UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-12231
COMMUNITY HOSPITAL SOUTH	)	License No. 13-17124-01
Indianapolis, Indiana	)	EA 93-022

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Community Hospital South, Indianapolis, Indiana (Licensee) is the holder of Byproduct License No. 13-17124-01 first issued by the Nuclear Regulatory Commission (NRC or Commission) on October 7, 1976, and renewed in its entirety on March 31, 1988. The license expired on June 30, 1993, and is currently under timely renewal. The license authorizes the Licensee to use any radiopharmaceutical identified in 10 CFR 35.100, to use any radiopharmaceutical identified in 10 CFR 35.200 except technetium-99m generators, any radiopharmaceutical for therapy identified in 10 CFR 35.300, and any brachytherapy source identified in 10 CFR 35.400, in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on November 17, 1992. The results of the inspection 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 March 10, 1993. The Notice stated the

nature of the violations, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice by letter dated April 5, 1993. In its response, the Licensee denied Violations I and K, admitted Violations N and S with mitigating circumstances, admitted fully the remainder of the violations, and requested remission of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that with the exception of Violations M, O, and P, which are withdrawn, the violations occurred as stated; that the penalty proposed for the remaining violations designated in the Notice should be mitigated by $1,250 based on reconsideration of the application of the factor in the Enforcement Policy for Prior Opportunity to Identify; and that a civil penalty of $5,625 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 $5,625 within 30 days of the date of this Order, by check, draft, electronic transfer, or money order, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. 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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

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, 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 Violations I and K in the Notice referenced in Section II above, and

(b) whether, on the basis of such violations and the additional violations set forth in the Notice of Violation as modified in Section III above that the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 11th day of August 1993

APPENDIX
EVALUATION AND CONCLUSIONS

On March 10, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection on November 17, 1992, at Community Hospital South, Indianapolis, Indiana (Licensee). Community Hospital South responded to the Notice by letter dated April 5, 1993. In its response, the Licensee denied Violations I and K, admitted Violations N and S with mitigating circumstances, and admitted the remaining violations. In addition, the Licensee believes the NRC's assessment of the civil penalty adjustment factors was based on incorrect information. The Licensee disagreed with the NRC position (set forth in the March 10, 1993, letter transmitting the Notice) on escalating the amount of the base civil penalty for identification (50 percent) and for prior opportunity to identify (100 percent). The Licensee states that extenuating circumstances exist. Further, the Licensee requested remission of the civil penalty because of prior good performance. The NRC's evaluation and conclusions regarding the Licensee's request are as follows:

I. Violations Assessed Civil Penalties

A. Restatement of Violation I.

10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

Contrary to the above, from about February 15, 1990, to November 17, 1992, the licensee, through its Radiation Safety Committee, did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program annually.

Restatement of Licensee's Response to Violation I.

The annual review of the operations was performed. The personnel exposure assays and the consulting physicist/lab reviews were reviewed at every meeting. The construction of the report was delegated by the Radiation Safety Officer to the Consultant.

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

The Licensee's response refers to certain activities that were reviewed at each Radiation Safety Committee meeting. However, review of these activities does not constitute an "annual review of the radiation safety program." 10 CFR 35.22(b)(6) distinguishes the annual review of the radiation safety program from the other

reviews delineated in 10 CFR 35.22(b)(1) through 35.22(b)(5). Several of the required reviews are part of the routine business of the Radiation Safety Committee (e.g. recommendations for maintaining individual and collective doses as low as reasonably achievable (10 CFR 35.22(b)(1)), approval of specified individuals (10 CFR 35.22(b)(2)), and approval of minor changes in radiation safety procedures (10 CFR 35.22(b)(3))). Other reviews are required at quarterly intervals (e.g. a review of a summary of the occupational radiation dose records (10 CFR 35.22(b)(4)), and a review of all incidents involving byproduct material (10 CFR 35.22(b)(5))). However, in addition to these reviews, the Radiation Safety Committee is also required by 35.22(b)(6) to review the radiation safety program annually.

The annual review of the Licensee's radiation safety program by the Radiation Safety Committee is described in Regulatory Guide 10.8, Appendix F, "Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority." The Licensee committed to Appendix F in Section 10.1 of the application dated February 29, 1988. Additionally, Appendix F is referenced in Condition 15.A of the NRC License. Responsibility No. 7 of Appendix F of Regulatory Guide 10.8 indicates that, "The Committee shall...review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with NRC regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of NRC inspections, written safety procedures, and the adequacy of the management control system."

