Dated at Rockville, Maryland, this 21st day of May, 1997.

For the Nuclear Regulatory Commission.

Arnold E. Levin,

Acting Designated Senior Official for Information Resources Management.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 030–01786, License No. 19–00296–10, EA No. 96–027]

Department of Health and Human Services, National Institutes of Health Bethesda, Maryland; Order Imposing a Civil Monetary Penalty

I

The National Institutes of Health (NIH or Licensee), part of the United States Department of Health and Human Services, is the holder of Byproduct Materials License No. 19–00296–10 (license) issued by the former Atomic Energy Commission on December 7, 1956, and most recently renewed by the Nuclear Regulatory Commission (NRC or Commission) on May 19, 1990. The license is currently under timely renewal. The license authorizes the Licensee to possess and use certain byproduct materials in accordance with the conditions specified therein at the Licensee's facilities in Bethesda, Rockville, Poolesville, and Baltimore, Maryland.

II

Inspections of the Licensee's activities were conducted by the NRC Augmented Inspection Team (AIT) from June 30 through November 15, 1995, and by a Special Inspection Team on October 23–24, and November 6–10, 1995, at the Licensee's facility located in Bethesda, Maryland. The results of these inspections indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated August 23, 1996. The Notice states the nature of the violations, the provisions of the NRC requirements that the Licensee had violated, and the amount of the civil penalty proposed for one of the violations (Violation I). The Licensee responded to the Notice in a letter dated September 23, 1996. In its response, the Licensee disputes Violation I as well as the severity level associated with the violation, and requests withdrawal of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the Licensee has not provided an adequate basis for withdrawing Violation I or mitigating the severity level of this violation, or for mitigating the civil penalty associated with this violation. Therefore, a civil penalty in the amount of $2,500 should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, *It is hereby ordered* That:

The Licensee pay a civil penalty in the amount of $2,500 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852–2738.

V

The Licensee may request a hearing within 30 days of the date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, and include a statement of good cause for the extension. A request for a hearing should be clearly marked as a ''Request for an Enforcement Hearing'' and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order (or if written approval of an extension of time in which to request a hearing has not been granted), the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) Whether the Licensee was in violation of the Commission's requirements as set forth in Violation I of the Notice referenced in Section II above, and

(b) Whether on the basis of this violation, this Order should be sustained.

Dated at Rockville, Maryland this 20th day of May 1997.

For the Nuclear Regulatory Commission.

Edward L. Jordan,

Deputy Executive Director for Regulatory Effectiveness, Program Oversight, Investigations and Enforcement.

Appendix

Evaluations and Conclusion

On August 23, 1996, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during two NRC inspections conducted at the Licensee's facility. The Licensee responded to the Notice in a letter dated September 23, 1996. In its response, the Licensee disputes Violation I, for which the civil penalty was assessed, disputes the severity level of the violation, and requests withdrawal of the civil penalty. The NRC's evaluation and conclusions regarding the Licensee's requests are as follows:

I. Restatement of Violation I

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above:

(a) On July 6, 1995, the licensee did not secure from unauthorized removal or limit access to licensed material stored in laboratory 5D12 of Building 37, an unrestricted area. Specifically, a member of the NRC AIT found the licensed material inside an unlocked refrigerator that was located within the unlocked laboratory 5D12, and no one was present to control access to this material. The licensed material consisted of approximately 20 millicuries of tritium (H–3) and 2.5 millicuries of carbon-14 (C–14).

(b) On October 23, 1995, the licensee did not secure from unauthorized removal or limit access to licensed material stored in laboratories 4D25,

4D06, 4B03, 6C13, 1B03, and 3C01 of Building 37, unrestricted areas. Specifically, members of the NRC Special Inspection Team found the licensed material inside unlocked refrigerators located in unlocked laboratories, and no one was present to control access to this material. The licensed material consisted of 234 microcuries of phosphorus-32 (P–32) and 720 of microcuries of sulphur-35 (S–35) in Lab 4D25; 20 microcuries of P–32 in Lab 4D06; 3.4 millicuries of H–3 in 4B03; 900 microcuries of S–35 in Lab 6C13; 200 microcuries of S–35, 1140 microcuries of P–32, and 3.7 millicuries of chromium-51 (Cr–51) in Lab 1B03; and 41 microcuries of P–32 and 250 microcuries of S–35 in Lab 3C01.

II. Summary of Licensee's Response to Violation I

NIH disputes that a violation occurred because, according to NIH, ''there is no definition of the term 'secured from unauthorized removal or access' within the NRC regulations.'' NIH also disputes that this violation should be categorized at Severity Level III, and in support references its May 23, 1996 submission (''Specific Responses of NIH to the Apparent Violations Found in Inspection Reports 030–01786/95–002 (REDACTED) and 030–01786/950203'' at pages 1–3 and 21–25, and ''Factors for Consideration in Determining Severity Levels of Apparent Violations.'')

In particular, NIH contends that Violation I was not ''significant'' such as to constitute a Severity Level III violation under Supplement IV.C.12 of the Enforcement Policy, NUREG–1600, because:

(1) According to NIH, it maintained control of licensed material through posting laboratories at all times and storage in posted refrigerators in properly labeled containers, and the period of time during which materials were not under surveillance was brief. NIH contends that this degree of control had been acceptable to the NRC for many years, that the violations arose because of the adoption of more stringent enforcement standards, and that the violations occurred within three months of the adoption of NIH's final security policy responding to these more stringent enforcement standards.

