96-027

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DCS
PDR

September 23, 1996

Mr. James Lieberman
Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852-2738

Re: Reply to a Notice of Violation and Answer to Proposed Imposition of Civil Penalty

Docket No. 030-01786
License No. 19-00296
Inspection Reports: 30-1786/95-002 (REDACTED)
and 030-1786/95-203

Dear Mr. Lieberman:

Enclosed, in reply to Mr. Hubert J. Miller's letter to me of August 23, are responses to each of the five violations (four Severity Level IV violations and one Severity Level III violation) cited in the Notice of Violation and Proposed Imposition of Civil Penalty forwarded with Mr. Miller's letter, and an answer protesting the proposed imposition of a civil penalty of $2,500 for the Level III violation.

As stated in my May 23 letter to Mr. Thomas J. Martin, Administrator, Region I, Nuclear Regulatory Commission (NRC), the National Institutes of Health (NIH) will continue to work with the NRC, as it always has, to ensure the safe use of radioactive material at the NIH, including appropriate security for radioactive materials. However, we have the following specific concerns regarding the Notice of Violation.

I. NRC's Apparent Failure to Consider NIH's May 23 Submission

Neither Mr. Miller's letter nor the Notice of Violation indicate in any meaningful way that NRC considered NIH's showing in our May 23, 1996 submission that: (i) many of the alleged violations never occurred or were of minor safety or environmental concern so that the Severity Level IV findings were not justified, and (ii) that any remaining alleged violations did not exceed Severity Level IV. We believe these conclusions were well established by the extensive evidence and arguments in our May 23 submission and thus we incorporate that evidence and argument in

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our reply and answer to the Notice of Violation. In repeating these arguments, however, we are placed at a disadvantage, because we do not know whether or how NRC weighed the arguments, or its reasoning in not accepting them. We need to understand why we were cited, not only in order to make a meaningful response, but also to prevent future violations through appropriate corrective action.

Section V of NUREG-1600, 60 Fed. Reg. At 34386, provides that licensees will normally be requested to provide a written response to an inspection, if a predecisional enforcement conference is not held. Section V indicates that the purpose of providing licensees an opportunity to respond, either at an enforcement conference or in writing is to enable the NRC to make an informed enforcement decision. Having established a procedure that on its face provides licensees a meaningful opportunity to respond to inspection reports and notices of violation, the NRC must ensure that the opportunity is meaningful by actually considering each response and stating the reasons why it has either accepted or rejected the evidence and argument presented.

Basic fairness and due process require such a reasoned, responsive process. As stated in Vol. II,Davis,Kenneth C., Administrative Law Treatise, 9.5 at p. 48 (3rd ed. 1994), the four core procedural safeguards are: notice of the proposed action and the grounds for it; an opportunity to present reasons why the action should not be taken; an unbiased tribunal; and a statement of the reasons for the decision. Citing: Friendly, Some Kind of Hearing, 123 U.Pa. L. Rev. 1267 (1975). Note that three of these four core safeguards relate to the tribunal advising the affected party of the grounds for the action and the affected party being given an opportunity to respond. Thus, a clear statement of the reasons for governmental action and a meaningful opportunity to respond are basic tenets of fairness and procedural due process.

In those few instances where NRC does state reasons for its conclusions, the brief references create confusion. For example, in section II.C.1. on page 3 of the Notice of Violation, NIH is cited for violating a license condition that requires workers to complete successfully a formal training course entitled, "Radiation Safety in the Laboratory," prior to using radioactive materials. Yet the violation described in the Augmented Inspection Team (AIT) Report, at pages 5, 18, 21 and 22 is only a failure to document the workers' receipt of informal radiation safety training prior to their attending the formal "Radiation Safety in the Laboratory" training session. The AIT Report specifically states that the NIH license permits use of

radioactive materials prior to the formal training if the Authorized User certifies that the informal training has been provided. Thus, the Notice of Violation significantly changes the violation to which NIH responded previously; the only explanation for this significant change is that "it is not acceptable under your current license to permit individuals to use license material before receipt of the course 'Radiation Safety in the Laboratory'." August 23, 1996 letter to Michael Gottesman from Hubert Miller, p. 3. That statement is not accurate, as we explain in detail at page 7 of the enclosed Reply To Notice Of Violation. The NIH license was amended to permit workers to use radioactive materials prior to their attending the formal radiation safety training course, if they first received radiation safety orientation, or other safety training commensurate with the work to be performed.