The Licensee's response does not indicate that the Committee reviewed the RSO's summary report of the entire radiation safety program to determine that all activities were being conducted safely and in accordance with NRC regulations and the conditions of the license and the ALARA program and philosophy. The Licensee's response also does not indicate that the Radiation Safety Committee made a determination of the adequacy of the radiation safety program on an annual basis.

All of the reviews required by 10 CFR 35.22(b) are conducted for the purpose of maintaining individual and collective occupational doses as low as reasonably

achievable (ALARA). To oversee the use of licensed material, the Committee must complete each of these six reviews at the times and occasions indicated by 10 CFR 35.22(b). If the Committee does not complete each of these six reviews, then the Committee has failed to oversee the use of licensed material. Conducting the other reviews required by 10 CFR 35.22(b)(1) through 35.22(b)(5) does not substitute for the annual review required by 10 CFR 35.22(b)(6).

The Licensee's response indicated that the RSO delegated many of the RSO's regulatory responsibilities to the consultant, including documenting the Radiation Safety Committee's annual review. NRC Information Notice No. 90-71, "Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs," describes the responsibilities of the Radiation Safety Committee that includes the annual review of the radiation safety program, responsibilities of the RSO, and use of consultants. If the Radiation Safety Committee does not possess the necessary experience or training to perform the required annual review, then the Licensee may seek qualified assistance from outside consultants. However, it is the Licensee's responsibility to ensure that the review, even if performed by a consultant, and corrective actions meet the regulatory requirements.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that the annual review was performed as required; therefore, the violation occurred as stated.

B. Restatement of Violation K.

10 CFR 35.220 requires that a Licensee authorized to use byproduct material for imaging and localization studies possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, as of November 17, 1992, the licensee did not possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour.

Restatement of Licensee's Response to Violation K.

The survey instruments possessed did not meet the intent of 10 CFR 35.220. The instruments, Victoreen CDV-700 and Victoreen 740F, were identified in various communications with the NRC. Because the range was covered and the NRC had approved amendments listing those instruments, the Licensee stated it believed it was in full compliance.

However, the Licensee stated that immediately following the November 17 inspection, it obtained a survey meter from Community Hospital East that covered the range up to 100 millirem per hour. It also purchased a Ludlum Model 14-C that covered the required range. This instrument had been budgeted for prior to the site survey and was received, calibrated and placed into service on December 12, 1992.

NRC's Evaluation of Licensee's Response to Violation K.

The Licensee admits that the survey instruments described in its written correspondence with the NRC did not meet the intent of 10 CFR 35.220. In addition, that correspondence (including the Licensee's renewal application of February 29, 1988) merely lists the survey instruments as "additional equipment" and does not request the staff to approve them for any particular purpose. In reviewing the license, the staff did not approve the instruments as satisfying the requirements of 10 CFR 35.220. Regardless of the Licensee's renewal application submitted to the NRC (dated February 29, 1988) and its assertion of tacit approval of the instrumentation in its possession at the time of submission of the license renewal, 10 CFR 35.999 (effective April 1, 1987) provides, in part, that at the time of license renewal and thereafter the amendments to 10 CFR Part 35 shall apply. Therefore, effective April 1, 1987, the Licensee was required to comply with any new requirements found in amended 10 CFR Part 35, in addition to the conditions of the existing license. 10 CFR 35.220 (effective April 1, 1987) required that the Licensee possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour. The detection survey instrument possessed by the Licensee at the time of the inspection on November 17, 1992, was only capable of measuring dose rates over the range 0.1 millirem per hour to 50 millirems per hour.

The NRC notes that prior to the NRC inspection, the Licensee had budgeted for the purchase of a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour; however, the Licensee had delayed that purchase for almost one year. The violation was identified by the Licensee's consultant (as described below). Therefore, once the Licensee identified the problem, the Licensee should have corrected the problem by obtaining the instrument on a timely basis. Further, the inspector found it necessary on several occasions during the inspection to remind the Licensee to obtain the required instrumentation. During the inspection, the Licensee borrowed an appropriate survey instrument until one could be purchased.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that the Licensee possessed the required survey instrumentation; therefore, the violation occurred as stated.

C. Restatement of Violation N.

10 CFR 35.50(e) requires, in part, that a licensee retain records of dose calibrator tests for accuracy, linearity and geometrical dependance and the records must include the signature of the Radiation Safety Officer.

Contrary to the above, from [illegible] February 17, 1989, to November 17, 1992, the licensee [illegible] records of dose calibrator tests for accuracy, linearity and geometrical dependence did not include the signature of the Radiation Safety Officer.

Restatement of Licensee's Response to Violation N.