(2) According to NIH, it 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.

(3) According to NIH, the violations pose little or no risk of harm because of the low levels of radioactivity involved. NIH claims that there has been no more than minimum risk to health and safety and that none of the violations resulted in any radiation exposure of an NIH employee or a member of the public.

NIH contends that the violations do not constitute a failure to control access to licensed materials for radiation purposes as specified by NRC requirements, such as to constitute a Severity Level III violation under Supplement VI.C.1 of the Enforcement Policy, for two reasons: (1) NIH claims that this standard conflicts with the ''significant failure'' standard of Supplement IV.C.12 of the Enforcement Policy; and (2) NIH argues that ''access* * * for radiation purposes'' refers to access for medical treatment or diagnostic purposes, which were not involved in the violations.

NIH argues that only Severity Level IV or greater violations can be the basis for considering aggregation or repetition, and that to categorize Violation I at Severity Level IV would be questionable. NIH contends that escalating this violation to Severity Level III on the basis of repetitive or aggregated violations is contrary to the Enforcement Policy, because the number of violations is small compared to the number of restricted use areas (0.2%) or to the number of workers using radioactive material. NIH further maintains that this violation should not be considered a repeat violation unless it occurs in the same laboratory, because the cause of this violation is not a failure of the NIH Radiation Safety Branch to train workers, promulgate security requirements, or respond quickly to violations, but rather lack of attention and carelessness by individual researchers. NIH contends that under the Enforcement Policy, aggregation is appropriate only where the violations have the same underlying cause or programmatic deficiencies or the violations contributed to or were unavoidable consequences of the underlying problem. NIH contends that these were unconnected occurrences that have no fundamental underlying cause or common cause that can be eliminated by NIH. NIH argues that these violations are unconnected and are not an indication of the adequacy of previous corrective actions, which should be judged on the basis of their scope, content, and potential deterrent effect, and not on the basis of whether they eliminate all human error.

NIH states that its corrective actions, described in its May 23, 1996 response, have made all researchers aware of, or they should be aware of, security requirements. These corrective actions include: (1) Confiscating the licensed material identified by the NRC AIT on July 6, 1995; (2) adopting the Interim Security Policy as permanent on July 20, 1995; (3) the RSO performing extensive surveillance and taking appropriate enforcement action for violations of the NIH Security Policy; and (4) conducting a follow-up investigation after the Special Inspection of October 23–24 and November 6–10, 1995. NIH states that full compliance has largely been achieved and that it will continue to diligently pursue the current corrective actions. Further, NIH states 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.

III. NRC Evaluation of Licensee's Response to Violation I

The failures of NIH to secure licensed material from unauthorized removal or access do constitute a violation. Contrary to NIH's contentions, the meaning of the phrase ''secured from unauthorized removal or access'' is abundantly clear. Among the common meanings of the verb ''to secure'' is to guard, to shield from interference, or to restrain or make fast. Webster's Third New International Dictionary (unabridged) (1986). The statements of consideration for 10 CFR 20.1801 and 1802 and their predecessor requirements, 10 CFR 20.207 (a) and (b), make it clear that Section 1801 and 1802 were intended to require licensees to guard or make licensed material safe from unauthorized removal or access, by use of physical restraint. For example, when Part 20 was first promulgated in 1957, section 20.207 required that ''[l]icensed materials stored in an unrestricted area shall be secured against unauthorized removal from the place of storage.'' In 1975 the Commission modified this requirement by an immediately effective rule, explaining in the statements of consideration that the ''references to 'storage' might not convey clearly the intention that constant control be maintained over all licensed radioactive materials in unrestricted areas [emphasis added]'' (40 FR 26679, June 25, 1975). Section 20.207(b) was added, requiring that ''licensed materials in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee.'' When 10 CFR 20.1801 and 1802 were promulgated, the statements of consideration further discussed the need to secure even small

quantities of licensed materials (56 FR 23360 at 23379, May 21, 1991).

[Commenter]: * * * the requirement to secure small quantities of licensed radioactive materials when they are not in use would interfere with university research.

[Commission Response]: * * * locking radiotracer laboratories when they are not being used is a small nuisance compared to the consequences of unauthorized access to, or theft of, radioactive materials, which could result in contamination of unrestricted areas or exposure to individuals, as well as having to report a loss of licensed material to the NRC.

Contrary to NIH's contention, Violation I was a ''significant failure to control licensed material'' within the meaning of Supplement IV.C.12 of the Enforcement Policy. The NRC acknowledges that NIH posted rooms and refrigerators in which radioactive materials were stored, and radioactive material was in properly labeled containers. Accordingly, the NRC did not cite NIH for violation of NRC requirements for posting or labeling radioactive material. However, NIH does not deny that licensed material was left unattended inside unlocked refrigerators in unlocked laboratories. While the measures taken by NIH provided a method of warning individuals of the presence of radioactive material and potential hazards, they did not secure licensed materials from unauthorized removal or access, which is the requirement.