In summary, the failure of NRC to explain more clearly the basis for its actions and to address the evidence and arguments in the previous NIH response deprives NIH of a fair opportunity to demonstrate its compliance with NRC requirements and is inconsistent with the purposes of enforcement action stated in NUREG-1600, i.e., as a deterrent to emphasize the importance of compliance and to encourage the prompt identification and comprehensive correction of violations. NUREG-1600, Sec. I., 60 Fed. Reg. At 34383.

II. NRC's Failure to Consider Mitigating Factors

In establishing severity levels and proposing a civil penalty, the NRC has failed to properly weigh the pertinent factors and to give NIH appropriate credit for its longstanding good safety record and its prompt and comprehensive corrective action under the difficult circumstances posed by a changing enforcement climate.

In over three decades of using radioactive materials in its research, the NIH has never previously been the subject of escalated enforcement action by the NRC, and NIH's use of radioactive materials has never resulted in any negative health consequences to NIH workers or to the public. Prior to May 1994, the security of radioactive materials from deliberate misuse was not raised as an issue by the NRC apparently because the amounts used in our laboratories are small, and the areas in which radioactive materials are used are clearly marked to prevent inadvertent exposure to radioactive materials in use or storage. In a significant departure from prior practice, the NRC issued a Confirmatory Action Letter in May, 1994, imposing more stringent security requirements. In response to that letter, the NIH

Radiation Safety Program developed new requirements that radioactive materials above certain thresholds of radioactivity be secured in locked containers or through close surveillance. Subsequently, following the routine inspection of the NIH by the NRC ending on June 30, 1995, the Confirmatory Action Letter of 1994 regarding security was closed out by the NRC.

Following the deliberate contamination that occurred at the end of June 1995, both the NIH and the NRC were convinced that enhanced control of radioactive materials was needed to assure NIH staff and the public that there would be no unauthorized access to radioactive materials. The final NIH security policy that was approved and distributed to all users on July 21, 1995, reflected those convictions. The final NIH security policy was clarified on October 26, 1995, to include NRC's requirement to secure radioactive waste and to require security measures for any quantity of radioactive material, so that locking was required for any unoccupied room containing any unsecured radioactive materials or waste. On that same date, NIH initiated a security surveillance program. It must be emphasized that all these steps were taken prior to NIH being advised, through the issuance of the AIT Report on January 29, 1996, that the single breach of security found on July 6, 1995, was considered sufficiently significant by the NRC to be identified with the security weaknesses found subsequently in October and November. On January 19, 1996, NIH submitted to the NRC a request for a license amendment to redefine NIH's security policy. The NRC has not yet acted upon that request.

The security policies developed and enforced by the NIH in 1995 imposed increasingly strict security requirements for the storage and control of radioactive materials, in line with NRC's changing expectations. Currently, licensed materials of any quantity are required to be in locked storage when unattended. The Radiation Safety Program conducts a program of surveillance monthly to ensure compliance with the requirements and the Radiation Safety Officer takes swift, appropriate enforcement action when noncompliance is discovered, including the suspension of the privilege to use radioactive materials in certain cases. As detailed in my May 23 letter to Mr. Martin, these strict standards for the security of radioactive materials have necessitated very significant changes in the way our scientists have conducted research for many years. Accordingly, despite our best efforts, there have been rare lapses on the part of individual scientists in complying with the new requirements.

Given NIH's longstanding record of compliance with NRC requirements, it is apparent that the significant change in enforcement standards has been a major contributing factor to the security violations for which NRC now seeks to impose a civil penalty. We show in the enclosed Answer To A Notice Of Violation how the NIH corrective action has been prompt and comprehensive

and why the occurrence of some additional violations does not establish the lack of such corrective action. Essentially, this is a situation in which the NIH has worked diligently to meet more stringent standards for the security of radioactive materials, but, as one would expect when approximately 6000 workers must meet stringent standards after many years of conducting research under more lenient standards, human error has led to violations. It is significant that the violations for which NIH is being cited occurred within three months of the adoption of NIH's final security policy. It is inherent in the nature of human beings and their institutions that significant changes in behavior take time; certainly longer than three months. Furthermore, the few instances of noncompliance posed little or no risk of harm because (i) only low levels of radioactivity were involved, (ii) the materials were in laboratories clearly identified as areas in which radioactive materials were stored or in use, and (iii) the materials were stored in posted refrigerators, in clearly labeled vials. Considering all these circumstances, the NIH corrective action has been prompt and comprehensive as noted by NRC inspectors (pp. 19-21, AIT Report) and there has been no more than minimum risk to health and safety (News Release from the Subcommittee on Human Resources and Intergovernmental Relations, March 21, 1996).