Violation admitted with mitigating circumstances. The tests were performed and the results were reviewed by the Radiation Safety Committee. The consulting physicist was authorized by the Radiation Safety Officer to perform the review.

NRC's Evaluation of Licensee's Response to Violation N.

The Licensee admitted the violation because the Radiation Safety Officer did not sign the records of

dose calibrator quality assurance tests. The NRC recognizes the Radiation Safety Officer as the individual who is responsible for ensuring the safe use of licensed material for the institution. Although certain tasks may be delegated, the Radiation Safety Officer may not delegate responsibility for certain matters specifically assigned by regulation (including the obligation to sign records imposed by 10 CFR 35.50(e)) to another individual. The signature of the Radiation Safety Officer is an indication of acknowledgement of the test results on behalf of the Licensee. Lack of the Radiation Safety Officer's signature is an indication that dose calibrator quality assurance test results were not directly within the knowledge of the Licensee.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that the Radiation Safety Officer signed the records as required; therefore, the violation occurred as stated.

D. Restatement of Violation S.

10 CFR 35.70(h) requires, in part, that a licensee retain records of each contamination survey required by 10 CFR 35.70. The records must include, in part, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

Contrary to the above, from January 2, 1992 to November 17, 1992, the licensee failed to retain records of surveys required by 10 CFR 35.70 that included the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. Specifically, removable contamination was expressed in counts per minute.

Restatement of Licensee's Response to Violation S.

The Licensee admitted the violation with mitigating circumstances. The counting efficiency of the Licensee's well counter had been determined and trigger levels established. However, the data from the well counter was stored as counts per minute (cpm) on the well counter tape.

NRC's Evaluation of Licensee's Response to Violation S.

Notwithstanding the Licensee's description of its method of counting samples and the form in which the data were recorded, the Licensee did not deny that the data in the records were in incorrect units. In summary, the Licensee admitted the violation.

Conclusion

The NRC has concluded that the information provided in the Licensee's response does not provide a basis to find that it recorded removable contamination results in disintegrations per minute per 100 square centimeters; therefore, the violation occurred as stated.

E. NRC Withdrawal of Violations M, O, and P.

Violation M was for the Licensee's failure to test a sealed source containing 224 microcuries of cesium-137 for leakage at required six month intervals, with no other interval approved by the Commission or an Agreement State. This failure also resulted in Violation O and P because the Licensee had no records of leakage test results and physical inventories containing the signature of the Radiation Safety Officer.

The Licensee stated that at the time of the last NRC inspection on February 16, 1989, the inspector advised it to discontinue doing leak tests on its source because the activity level was below the requirement. This was questioned by the physicist and documented in the Radiation Safety Committee meeting minutes. However, the Licensee stopped doing leak tests on this source based on this advice, and discontinued the preparation of any records for those tests.

Although the Licensee unconditionally admitted Violation M and O, the staff has considered the Licensee's claim that an NRC inspector had advised the Licensee that leak tests were not necessary. Additionally, the staff has reviewed the Licensee's contention that the physical inventory was not signed by the Radiation Safety Officer because the source was below the activity that required a leak test. The staff did provide such advice for leak tests during the February 16, 1989, inspection. In view of that advice, which was erroneous because 10 CFR 35.59(b)(2) was in effect at the time of that inspection, the Licensee

discontinued the leak test of its sealed source and preparation of records for those tests as required by 10 CFR 35.59(d). Additionally, the Licensee's Radiation Safety Officer discontinued signing records of physical inventories for this source as required by 10 CFR 35.59(g). While it appears that the Licensee was in violation of 10 CFR 35.59(b)(2) and 35.59(d) from January 17, 1991 through November 17, 1992, and 10 CFR 35.59(g) from February 17, 1989 through November 17, 1992, the Licensee did act in good faith based upon the advice of an NRC inspector.

Subsequent to the inspection, the NRC inspector was in contact with the Licensee's consulting medical physicist. The consultant performed the required leak test and removable radioactivity was not detected. However, the record of that leak test was not signed by the Licensee's Radiation Safety Officer because he had delegated to the consulting medical physicist the authority to sign that record. As stated above with reference to records of dose calibrator tests, the Radiation Safety Officer cannot delegate such authority.

Conclusion

The evidence supports the Licensee's position that during a February 16, 1989, inspection, the NRC inspector provided erroneous advice and the Licensee in good faith discontinued performing the leakage test for its sealed source and preparation of records for those tests. Additionally, the Licensee's Radiation Safety Officer discontinued signing records of leak tests and physical inventories. Therefore, in the staff's discretion, Violations M, O, and P are withdrawn. However, as explained in Section II below, this does not affect either the scope of the Severity Level III problem or the amount of the civil monetary penalty assessed to the problem.