The significance of Violation I is based on the potential for harm, which involves the type of licensed material left unsecured and accessible by the public, the number of examples of the violation (i.e. the number of times licensed radioactive material was identified to be unsecured), and the repetitive nature of the violation. As stated in NRC's August 23, 1996, letter ''[I]t is a significant regulatory concern that NRC inspectors repeatedly have been able to gain access to licensed material at your facility without challenge * * * Given the repetitive nature and the number of examples of the violation, the violation has been categorized in accordance with the ''General Statement of Policy and Procedure for NRC Enforcement Actions'' (Enforcement Policy), NUREG–1600, at Severity Level III.''

Categorizing Violation I at Severity Level III is appropriate pursuant to Sections IV.A. and IV.B. of the Enforcement Policy, based on the number of examples of the violation and the repetitive nature of the violation. NIH is correct that escalation of Severity Level IV violations into a Severity Level III violation is based in part upon the violations having a common underlying cause. Aggregating the failures to control licensed material and characterizing them as a Severity Level III violation is appropriate in this case because numerous isotopes were left unsecured in numerous locations, not as a result of isolated occurrences, but due to the same underlying cause, which was the Licensee's failure to effectively oversee and ensure compliance with security requirements by its employees. NIH also is correct that in escalating Severity Level IV violations to Severity Level III for repetitiveness, a factor to be considered is the adequacy of corrective action for previous similar violations. Escalation of the numerous failures to control licensed material to a Severity Level III violation is also appropriate in this case because of the repetitive nature of the violation. NIH had been cited previously for failures involving security of licensed radioactive materials. Specifically, security failures were identified by the NRC during an NRC inspection conducted in April and May of 1994, which resulted in the issuance of Confirmatory Action Letter 1–94–006 and subsequent issuance of a Severity Level IV violation. As explained in the Notice of Violation, a violation need not occur in the same laboratory in order for it to be considered repetitive.

NIH argues that the number of violations in this case is small compared to the total number of restricted use areas at NIH. However, NRC did not inspect the total number of restricted use areas at NIH. Additionally, NRC chose not to cite some of the security failures that the NRC inspectors identified because, although the presence of unsecured radioactive material was confirmed by survey meter, the activity of the material was not known. See, for example, NRC Inspection Report No. 030–011786/95–203 (December 21, 1995), Section 3.d. Moreover, the programmatic issue of significant regulatory concern involves much more than just the number of violations. Specifically, these violations, viewed in the context of the history of security violations at NIH beginning in 1994, indicate that previous corrective actions were not effective. Contrary to NIH's assertion that there is no common underlying cause for the violations that can be eliminated by NIH, the common root cause for these violations is NIH's failure to effectively oversee its employees and ensure their compliance with security requirements. NIH must recognize that, in order to assure that public health and safety are protected, the Commission expects and requires that its regulations be met by all licensee employees, regardless of the licensee's size or the volume of the licensee's activities. NRC licenses the entity. NRC does not separate licensee management from licensee employees. Licensees are responsible for the acts of their employees. In the matter of Atlantic Research Corporation, (CLI–80–7), 11 NRC 413, 422 (1980).

Further, the violations do pose a credible risk of harm, given the types and quantities of licensed material listed in the citation. Radiation exposure and/or contamination may be posited through both accidental and intentional pathways anytime a member of the public has access to such materials. The purpose of the requirement is to prevent access to such materials by unauthorized individuals because access could result in unnecessary radiation exposure as well as harm to the environment.

The violation did not arise from more stringent enforcement standards, as claimed by NIH, but from the failure of NIH to effectively ensure compliance with NRC requirements. NIH does not identify new or more stringent NRC requirements or standards. The only new policy identified by NIH was its July 1995 final security policy, adopted as part of the Licensee's corrective action for previously cited violations of security and control requirements of 10 CFR Part 20.

NIH offers no explanation for its contention that Supplements IV.C.12 and VI.C.1 of the NRC Enforcement Policy conflict with each other. Supplement IV.C.12 gives as an example of a Severity Level III health physics violation, ''a significant failure to control licensed material,'' and Supplement VI.C.2 gives as an example of a Severity Level III fuel cycle and materials operation violation, ''a failure to control access to licensed materials for purposes as specified by NRC requirements.'' Supplement IV.C.12 concerns control of material and Supplement VI.C.1 addresses access to material. A failure to control access to licensed material is one type of a failure to control licensed material. In the circumstances of this case, NIH's failure to secure licensed material constitutes a Severity Level III violation under both Supplements IV and VI.

NIH incorrectly asserts that Supplement VI.C.1. applies only to violations concerning access to licensed material used for medical treatment or diagnostic purposes. Supplement VI is titled ''Fuel Cycle and Materials Operations'', and does not single out uses for medical or diagnostic purposes, but refers by its title and content to all

uses of byproduct materials. Based on the above, the NRC concludes that NIH did not provide an adequate basis to mitigate the Severity Level of Violation I.

IV. Summary of Licensee's Request for Withdrawal of the Civil Penalty

The Licensee protests the proposed civil penalty based on the following contentions: (1) Violation I was improperly categorized as an escalated Severity Level III violation; (2) Violation I 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; and (3) the NRC did not apply the civil penalty assessment factors to Violation I in accord with the Enforcement Policy, NUREG–1600. NIH contends that three of the four civil penalty assessment factors favor no civil penalty because:

(a) NIH has not had any escalated enforcement action against it during the past two years or past two inspections, whichever is longer; in over three decades of using radioactive materials in research, NIH has never before 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 workers or the public.