Section III of NUREG-1600, 60 Fed. Reg. at 34384, recognizes that because the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, judgment and discretion must be exercised in determining appropriate severity levels and penalties for violations. Consistent with that recognition, we ask that the NRC exercise judgment and discretion here: (1) to fully consider and address the evidence and arguments we have presented herein and previously regarding the establishment of violations and/or severity levels and adjust its findings accordingly; and (2)to consider fully the circumstances in which the security violations occurred, including NIH's past safety record, the safety significance of the violations, the significant changes that were made in the security standards, NIH's prompt and comprehensive corrective action and the fact that the violations occurred a short time after the change in NIH security policies. On the basis of those considerations, the NRC should retract the civil penalty either through application of the civil penalty assessment process, or through the exercise of NRC's discretion to adjust civil penalties notwithstanding the outcome of the civil penalty assessment process.

This submission has been prepared from various sources within the NIH. I have first-hand knowledge of some of the facts, and as to other facts of which I do not have such knowledge, I believe them to be true and correct. I declare, under penalty of perjury that

this submission is true and correct to the best of my knowledge and belief based upon my review of the available records, statements and other relevant information.

Sincerely,

Michael M. Gottesman

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

Enclosures

cc:
Hubert J. Miller
Regional Administrator, Region I

Sworn to and signed before me, a Notary Public in and for Montgomery County, Maryland, the 23rd day of September 1996, at 9000 Rockville Pike, Bethesda, Maryland.

Dated: 9/23/96

Patricia A. Kvochak

Patricia A. Kvochak

My Commission expires 2/21/00

REPLY TO NOTICE OF VIOLATION

Department of Health and Human Services
National Institutes of Health
Bethesda, Maryland 20892

Docket No. 030-01786
License No. 19-00296-10

The National Institutes of Health (NIH) is responding to each of the alleged five violations (one Severity Level III violation and four Severity Level IV violations) cited in the Notice of Violation and Proposed Imposition of Civil Penalty forwarded with Mr. Hubert J. Miller's letter of August 23. Each alleged violation is identified and the five items which must be addressed under the Notice are presented in order for each alleged violation.

I. Violation of Security Requirements

(1) NIH denies that a Severity Level III violation has occurred.

(2) As the bases for its denial that a Severity Level III violation has occurred, NIH incorporates from its May 23 submission to NRC the discussion of Apparent Violations (1) and (A) (pages 1-3 and 21-25 of the Specific Responses of NIH To Apparent Violations Found In Inspection Reports 030-01786/95-002 (REDACTED)and 030-01786/95-203) and the Factors for Consideration in Determining Severity Levels of Apparent NIH Violations, and further argues as set forth below.

Under Sec. IV of NUREG-1600 Severity Level III violations, "are of very significant regulatory concern," while Severity Level IV violations "are less serious but are of more than minor concern, i.e., if left uncorrected they could lead to a more serious concern." 60 Fed. Reg. at 34385. The Notice of Violation cites Supplements IV and VI of NUREG-1600 in support of the NRC determination that a Severity Level III violation has occurred. Supplement IV, 'Health Physics (10 CFR Part 20)" gives as an example of a Severity Level III violation in paragraph C.12, "a significant failure to control licensed material." 60 Fed. Reg. at 34400. The alleged violations at NIH involving the control of licensed material are not significant because (1) control was maintained through the fact that the materials were in posted laboratories at all times and were stored in posted refrigerators in properly labeled containers, and the period of time during which the materials were not under surveillance was brief; (2) NIH has made extensive, good faith corrective efforts during the transition to more stringent enforcement standards to ensure compliance, but human oversight has resulted in violations; and (3) the violations pose little or no risk of harm because of the low levels of radioactivity that are involved. Because the degree of control maintained by NIH that resulted in the alleged violations was acceptable to NRC for many years, and NIH has made extensive, good faith efforts to comply with more stringent standards that were first enforced in 1994, the failure during

this transitional period to maintain in a few laboratories a new, higher level of control cannot reasonably be considered "a significant failure to control licensed material." This is not a comparison between control and no control, but rather a comparison of degrees of control, where the lesser degree of control had been shown for many years to be sufficient for the protection of workers and the public, because of the low levels of radioactivity involved. See Radiation In Medicine, A Need For Regulatory Reform, pp. 100-101, (Institute of Medicine, 1996).