II. Summary of Licensee's Request for Mitigation

The Licensee requests remission of the proposed civil penalty because according to the Licensee, the asserted bases for the increase of the base civil penalty are factually incorrect and extenuating circumstances exist. Acknowledging that violations did occur, the Licensee asserts that it was acting to perform the duties, in substance, expected of it. The Licensee also asserts that it acted promptly to correct the violations.

The Licensee states that it is not fair or desirable to penalize the hospital under the civil penalty adjustment factors of Identification and Prior Opportunity to Identify. The Licensee contends that the NRC inappropriately escalated the civil penalty because not all of the violations were identified by the NRC, the Licensee took corrective action, and the Licensee's medical physicist diligently reviewed and reported on compliance matters. Therefore, any increase in the amount of the civil penalty would discourage a licensee from finding and correcting issues and would be in direct opposition to the NRC's enforcement philosophy of encouraging licensees to identify issues.

The Licensee argues that in most instances, the goals of the NRC's regulations have been accomplished and that the hospital and its employees, especially the consulting physicist, have acted responsibly. The Licensee states that in a few instances there was ignorance of the requirement; however, in most circumstances there was a genuine effort to comply. Therefore, as a result of positive licensee performance, the Licensee requests mitigation by at least 50 percent and as much as 100 percent of the base civil penalty.

The Licensee opposes the 25 percent escalation based on the Corrective Action factor. The Licensee argues that xenon-133 procedures were immediately terminated when the Licensee was informed by the NRC inspector on November 17, 1992, of the apparent violation. Additionally, the Licensee believes that the promptness with which it corrected all the violations that involved use of radioactive materials should be considered a mitigating factor. Therefore, as a result of prompt and immediate corrective action, the Licensee requests the base civil penalty be reduced by 50 percent . Additionally, the Licensee took exception to a statement in NRC's letter of March 10, 1993, transmitting the Notice of Violation and Proposed Imposition of Civil Penalty that the proposed corrective actions did not include measures to ensure management involvement in radiation safety.

In conclusion, the Licensee states that mitigation of 100 percent of the civil penalty amount is justified as a result of reducing the base civil penalty by 50 percent under licensee performance and 50 percent under corrective action.

NRC Evaluation of Licensee's Request for Mitigation

The Licensee is correct that the NRC Enforcement Policy (Policy) encourages licensees to monitor, supervise and audit activities in order to assure safety and compliance. However, this is only one goal of the Policy. The purpose

of the Policy is to ensure compliance, obtain prompt correction of violations, deter future violations and encourage improvement in the performance of a licensee.

The findings of the November 17, 1992, inspection and the discussions with the Licensee's representatives during the February 18, 1993, enforcement conference clearly indicated that the Licensee's Radiation Safety Officer (RSO) was not ensuring that radiation safety activities were performed in accordance with approved procedures and regulatory requirements in the daily operation of the Licensee's byproduct material program, as required by 10 CFR 35.21(a). This was clearly the root cause of all the violations.

Furthermore, the RSO permitted the consulting medical physicist to assume his (the RSO's) duties. The Licensee is still responsible for the radiation safety program, as required by the license, if the licensee employs a consultant to assist the RSO. In this instance, the consulting medical physicist identified some violations in the radiation safety program and communicated those violations to Licensee management; however, few if any corrective actions were initiated by the RSO or Licensee management. The fact that previously identified violations went uncorrected demonstrates the lack of managerial attention to radiation safety; and, in the aggregate, the violations represent a significant breakdown in the control of NRC licensed activities at Community Hospital South. Therefore, the violations were appropriately categorized as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C. The staff's withdrawal of Violations M, O, and P does not negate the above facts or conclusions. Accordingly, the remaining violations represent a Severity Level III problem, and the staff's withdrawal of Violations M, O, and P is not a basis for reduction of the proposed civil penalty.

The Licensee contends that the NRC was inconsistent in applying the civil penalty adjustment factors and the Licensee was penalized because the consulting medical physicist diligently reviewed and reported on compliance matters. However, while the consulting medical physicist identified four violations to management, Licensee management was unresponsive and permitted these four violations to continue uncorrected.