(b) NIH's corrective actions were prompt and comprehensive in the context of transition to more stringent security standards and the violations arose from human error that could not have been prevented by prompt and comprehensive corrective action. NIH contends that the NRC erroneously relied entirely on the occurrence of additional security violations instead of focusing on the scope and content of earlier corrective actions, in denying NIH credit for its corrective actions. NIH further contends that the violations found by NRC in October 1995 cannot reasonably be considered recurring because, at that time, NIH had not been informed that the July 1995 inspection finding was considered a violation, and notification did not occur until the AIT Report was forwarded to NIH on January 29, 1996. NIH also states that its July 20, 1995 final security policy was instituted after the July 6, 1995, violation, and thus was prompt and comprehensive corrective action. NIH argues that the root cause of Violation I is unrelated to earlier similar violations, and that NUREG–1600 does not indicate that the determinative factor in assessing the adequacy of corrective action is whether similar violations occur after corrective action has been taken. NIH further states that a civil penalty would penalize NIH for fine-tuning and strengthening its newly-adopted more stringent security policy, and is not consistent with the purpose of the Corrective Action factor. According to NIH, that purpose is to encourage licensees to take immediate action to address violations. Finally, NIH states that there is no indication that the NRC considered the adequacy of NIH's root cause analysis. NIH contends that it prevented recurrence of the security violations because the laboratory involved in the July 6 violation was not the same as the laboratories involved in violations after July 6.

(c) NRC should exercise its discretion under Section VII.B.6 of the Enforcement Policy to refrain from imposing a penalty because of the lack of safety significance of the violation, the overall sustained excellent performance of NIH prior to the violation, and NIH's comprehensive good faith corrective actions. NIH states that its corrective actions were prompt and comprehensive when properly reviewed in the context of the transition to more stringent security standards, and that the violations arose from human error and could not have been prevented by prompt and comprehensive corrective action.

NIH generally contends that contrary to the requirements of due process, the NRC failed to explain why it accepted or rejected all evidence and each argument presented by NIH in its May 23, 1996, response to the AIT Report and Special Team Inspection (STI) Report before issuing the August 23, 1996, Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and failed to indicate in any meaningful way that it considered the May 23, 1996, submission before issuing the Notice. In support, NIH cites *Administrative Law Treatise*, Kenneth C. Davis, Volume II, § 9.5 at p. 48 (3d ed. 1994) and *Some Kind of Hearing*, Friendly, 123 U. Pa. L. Rev. 1267 (1975).

V. NRC Evaluation of Licensee's Request for Withdrawal of the Civil Penalty

The Violation I failure to secure licensed material from unauthorized removal was properly categorized as a Severity Level III violation. See Section III, *supra*. The NRC's letter, dated August 23, 1996, transmitting the civil penalty, states that the base civil penalty amount of $2,500 was warranted in this case because the violation was identified by the NRC, and NIH's corrective actions were not appropriately comprehensive to prevent recurrence after NIH was made aware of the repetitive July 6, 1995, security violation, and were not adequate to prevent similar violations from occurring as evidenced by the results of the October 23, 1995, inspection. As a result, a penalty of $2,500 was proposed. Violation I arose from NIH's failure to implement effective corrective action to prevent recurrence of the previously-cited Severity Level IV security and control failures, and from the failure to implement effective corrective action to prevent recurrence of the July 6, 1995, security violation, not from ''unconnected instances of human error.''

The NRC correctly applied the civil penalty assessment factors in accordance with the Enforcement Policy. NIH misapprehends the basic provisions of the Enforcement Policy. Because the NRC identified Violation I and because NIH's corrective actions were inadequate to prevent recurrence of the violation, even though NIH had not been the subject of escalated enforcement action during the past two years or past two inspections, the NRC correctly proposed the base civil penalty of $2,500. See Enforcement Policy, NUREG–1600, Section VI.B.2.a.–c.

NIH erroneously contends that the occurrence of similar violations after corrective action has been taken is not a factor in assessing the adequacy of corrective action. The Enforcement Policy states that one of the purposes of the corrective action factor is to encourage licensees to implement lasting action that will ''prevent recurrence of the violation at issue.'' In this case, the October 23, 1995, violation is repetitive not only of the July 6, 1995, violation, but also of the previously-cited Severity Level IV violations. The $2,500 proposed civil penalty does not penalize NIH for fine-tuning or strengthening its July 1995 final security policy, but rather is a result of the Licensee's failure to effectively implement corrective actions to prevent recurring violations. NIH is mistaken in contending that as long as the same laboratories are not involved in security violations, the violations cannot be considered recurring or repetitive. Finally, NIH is mistaken in arguing that the October 23, 1995, example of the violation cannot be considered recurring because NIH did not have notice of the July 6, 1995, example of the violation until January 1996. NIH had notice of the July 6, 1995, example of the violation long before January 1996. NIH claims, as one of its corrective actions, that it confiscated the licensed material identified as unsecured by the AIT on July 6, 1995. Further, the preliminary findings of the AIT inspection were

discussed with NIH in a technical briefing held on August 8, 1995.