Supplement VI, "Fuel Cycle and Materials Operations," which NRC cites in support of its finding of a Severity Level III violation, provides an example of a Severity Level III violation in paragraph C.1., "a failure to control access to licensed materials for radiation purposes as specified by NRC requirements." 60 Fed. Reg. at 34401. We do not believe this example can reasonably be applicable to the case at hand, because its standard for failure to control conflicts with the "significant failure" standard in Supplement IV. (As discussed above, there was no significant failure to control licensed materials at the NIH.) Furthermore, the "access...for radiation purposes" seems to refer to access for medical treatment or diagnostic purposes, a use that was not involved in the alleged violations at NIH. We note that in paragraph D.2 of Supplement VI "other violations that have more than minor safety or environmental significance" is an example of a Severity Level IV violation. 60 Fed. Reg. at 34402. We believe the non-significant security violations involved here are in this category, so that even if Supplement VI applies, the applicable severity level is IV.

For much the same reasons as set forth above, it is not appropriate to escalate this alleged violation to a Level III violation on the basis of repetitive or aggregated violations. The August 23 letter forwarding the Notice states that the determination of a Severity Level III violation is based on "the repetitive nature and number of examples of the violation." NUREG-1600 states that the decision to escalate the severity level of a repetitive violation will depend on the circumstances, such as the number of times the violation has occurred, the similarity of the violations and their root causes, the adequacy of previous corrective actions, the period of time between the violations, and the significance of the violations. 60 Fed. Reg. at 34385.

We believe the NRC has incorrectly applied these factors in finding a Severity Level III violation and that when these factors are properly balanced they favor no escalation of the severity level. Here, the number of violations is small, especially when compared to the number of restricted use areas in the NIH research program (0.2.%) or to the number of workers using radioactive materials. It is our view that the recurrence

of this type of violation should not be considered a repeat violation unless it occurs in the same laboratory. This is because the cause of this type of violation is not a failure of the NIH Radiation Safety Branch (RSB) to train workers, promulgate security requirements, or respond quickly to violations, but rather lack of attention and carelessness on the part of some researchers.* Given this cause, enforcement action against one laboratory does little to prevent a lapse of attention in another laboratory. This same reasoning supports not aggregating the violations. As stated in NUREG-1600, 60 Fed. Reg. at 34385, aggregation is to:

> focus the licensee's attention on the fundamental underlying causes for which enforcement action appears warranted and to reflect the fact that several violations with a common cause may be more significant collectively than individually and may therefore, warrant a more substantial enforcement action.

Here, there is no fundamental underlying cause or common cause that can be eliminated by NIH, but rather individual causes as diverse and unconnected as the individuals involved. The only way to stop human error is to stop human endeavor, a solution that is unacceptable. The unconnected occurrences are no more significant collectively than individually. Each is a separate occurrence and the probability of any harm resulting from it must be calculated on the basis of that event, not on whether similar but unconnected events preceded or followed that event. Accordingly, the recurrence of these unconnected violations is not an indication of the adequacy of previous corrective actions. Those corrective actions should be judged on the basis of their scope, content, and potential deterrent effect, not on the basis of whether they eliminate all human error. Under this standard, NIH corrective action has been adequate and the NRC so concluded at pages 19-20 of the Augmented Inspection Team Report. For all these reasons there is no reasonable basis for escalating the security violations because of "the repetitive nature and number of examples of the violation."

(3) The corrective steps that have been taken are set forth at pages 2-3 and pages 24-25 of the Specific Responses of NIH to Apparent Violations Found in Inspection Reports 030-01786/95-002 (Redacted) and 030-01786/95-203 a part of NIH's May 23 response.

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*In Radiation in Medicine, A Need for Regulatory Reform, p. 117 (Institute of Medicine, 1996), it is stated: "By educating health care workers, and by circumscribing their actions, human errors may be minimized. However, some number of mistakes will always, unavoidably, be made and no amount of training or double-checking can erase that fact."

The results of these corrective actions are that all researchers are, or should be aware of the security requirements, but human error still results in some violations that are self-identified by the NIH. None of these violations has resulted in any radiation exposure of an NIH employee or a member of the public.

(4) The NIH will continue to pursue diligently the current corrective actions. The NIH believes that the most reasonable and effective corrective action will be the establishment of an enforcement policy that is directed toward quantities of radioactive materials that pose a real risk of harm; thus limiting the potential for human error by focusing on significant safety risks that all will recognize as such. See Radiation in Medicine, A Need For Regulatory Reform, p. 101 (Institute of Medicine, 1996) where the Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission states: "Several RSOs stated that regulations and procedural requirements that are 'clearly out of line with common sense' erode the collaborative relationship between radiation protection staff and users of licensed materials; for this reason, these experts believe that such stringent requirements and aggressive enforcement strategies may ultimately reduce rather than heighten safety."

