBI transmission was made by the NRC in 2005. It is short-sighted to limit the wording of 37.31(b) to only permit fingerprint collection and transmission to the FBI by the NRC, and it is contrary to the information given to the NIH by the NRC in 2005.

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 currently being met using category 1 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 yours,

Michael Gottesman, M.D.
Deputy Director for Intramural Research, NIH

cc: Mr. Robert Zoon, Radiation Safety Officer, NIH
Dr. Ira Levin, Chair, Radiation Safety Committee, NIH

Rulemaking Comments

From: Horn, Merri
Sent: Monday, June 15, 2009 7:13 AM
To: Rulemaking Comments
Subject: FW: NIH Comments on Part 37 preliminary draft language
Attachments: NRC Comments Part 37 (signed).pdf

Attached is comments from NIH on the Part 37, Subpart B (74 FR 17794)

From: Ribaudo, Cathy (NIH/OD/ORS) [E] [mailto:ribaudoc@ors.od.nih.gov]
Sent: Thursday, June 11, 2009 4:29 PM
To: Horn, Merri
Subject: RE: NIH Comments on Part 37 preliminary draft language

Here is the signed version. Thanks!!
Cathy

From: Merri Horn [mailto:Merri.Horn@nrc.gov]
Sent: Thursday, June 04, 2009 1:12 PM
To: Ribaudo, Cathy (NIH/OD/ORS) [E]
Subject: RE: NIH Comments on Part 37 preliminary draft language

I received your comments and the "unofficial" version is adequate for my needs. When you get the signed version, you may send it to me or submit it via any of the methods mentioned in the FRN. The comments would then be docketed and included in the official files.

Merri Horn
Senior Project Manager
Nuclear Regulatory Commission
301.415.8126
Merri.Horn@nrc.gov

From: Ribaudo, Cathy (NIH/OD/ORS) [E] [mailto:ribaudoc@ors.od.nih.gov]
Sent: Wednesday, June 03, 2009 4:21 PM
To: Merri Horn
Subject: NIH Comments on Part 37 preliminary draft language

Hi Merri,
Thanks so much for accepting this. We'll send the "official" (signed) submission as soon as I get it from NIH management.

Best,
Cathy

Catherine Ribaudo, Chief
(Radioactive) Materials Control and Analysis Branch
Division of Radiation Safety, NIH
Building 21, Room 104
Bethesda, MD 20892-6780

301-594-1303 (direct)
301-496-5774 (main)
301-496-3544 (fax)
cribaudo@nih.gov

Received: from HQCLSTR01.nrc.gov ([148.184.44.76]) by OWMS01.nrc.gov
([148.184.100.43]) with mapi; Mon, 15 Jun 2009 07:13:12 -0400
Content-Type: application/ms-tnef; name="winmail.dat"
Content-Transfer-Encoding: binary
From: "Horn, Merri" <Merri.Horn@nrc.gov>
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>
Date: Mon, 15 Jun 2009 07:13:11 -0400
Subject: FW: NIH Comments on Part 37 preliminary draft language
Thread-Topic: NIH Comments on Part 37 preliminary draft language
Thread-Index: AcnkiMq+klG0Fg+2S72PCrk6YGj7jgAroJdgAWb2MPAAtb7FsA==
Message-ID:
<D841D501B2C4D244B75AB897F70C14949A1650496C@HQCLSTR01.nrc.gov>
Accept-Language: en-US
Content-Language: en-US
X-MS-Has-Attach: yes
X-MS-Exchange-Organization-SCL: -1
X-MS-TNEF-Correlator:
<D841D501B2C4D244B75AB897F70C14949A1650496C@HQCLSTR01.nrc.gov>
MIME-Version: 1.0