NIH's argument that the NRC did not indicate that it considered the adequacy of NIH's root cause analysis does not provide a basis to disturb the proposed civil penalty. The NRC did not deny credit for corrective action because of an inadequate root cause analysis, but because of the failure to implement effective corrective actions to prevent recurrence of the violations between the time of the repetitive July 6, 1995, violation and the October 23, 1995, violations. For example, during the October 1995 STI, NRC inspectors found that the Licensee's staff lacked a complete understanding of the Licensee's Enhanced Interim Security Policy (EISP), confirmed by the NRC in Confirmatory Action Letter 1–95–011 on July 21, 1995. As noted in NRC Inspection Report No. 030–01786/95–203 (December 21, 1995), Section 3.b:

> The degree of understanding of how the EISP was to be implemented varied among the individuals interviewed. In general, individuals understood that the EISP called for certain materials to be locked, but there was not a clear understanding of what quantities were to be locked and when. A common understanding was that laboratories were to be locked at night when unattended * * * However, individuals interviewed stated that laboratory locking was not required if an individual's absence was of short duration for a break or while the researcher was working in a nearby laboratory * * * Many researchers stated that they thought it was acceptable to leave laboratories open under these circumstances.

In addition, at the time of the October 1995 STI, NIH was not conducting security audits during lunch periods and after normal working hours, which are times when non-compliance logically may be expected to occur. Additional procedures to address these shortcomings had to be confirmed in Confirmatory Action Letter 1–95–018, issued by the NRC staff on October 23, 1995. Under these circumstances, the NRC staff cannot conclude that NIH implemented effective corrective action.

NIH fails to demonstrate a basis for the NRC to exercise discretion to refrain from imposing a civil penalty. As explained in Section III, supra, Violation I is a significant regulatory concern. Additionally, the Licensee's corrective actions were not sufficiently comprehensive to prevent recurrence until after the recurring violations were identified by the STI on October 23, 1995, and the NRC staff took additional measures by issuing Confirmatory Action Letter 1–95–018 on October 27, 1995. Comprehensive corrective action is a necessary element in considering the exercise of discretion.

NIH erroneously contends that due process requirements were violated because the NRC did not explain why it accepted or rejected the evidence and arguments presented by NIH in its May 23, 1996, response to the AIT Report and SIT Inspection Report before issuing the August 23, 1996, Notice of Violation and Proposed Imposition of Civil Penalty. In essence, NIH argues that before even proposing a civil penalty, the NRC must issue the equivalent of an initial decision weighing all evidence and argument presented at a ''hearing.'' The Licensee's argument rests upon a fundamental misapprehension of the procedural steps in NRC's enforcement process and the nature of a Notice of Violation and Proposed Imposition of Civil Penalty. The authority cited by NIH does not mandate a ''hearing'' meeting the basic requirements of due process before an agency may merely propose a civil penalty.

The August 23, 1996, Notice merely proposes a civil penalty. In accordance with the Enforcement Policy, NIH was offered, by letter dated January 29, 1996, from Charles W. Hehl, Director, Division of Nuclear Materials Safety, U.S. NRC Region I, the opportunity to attend a predecisional enforcement conference, the very purpose of which is to provide an opportunity for the licensee to present information concerning the facts associated with the apparent violations, corrective action taken or planned, and the significance of the apparent violations. NIH, however, by letter dated April 16, 1996, from Harriet S. Rabb, General Counsel, Department of Health and Human Services, declined this opportunity. Instead, NIH contested the NRC's identification of apparent violations and their significance by responding in writing to NRC inspection reports on May 23, 1996. That submission was considered by the NRC staff before issuance of the August 23, 1996, Notice of Violation and Proposed Imposition of Civil Penalty. Additionally, NIH responded to the August 23, 1996, Notice by its September 23, 1996, written submission, the factual and legal arguments of which have been considered and evaluated herein. Finally, under the Commission's regulations, NIH may request a hearing to contest this Order Imposing Civil Monetary Penalty. NIH has been provided all the process that is due at this stage of the proceeding.

VI. NRC Conclusion

The NRC staff concludes that the Licensee did not provide an adequate basis for mitigating either the Severity Level of Violation I or the civil penalty for Violation I. Accordingly, an order imposing a civil penalty in the amount of $2,500 should be issued.

Evaluation of Violations Not Assessed a Civil Penalty

Of the violations not assessed a civil penalty, the Licensee admits Violation II.A in part; admits Violation II.B; denies the first and second examples of Violation II.A; denies Violations II.C and II.D; and disputes the severity level assigned to Violations II.A and II.B and the first example of Violation II.C.

Restatement of Violation II.A

Condition 29 of License No. 19–00296–10 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 28, 1986.

Attachment 10–D of the July 28, 1986, application, requires, in part, that an extremity monitor be worn when using greater than 0.5 millicuries of phosphorus-32 (P–32), and that film badges and ring badges be returned promptly each month.

Contrary to the above, during 1995:

1. The licensee did not supply extremity dosimetry to eight individuals who worked with greater than 0.5 millicuries of P–32; and
2. Five individuals did not wear the extremity dosimetry that was issued to them while working with greater than 0.5 millicuries of P–32; and
3. Numerous individuals failed to return the monitoring devices (film badges and ring badges) monthly.

Summary of Licensee's Response to Violation II.A

NIH disputes that this violation should be classified at Severity Level IV, and also denies Examples 1 and 2 of the violation. In support, NIH references its May 23, 1996, submission (''Specific Responses of NIH to the Apparent Violations Found in Inspection Reports 030–01786/95–002 (REDACTED) and 030–01786/950203'' at pages 29–33).