(5) The NIH believes that full compliance has largely been achieved, given the large number of users of radioactive materials at the NIH, the potential for human error, and the strict enforcement standards NRC applies to low level radiation materials.

II. Other Violations - Failure to Issue and Wear Dosimetry

(1) NIH denies that this is a Severity Level IV violation and also denies the parts of the violation claiming that NIH did not supply extremity dosimetry to eight individuals and that five individuals did not wear the extremity dosimetry.

(2) The bases for the NIH denial are set forth in the discussion of Apparent Violation (c) (pages 29-33 of the Specific Responses) in the May 23 NIH submission. In brief, this is a self-identified violation, based entirely on the actions and records of the NIH RSB. Those records do not support the parts of the violation claiming that extremity dosimetry was not issued to eight individuals and that five individuals did not wear the extremity dosimetry that was issued to them. Rather, the RSB investigation found that all 13 users had been issued badges, that all but one researcher were wearing the dosimetry, and that researcher was not required to wear dosimetry because of the small amount of P-32 he was using.

The remaining part of the alleged violation, that numerous individuals failed to return dosimetry, is not of sufficient significance to warrant the Severity Level IV finding, particularly given that persons using P-32 at NIH are not required to wear dosimetry, and, upon identification of the failure to return by the RSB, the badges were returned and no measurable exposures were detected. Furthermore: (1) the Special Team Inspection (STI) Report concluded at page 22 that the dosimetry program was in compliance with Subpart C of 10 CFR Part 20 and was effective in monitoring occupational external dose; and (2) NRC Information Notice No. 90-01, January 12, 1990, states, "NRC will not generally issue a Notice of Violation for a non-repetitive Severity Level IV or V violation that is self-identified, properly corrected and reported (if required)." (Emphasis in original.) Under these circumstances, the violation cannot reasonably be established as a Severity Level IV violation, i.e., one that is of more that minor concern, so that if left uncorrected it could lead to a more serious concern. Sec. IV NUREG-1600, 60 Fed. Reg. at 34385. Rather, it should be determined to be a violation of minor safety or environmental concern, a Non-Cited Violation that should not have been formalized into a Notice of Violation. Id.

(3) The corrective action for this self-identified violation had been completed at the time of the STI inspection and there was no continuing violation. Those corrective actions are described at page 32 of the Specific Responses part of the May 23 NIH submission.

(4) The corrective steps described in the May 23 submission will avoid further violations.

(5) Full compliance has been achieved as described in (3) above.

III. Other Violations - Incomplete Forms NIH 88-1

(1) NIH denies that this is a Severity Level IV violation.

(2) The bases for the NIH denial are set forth in the discussion of Apparent Violation (3), (pp. 8-10 of the Specific Responses) and Apparent Violation (B), (pp. 26-28 of the Specific Responses) in the May 23 NIH submission. As stated therein, the two parts of the alleged violation, whether considered individually or cumulatively, posed only minor safety or environmental concerns that were below the level of significance for Severity Level IV violations and thus this violation should not have been formalized into the Notice of Violation. NUREG-1600,Sec. IV, 60 Fed. Reg. at 34385.

The first part of the alleged violation is that between October 3 and November 20, 1995, NIH allowed users to request the purchase of radioactive materials electronically without the signature of

the Authorized User (AU). The correction of this alleged violation was NRC approval on November 20, 1995 of a license amendment permitting electronic requests for radioactive materials, without the signature of the AU. Thus, because NRC approved a license amendment that permitted continuation of the same practice for which NIH is being cited for a violation and NRC would not have approved that amendment if it raised significant safety or environmental concerns, a priori, such concerns could not have been raised by the same practice for the 47 day period prior to NRC approval of the license amendment. Accordingly, we do not see how this can be considered anything other than a technical violation (failure to submit promptly a request for amendment of license) of no more than minor safety or environmental concern, that is not appropriate for formal enforcement action.

The second part of the alleged violation is that one 88-1 form submitted for the purchase of radioactive materials received on September 9, 1994, listed as the only user an individual who had left NIH; thus the form did not properly identify the persons who were intended to use the materials. As shown in our May 23 submission, the signing and submission of this form by the Authorized User was an inadvertent error that did not result in any use of materials by untrained users. Thus, this single failure to list the proper user on a form 88-1 is a technical violation that raises no more than minor safety or environmental concerns. As such, it should not be part of the Notice of Violation.