NIH states that records of the NIH Radiation Safety Branch (RSB) do not support Examples 1 and 2 of the violation. NIH contends that a RSB investigation found that all 13 users had been issued badges, that all but one researcher was wearing the dosimetry, and that researcher was not required to wear dosimetry because of the small amount of P–32 (0.047 microcuries) he was using.

Additionally, NIH states that Example 3 of the violation is not of sufficient significance to warrant the Severity

Level IV classification, particularly given that persons using P–32 at NIH are not required to wear dosimetry, the RSB identified the failure to return badges, and no measurable exposures were detected.

NIH further contends that Violation II.A. is of minor safety or environmental concern and should be treated as a Non-Cited Violation and not formalized into a Notice of Violation based on the Special Team Inspection (STI) Report and NRC Information Notice No. 90–01. NIH states that the STI Report concluded that the NIH dosimetry program was in compliance with 10 CFR Part 20, Subpart C, and was effective in monitoring occupational external doses. NIH notes that 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).'' NIH states that corrective action for this self-identified violation had been completed at the time of the NRC Special Team Inspection and will prevent further violations, and that there was no continuing violation.

NRC Evaluation of Licensee's Response to Violation II.A

NIH failed to support its denial of Examples 1 and 2 of Violation II.A. with the documentation which NIH claims disprove those violations. Accordingly, the NRC staff concludes that the violation occurred as stated in the Notice. Additionally, NIH asserts that persons using P–32 at NIH are not required to use dosimetry, but does not dispute that Condition 29 of the License and Attachment 10–D of the July 28, 1996, application require extremity dosimetry to be worn by individuals using more than 0.5 millicuries of P–32.

NRC chose to treat Violation II.A. as a cited violation in order to highlight interrelated concerns over failures to supply, wear, and return dosimetry, particularly as related to the use of P–32. Under the Enforcement Policy, NRC may refrain from citing a violation under certain circumstances, but is not compelled to do so. See NUREG–1600, Section VII.B.

NIH mischaracterizes the STI Report, NRC Inspection Report No. 030–01786/95–203 (December 20, 1996) by implying that the Special Inspection Team found perfect compliance with NRC requirements. To the contrary, the STI Report concluded that ''one apparent violation was identified involving the failure to issue, wear and return individual monitoring devices [Violation II.A. herein]. Otherwise, the licensee's external dosimetry program was in compliance with Subpart C of 10 CFR Part 20, and was effective in monitoring occupational external dose.''

The Licensee's failure to meet its commitments, formalized by license condition, regarding extremity dosimetry for individuals who work with greater than 0.5 millicuries of P–32 does involve potential safety significance and therefore is appropriately classified as a Severity Level IV violation.

Restatement of Violation II.B

Condition 29 of License No. 19–00296–10 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 28, 1986.

Item 10.6 of the July 28, 1986, application requires, in part, that the Authorized User provide to the Radiation Safety organization a completed Form NIH 88–1, ''Request for Purchase and Use of Radioactive Materials'', for each incoming shipment before the materials will be released to the investigator. Form NIH 88–1 was provided as Attachment 10–F to the July 28, 1986, application. Form NIH 88–1 requires, in part, that the radiation safety identification number and names of all persons who will use the radioactive material, the name of the authorized investigator, and the signature of the authorized investigator, be entered on the form.

Contrary to the above:

Users did not provide the Radiation Safety organization with a completed Form NIH 88–1 for each incoming shipment before the materials were released to the investigator. Specifically, between October 3 and November 20, 1995, the licensee allowed users to request the purchase of radioactive materials electronically without the signature of the authorized investigator.

An NIH 88–1 form, submitted for purchase and use of radioactive materials received on September 9, 1994, did not include the radiation safety identification number and names of all persons who were intended to use the radioactive material. Specifically, the NIH 88–1 form listed as the only user an individual who had left NIH.

Summary of Licensee's Response to Violation II.B

NIH disputes that Violation II.B. is a Severity Level IV violation. In support, NIH references its May 23, 1996 submission (''Specific Responses of NIH to the Apparent Violations Found in Inspection Reports 030–01786/95–002 (REACTED) and 030–01786/950203'' at pages 8–10 and 26–28, or ''May 23, 1996, submission''). NIH asserts that the two examples of Violation II.B. individually and collectively posed only minor safety or environmental concerns below the significance for Severity Level IV violations, and thus should not have been formalized in a Notice of Violation. NIH states that full compliance was achieved through its corrective actions.

In regard to the first example, NIH states that its electronic system for ordering radioactive materials collects the same data as did the Form 88–1, but in electronic form without a signature of an authorized user, and that the failure to provide a signature of the ordering authorized user was a technical violation resulting from implementation of the electronic system one month before NRC approval of the license amendment permitting use of the electronic system. NIH argues that since the NIH license amendment adopting the electronic system was approved one week after submission, the violation is not of more than minor significance and cannot be a Severity Level IV violation. NIH asserts in its August 23, 1996, response that by approving a license amendment which permitted continuation of the same practice for which NIH is being cited, the lack of the authorized users' signatures cannot raise a significant regulatory concern. NIH states that no apparent unauthorized use of radioactive materials or unnecessary exposure to radiation resulted.

In regard to the second example, NIH states in its May 23, 1996, submission that there is no NRC regulation requiring the use of NIH Form 88–1 or for collection of the information contained therein. NIH further states that Form 88–1 is an internal mechanism used to verify that users of materials have proper training and dosimetry, and that the single inadvertent failure to list the proper user on Form 88–1 is a technical violation that did not result in use of materials by untrained users.

NRC Evaluation of Licensee's Response to Violation II.B

With respect to the first example of the violation, the NRC acknowledges that a license amendment was approved that authorized an electronic method of ordering licensed radioactive material without the signature of an authorized user. However, the NRC approved this amendment only after receiving specific commitments from NIH that the electronic process would provide the same level of control of licensed material that Form 88–1 did, such that materials would be released and used

only by qualified or authorized individuals. For a licensee to take it upon itself to decide that it may proceed in violation of a license condition without a safety review by the NRC licensing authority is of more than minor regulatory concern in and of itself.

With regard to the second example of Violation II.B, the Licensee's procedures for ordering licensed radioactive material are not a mere internal mechanism. Those procedures are incorporated into the NIH license by license condition, and as a result, constitute regulatory requirements. Violation II.B is of more than minor regulatory concern because individuals who have not been trained, and therefore, not authorized, could have obtained licensed material, which could have resulted in improper use or disposal of the material.

Restatement of Violation II.C

Condition 29 of License No. 19–00296–10 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 28, 1986.

Item 10.3 of the July 28, 1986, application states that all radioactive material users are required to successfully complete an initial training course entitled, ''Radiation Safety in the Laboratory''.

Contrary to the above:

1. One or two researchers working in Laboratory 5D18 of Building 37 did not successfully complete the initial training course entitled, ''Radiation Safety in the Laboratory'' prior to their use of radioactive material. Specifically, during the month of October 1994, the researcher(s) used sulfur-35, phosphorous-32 and phosphorous-33, but did not receive ''Radiation Safety in the Laboratory'' training until November 29, 1994.

2. During the months of October and November 1995, an individual worked with microcurie quantities of C–14 in a Building 10 clinical pathology laboratory, and as of November 10, 1995, this individual had not completed the ''Radiation Safety in the Laboratory'' training.

Summary of Licensee's Response to Violation II.C

NIH denies the first and second examples of Violation II.C. In support, NIH references its May 23, 1996, submission (''Specific Responses of NIH to the Apparent Violations Found in Inspection Reports 030–01786/95–002 (REACTED) and 030–01786/950203'') at pages 11–13 and 38–41.

In regard to Example 1 of Violation II.C., NIH contends that the Notice does not accurately state the violation, and states that to the extent there was any violation, it was a technical violation of failing to certify the provision of orientation training in accordance with its license, which was a technical violation that did not amount to a Severity Level IV violation. NIH asserts that no NRC regulation or NIH license condition requires researchers to complete the formal Radiation Safety in the Laboratory training prior to their use of radioactive materials, and that the AIT Report recognized at pages 21–22 that 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 training described in the ''Radiation Safety Orientation for New Personnel Planning to Use Radioactive Material'' packet. On March 23, 1994, the NRC approved a license amendment to modify the NIH Radiation Safety Training Program, such that individuals working with radioactive materials must receive the ''Initial Orientation; Entry Level or Advanced 'Radiation Safety in the Laboratory course.' '' Accordingly, NIH concludes that the violation was a failure by the AU to certify such orientation training, which is of minor regulatory concern and not appropriate for formal enforcement action.

In regard to Example 2 of Violation II.B, NIH states that the individual involved was working with BacTec vials containing 10 microcuries of carbon-14, which under 10 CFR 31.11(a)(3) was subject to a general license and thus not subject to the training requirements applicable to materials subject to a specific license, because 10 CFR 31.11(f) excludes such generally licensed materials from the requirements of 10 CFR Parts 19 and 20. NIH contends that neither NIH license conditions nor NRC regulations required training of this individual.

NRC Evaluation of Licensee's Response to Violation II.C

With respect to the first example of Violation II.C, the NRC concludes that the violation occurred as stated. Condition 29 of NIH's license and Item 10.3 of the July 28, 1986 application require that all radioactive material users successfully complete an initial training course entitled ''Radiation Safety in the Laboratory''. Contrary to NIH's assertions, the license amendment issued on November 23, 1994, did not permit individuals to begin using radioactive materials prior to taking the ''Radiation Safety in the Laboratory'' if they had received orientation training. The language of the license amendment and of the February 14, 1994 amendment request refer to the orientation training as part of the NIH training program, not as an alternative to the required ''Radiation Safety in the Laboratory'' course. Condition 29 of the NIH license, which incorporates Item 10.3 of the July 28, 1986, application, was not modified by the license amendment issued on November 23, 1994. The AIT Report mistakenly stated that 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 provision of orientation training.

With respect to the second example of Violation II.C, the NRC agrees that NIH is not required by license condition to provide training to individuals who use BacTec vials that were obtained under the provisions of a general license issued pursuant to NRC regulations. Therefore, the NRC is hereby withdrawing this example of the violation.

Restatement of Violation II.D

Condition 29 of License No. 19–00296–10 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated July 28, 1986.

Item 10.9.2 of the July 28, 1986, application requires that the licensee conduct its bioassay program in accordance with Regulatory Guide 8.20, ''Applications of Bioassay for Iodine-125 and Iodine-131''. Section C.1.a. of Regulatory Guide 8.20 states that routine bioassay is necessary when, over any 3 month period, an individual handles in open form unsealed quantities of radioactive iodine exceeding those in Table 1. Table 1 of Regulatory Guide 8.20 states that bioassay is necessary for activity levels greater than 10 mCi of iodine-125 used in processes within a fume hood.