(3) The license amendment was the corrective action for the first part of this alleged violation. The corrective action for the second part of the violation is described at page 10 of the Specific Responses part of NIH's May 23 submission.

(4) No further corrective action is necessary.

(5) Full compliance was achieved through the corrective action that was described in NIH's May 23 submission.

IV. Other Violations - Failure to Provide Training for New Users of Radioactive Materials

(1) NIH denies that the first and second parts of the alleged violation, as they are stated on page 3 of the Notice of Violation, violate either NRC regulations or the conditions of NIH's license. To the extent there was any violation arising from the failure of NIH to certify the provision of training in accordance with its license, it was a technical violation that did not constitute a Severity Level IV violation.

(2) The general bases for the NIH denial are set forth in the discussion of Apparent Violation (4), (pp. 11-13 of the Specific Responses) and Apparent Violation (E), (pp. 38-41 of the Specific Responses) of the May 23 NIH submission. The first part of the alleged violation stated in the Notice of Violation is that two researchers did not receive the formal "Radiation Safety in the Laboratory" training prior to their use of radioactive materials. However, there is no NRC regulation or condition of the NIH license that requires researchers to complete the formal training prior to their use of radioactive materials. Rather, as the NRC recognized at pages 21-22 of its AIT Report, the NIH license permits the use of radioactive materials by individuals under the supervision of an Authorized User (AU) before receipt of formalized training, as long as the AU certifies to the provision of the training described in the "Radiation Safety Orientation for New Personnel Planning to Use Radioactive Material" training packet. AIT Report, pages 21-22. Thus, the violation, as described in the AIT Report, was that because of this failure to certify or document that the users received informal training, the use of radioactive materials prior to the formal training of the researchers on November 29, 1994 was not in accordance with the requirement of the NIH license. Based on the AIT Report, the Notice of Violation does not accurately state the first part of the violation. Contrary to that statement, the NIH license does not require that the "Radiation Safety in the Laboratory" training course be completed successfully before a researcher can use radioactive materials.

On February 14, 1994, NIH requested an amendment of its license to modify the NIH Radiation Safety Training Program. That request referred to the orientation training and Table ATT 8.1 (Amended) showed that individuals working with radioactive materials must receive the "Initial Orientation; Entry Level or Advanced 'Radiation Safety in the Laboratory'course." The license amendment was approved by NRC on March 23, 1994. If the first part of the violation were accurately stated, it would be apparent that it is not a Severity Level IV violation. As stated in the discussion of Apparent Violation (4) in the Specific Responses part of NIH's May 23 submission, training in excess of the orientation training permitted under the NIH license was provided to the researchers. The only failure of NIH was a failure to document that training. This failure to document is of minor environmental or safety concern and thus is not appropriate for formal enforcement action. NUREG-1600, Sec. IV, Severity of Violations. 60 Fed Reg. at 34385.

The second part of this alleged violation refers to an individual working with microcurie quantities of C-14 prior to completion of formal training. That individual was working with BacTec vials containing 10μ Ci of C-14 which, under 10 CFR § 31.11(a)(3) are not subject to the same license requirements as materials under a NRC specific license, e.g., training requirements. 10 CFR

§ 31.11(f) excludes these generally licensed materials from 10 CFR Parts 19 and 20. Thus, neither license conditions nor NRC regulations required training of this individual. Accordingly, there is no legal basis for the second part of the violation cited in the Notice of Violation.

(3) Corrective steps were taken even though there were no violations of NRC regulations or license conditions. Those corrective actions are described in the discussion of Apparent Violations (4) and (E) cited above.

(4) No corrective steps are necessary to avoid further violations, because there were no violations. To the extent there was a technical violation of documentation requirements, it has been fully corrected.

(5) Full compliance has been achieved.

V. Other Violations - Failure to Perform Bioassays in Accordance with License Requirements

(1) NIH denies that there was any violation of its license conditions relating to its bioassay program.