Contrary to the above, the licensee failed on two occasions to conduct bioassay measurements after workers handled greater than 10 mCi of volatile iodine-125 in an open unsealed form in gloveless containment boxes located in a fume hood. Specifically, as of November 10, 1995, two researchers had not received a thyroid bioassay measurement after handling 17 mCi and 15 mCi of volatile iodine-125 on June 21 and September 18, 1995, respectively.

Summary of Licensee's Response to Violation II.D

NIH denies Violation II.D. In support, NIH references its May 23, 1996, submission (''Specific Responses of NIH to the Apparent Violations Found in Inspection Reports 030–01786/95–002 (REDACTED) and 030–01786/950203'') at pages 34–37.

NIH argues that Section C.4.c. of Regulatory Guide 8.20, ''Applications of Bioassay for 1–125 and 1–131'' (September 1979), does not require when, but only makes recommendations as to when, quarterly bioassay measurements are to be taken, because of the use of the word ''should'' rather than ''shall'': ''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. This will provide a more representative assessment of exposure conditions.'' NIH claims that both researchers were bioassayed within the calendar quarters in which they handled iodine-125, and that the fact that both researchers did additional iodination work within the quarter is irrelevant because there is no requirement that there be a bioassay after the additional iodination work. NIH states that a bioassay at one week post-iodination is unnecessary, based upon the detection capabilities of the NIH thyroid analysis system and because air monitoring is performed for each and every iodination. NIH further states that 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.

NIH further argues that 10 CFR 20.1204 requires that for purposes of determining compliance with occupational dose limits, the licensee shall make suitable and timely measurements of either concentrations of radioactive material in air in work areas, or quantities of radionuclides in the body, or quantities of radionuclides excreted from the body, or a combination of these measurements, and thus the air sampling conducted was sufficient to satisfy 10 CFR 20.1204.

NRC Evaluation of Licensee's Response to Violation II.D

NIH does not dispute that License Condition 29 and Reg. Guide 8.21 require bioassay of individuals working with the quantities of I–125 involved. Regarding NIH's explanation that both researchers were bioassayed within the calendar quarters in which they handled iodine-125, Section C.4.b of Reg. Guide 8.21 does allow quarterly bioassays if initial bioassays are performed within 72 hours after use of iodine for the first three month period and provided that the use falls within certain quantities specified in the Guide. After the initial three month period, the Guide allows the Licensee to change the frequency to quarterly provided that other conditions specified in the Guide are met. NIH did not submit documentation to the NRC to show that all of the conditions necessary to move to a quarterly bioassay frequency were met. Even if the Licensee had met the conditions for a quarterly bioassay schedule, Section C.4.c. of Reg. Guide 8.21 provides that for individuals placed on a quarterly schedule, bioassay samples should be done within one week after a procedure involving the handling of I–125 or I–131 in order to provide a more representative assessment of exposure conditions. NIH has not provided the dates on which the workers were bioassayed to demonstrate that they were in fact conducted during the quarter or within one week after handling I–125.

NIH's argument that no violation occurred because of the detection capabilities of the NIH thyroid analysis system and because air monitoring is performed for each and every iodination is incorrect. Reg. Guide 8.21, which the Licensee agreed to follow, does not carve out an exception to the necessity of performance of bioassays for licensees, depending upon the quality of their thyroid analysis system or air sampling program. NIH's air sampling program does not support NIH's denial of the violation. NIH conducts its air sampling program to ensure compliance with 10 CFR 20.1204. The air sampling program does not address the requirements of License Condition 29 and Reg. Guide 8.21, which are concerned solely with criteria for conducting bioassays of individuals working with I–125 and I–131.

Accordingly, the NRC staff concludes that Violation II.D. occurred as stated.

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NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–413 and 50–414; Docket Nos. 50–369 and 50–370]

Catawba Nuclear Station, Units 1 and 2; McGuire Nuclear Station, Units 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from certain requirements of its regulations to Facility Operating License Nos. NPF–35, NPF–52, NPF–9, and NPF–17. These licenses are issued to Duke Power Company (the licensee) for operation of the Catawba Nuclear Station Units 1 and 2, located in York County, South Carolina, and the McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action is in response to the licensee's application dated February 24, 1997, for exemption from the requirements of 10 CFR 50.71(e)(4) regarding submission of revisions to the Updated Final Safety Analysis Report (UFSAR) and design change reports for facility changes made under 10 CFR 50.59 for the Catawba and McGuire nuclear stations. Under the proposed exemption, the licensee would schedule updates to the single, unified UFSAR for each of its two-unit sites based on the refueling cycle of Unit 2 of each station.

The Need for the Proposed Action

Section 50.71(e)(4) requires licensees to submit updates to their FSAR within 6 months after each refueling outage providing that the interval between successive updates does not exceed 24 months. Since Units 1 and 2 of Catawba and McGuire nuclear stations share a common UFSAR, the licensee must update the same document within 6 months after a refueling outage for either unit. Allowing the exemption would maintain the UFSAR current within 24 months of the last revision and still would not exceed a 24-month interval for submission of the 10 CFR 50.59 design change report for either unit.

Environmental Impacts of the Proposed Action

No changes are being made in the types or amounts of any radiological effluent that may be released off site. There is no significant increase in the allowable individual or cumulative