(2) The bases for the NIH denial are set forth in the discussion of Apparent Violation (D), (pp. 34-37 of the Specific Responses) in the May 23 NIH submission. As stated therein, Regulatory Guide 8.20, through use of the term "should" rather than "shall," makes recommendations regarding when bioassay measurements are to be taken. The final paragraph of section 4., "Frequency" on page 8.20-3 states in pertinent part: "For individuals placed on a quarterly bioassay schedule, the sampling *should* be randomly distributed over the quarter, but *should* be done within one week after a procedure involving the handling of I-125 or I-131." (Italics added.) Both researchers were bioassayed within the calendar quarters in which they handled I-125. The fact that both did additional iodination work within the quarter is irrelevant. There is no requirement that there be a bioassay after the additional iodination work. Furthermore, a bioassay at one week post-iodination is unnecessary. This is based upon consideration of both the detection capabilities of the NIH thyroid analysis system and the fact that air monitoring is performed for each and every iodination. Evaluation of exposure was conducted in accordance with acceptable methods as noted in 10 CFR §§ 20.1003; 20.1204 and 20.1502. NIH routinely determines compliance with section 20.1204 using bioassay or air sampling or a combination of the two. NIH complies with the regulations by performing individual monitoring, by the assessment of committed effective dose equivalent by bioassay, or by determination of the time-weighted air concentrations to which the individual has been exposed, i.e., DAC-hours. In the case of the two researchers

the actual airborne concentrations were so low that follow-up bioassays were not necessary to assess possible internal dose.

(3) No corrective steps were necessary because no violation occurred and the researchers were protected through the measurements that were taken.

(4) Because there were no violations, nc corrective steps need to be taken to avoid further violations.

(5) Full compliance has been achieved because there was no violation.

ANSWER TO A NOTICE OF VIOLATION

Proposed Civil Penalty of $2,500

Department of Health and Human Services
National Institutes of Health
Bethesda, Maryland 20892

Docket No. 030-01786
License No. 19-00296-10

The NIH protests the proposed imposition of a civil penalty of $2,500 for alleged violations of security requirements because:

1. The alleged violations are not Severity Level III violations. See Reply to Notice of Violation, Section I, which by this reference is incorporated herein.

2. There were extenuating circumstances based on the facts that the alleged violations arose from unconnected instances of human error, despite NIH's extensive, good faith efforts to enforce more stringent NRC requirements during a period of transition to those requirements. See response letter to James Lieberman and Reply to Notice of Violation, Section I, which by this reference are incorporated herein.

3. The NRC has not properly applied the civil penalty assessment factors set forth in NUREG-1600, Sec. VI. B.2. 60 Fed. Reg. at 34388-34392.

This Answer addresses only the third point as the other points are addressed fully in the documents that are incorporated by reference.

As stated in NUREG-1600, the civil penalty assessment process involves consideration of four factors: (1) Whether the licensee has had any previous escalated enforcement action during the past two years or the past two inspections, whichever is longer; (2) whether the licensee should be given credit for self-identification of the violation; (3) whether the licensee's corrective actions are prompt and comprehensive; and (4) whether, in view of all the circumstances, the matter requires the exercise of discretion by NRC. Under NUREG-1600, the outcome of the assessment process, absent the exercise of discretion, is limited to one of the following three results: no civil penalty, a base civil penalty, or a civil penalty escalated by 100 percent. 60 Fed. Reg. at 34388. The NRC imposed the base civil penalty of $2,500 after considering these factors. That action was in error because three of the four factors favor the imposition of no civil penalty.

The NIH has not previously had any escalated enforcement action against it. The second factor is not applicable as the security violations were not self-identified. The NIH corrective action

was prompt and comprehensive when properly reviewed in the context of the transition to more stringent security standards and the fact that the violations arose from human error that could not have been prevented by the prompt, comprehensive corrective action by the NIH Radiation Safety Branch (RSB).

Under NUREG-1600, Sec. VI.B.2.a., if corrective action is judged to be prompt and comprehensive, a Notice of Violation normally should be issued with no civil penalty, while if the corrective action is judged to be less then comprehensive, the Notice of Violation normally would be issued with a base civil penalty. 60 Fed. Reg. at 34390. It is apparent that the basis for NRC's proposed imposition of a base civil penalty is its judgement that "credit for corrective actions is not warranted because your corrective actions, judged from the time that you were made aware of the July 6, 1995 repetitive security violation, were not appropriately comprehensive to prevent recurrence." August 23, 1996 letter from Hubert J. Miller, NRC to Michael M. Gottesman, NIH, p.2. In reaching this conclusion, NRC recognized that the NIH corrective action "included immediate confiscation of unsecured radioactive materials, amendments of your security policy on October 26, 1995, and initiation of a security surveillance program on October 26, 1995." Id. Instead of focusing on the scope and content of these and earlier corrective actions, the NRC relied entirely on the occurrence of additional security violations to deny NIH credit for its corrective action. Furthermore, the violations found by the NRC in October 1995 cannot reasonably be considered recurring because at that time the NIH had not been informed that the July finding was considered a violation. That notification did not occur until the AIT Report was forwarded to NIH on January 29, 1996.

This narrow focus on the occurrence of a subsequent violation whose root cause is unrelated to the earlier violation is contrary to NUREG-1600, Sec. VI. B.2.c. which states that consideration is to be given to the timeliness of the corrective action, the adequacy of the licensee's root cause analysis for the violation and the comprehensiveness of the corrective action (i.e., whether the action is focused narrowly to the specific violation or broadly to the general area of concern). 60 Fed. Reg. at 34391. This provision states that the purpose of the Corrective Action Factor is:

> to encourage licensees to (1) take the immediate actions necessary upon discovery of a violation that will restore safety and compliance with the license, regulation(s), or other requirement(s); and (2) develop and implement (in a timely manner) the lasting actions that will not only prevent recurrence of the violation at issue, but will be

> appropriately comprehensive, given the significance and complexity of the violation, to prevent occurrence of violations with similar root causes. NUREG-1600, Sec. VI. B.2.c.; 60 Fed. Reg. 34391.

Thus, contrary to the NRC action, NUREG-1600 does not indicate that the determinative factor is to be whether similar violations occur after corrective action has been taken. Instead the determinative factors, listed in the apparent order of importance are: (1) the timeliness and comprehensive nature of the corrective action; (2) the adequacy of the licensee's root cause analysis; (3) prevention of the recurrence of the violation at issue; and (4) prevention of the occurrence of violations with similar root causes. The NIH corrective action taken on July 20, 1995, adoption of a final security policy after notice of a July 6, 1995 violation was prompt and comprehensive. This time frame shows that the action was prompt and its comprehensive nature is shown by the content of the policies adopted. These were broad-based actions directed toward security concerns throughout NIH. The fact that additional surveillance action was added on October 26, 1995 after an NRC inspection does not establish that the original action was not sufficiently comprehensive. To penalize NIH for fine-tuning and strengthening its newly-adopted more stringent security policy is not consistent with the purpose of the Corrective Action Factor to encourage licensees to take immediate action to address violations. This is particularly true where, as here, the policy is in response to more stringent enforcement standards, and the NRC had concluded on page 20 of its AIT Report that "the security of radioactive materials at NIH was adequate and improved."

There is no indication in the Notice of Violation or the letter forwarding it that the NRC considered the adequacy of NIH's root cause analysis. We believe adequacy of the analysis must be presumed based on the comprehensive nature of the new security policy that was based upon that analysis.

The NIH has satisfied the factor of preventing recurrence of the violation at issue because the security violations found by NRC after July 6 did not involve the laboratory in which the violation was found on July 6. (See also our discussion of repetitive violations in Section I of our Reply to Notice of Violation.) As further set forth in Section I of our Reply, the security violations resulted from unconnected human errors and thus there is no common root cause that can be addressed through corrective action to prevent such security violations. Radiation In Medicine, A Need For Regulatory Reform, p. 117 (Institute of Medicine, 1996). Certainly, NIH should be given the benefit of the doubt in this regard, because such human error or oversight is predictable given that the new, more stringent security policy represents a significant change from the prior policy and is at odds with the normal "free flowing" manner in which biomedical

research is conducted. Accordingly, we believe that a proper application of the civil penalty assessment factors discussed above should result in no civil penalty.

However, if the NRC's consideration of proper assessment factors (rather than relying as it has, on the single factor of recurrence) results in a finding that the base penalty should stand, NRC should nevertheless, exercise its discretion under Section VII, B.6 of NUREG-1600, 60 Fed. Reg. 34394 to refrain from issuing a civil penalty. In accordance with that provision, application of the normal guidance in the policy would be unwarranted if it resulted in a civil penalty and thus NRC should exercise its discretion to nullify any such penalty. The exercise of such discretion is justified based upon the lack of safety significance of the violation, the overall sustained excellent performance of NIH prior to these alleged violations (See the findings of the Human Resources and Intergovernmental Relations Subcommittee, House of Representatives cited in NIH's May 23, 1996 letter to Thomas T. Martin), NIH's comprehensive good faith corrective actions and all the other factors cited in this submission. As we have emphasized in this submission and in our May 23 submission, the security violations should not be considered Severity Level III violations because of their limited safety significance. The radioactive materials were at all times in posted laboratories, were stored in posted refrigerators in clearly labeled vials, and the period during which they were not under surveillance was brief. Given this lack of safety significance, NRC should exercise its discretion to retract the proposed civil penalty.