The Licensee believes that it should receive credit for the findings of the consultant medical physicist and that, therefore, the civil penalty adjustment factors of Identification and Prior Opportunity to Identify were

misapplied. The NRC disagrees that the Identification factor was misapplied. The Licensee is correct that the cover letter enclosing the Notice of Violation and Proposed Imposition of Civil Penalty incorrectly states that the NRC identified all the violations. In escalating the base civil penalty by 50 percent under the Identification factor, the NRC recognizes that the Licensee's consultant identified four of the violations prior to the NRC inspection (i.e. Radiation Safety Committee did not meet quarterly, ventilation rates were not measured in rooms of xenon-133 usage, need for proper survey instrumentation, and the lack of annual refresher training for ancillary personnel). However, the remaining 13 of the 17 violations (not counting Violations M, O, and P) were identified by the NRC. The NRC Enforcement Policy states, in part, "The purposes of this [Identification] factor is to encourage licensees to monitor, supervise, and audit activities in order to assure safety and compliance." NRC expects licensees to be pro-active in auditing their programs and instituting corrective action when violations are identified. In this case, the NRC identified the majority of the violations as a result of the Licensee's failure to effectively audit their program. Accordingly, 50 percent mitigation under the Identification factor is warranted.

In escalating the base civil penalty by 100 percent under the Prior Opportunity to Identify factor, the NRC considered the fact that the Licensee's consulting medical physicist provided periodic written reports to management that addressed four of the violations; however, management did not correct two of those violations (i.e. ventilation rates were not measured in rooms of xenon-133 usage, and the need for proper survey instrumentation). Additionally, Licensee management failed to plan and take effective corrective steps to correct the remaining violations (i.e. Radiation Safety Committee did not meet quarterly and the lack of annual refresher training for ancillary personnel) within a reasonable time after identification. Moreover, the NRC issued a Notice of Violation to the Licensee dated February 16, 1989, identifying five violations. Two of the violations (i.e. annual refresher training for ancillary personnel was not conducted, and ventilation rates were not measured in rooms of xenon-133 usage) were repeat violations identified during the November 17, 1992, inspection. The License should have identified these violations sooner as a result of the consultant's audit findings, and taken effective and lasting corrective steps within a reasonable time. Therefore, the Licensee had prior opportunity to identify and correct violations which, in part, contributed to the breakdown in the control of licensed activities and represent a lack of attention or carelessness toward

licensed responsibilities. However, since you only had a prior opportunity to identify some of the violations contributing to the breakdown in control of your program, the NRC staff has reconsidered its position and finds that, on balance, escalation of 50 percent, as opposed to 100 percent, is appropriate based on the Prior Opportunity to Identify factor.

The Licensee argues that escalation of the base civil penalty by 25 percent for corrective action is not appropriate since the example cited in the Notice describing the continued use of xenon-133 and the failure to perform room ventilation studies is incorrect. The NRC acknowledges that the Licensee discontinued performing xenon-133 studies in the unauthorized location ("Raytheon Room") upon identification of the violation by the NRC. On November 17, 1992, the Licensee changed locations where xenon-133 was administered and resumed the use of xenon-133 for patient studies in the original authorized location (Room 1). However, the Licensee failed to resume the performance of measurements of ventilation rates in Room 1 until February 1993. Therefore, the same violation for failure to perform measurements of ventilation rates continued in Room 1 after NRC identification of the initial problem in the "Raytheon Room". Additionally, the Licensee did not take immediate actions upon discovery of other violations (i.e., need for proper survey instrumentation and the lack of annual refresher training for ancillary personnel) to restore safety and compliance with the requirements. Once the consultant identified the failure to possess proper survey instrumentation, the Licensee did not purchase the instrumentation for almost a year. In addition, up to the time of the enforcement conference, the annual refresher training for ancillary personnel had not been conducted. In regards to these violations, the Licensee did not take prompt, extensive, or lasting corrective action upon their discovery to restore safety and compliance.

Addressing the Licensee's request for mitigation up to 100 percent for good past performance, the NRC Enforcement Policy provides in pertinent part, "License Performance .... Notwithstanding good performance, mitigation of the civil penalty based on this factor is not normally warranted where the current violation reflects a substantial decline in performance that has occurred over the time since the last NRC inspection ...." Even if the Licensee's past performance had been good, this guidance negates the Licensee's request for mitigation. Moreover, the Licensee's past performance has not been good such as to warrant mitigation under this factor. Five violations were identified during the last inspection on February 16, 1989.

Two of those violations had not been corrected at the time of the November 17, 1992, inspection. Those violations were: (1) annual refresher training was not conducted for employees involved with radiation safety; and (2) ventilation rates in rooms where xenon-133 was used were not done at six month intervals. Furthermore, the corrective action for a third violation from the February 16, 1989, inspection was not effective. While the Licensee did appoint a nursing representative to serve on the Radiation Safety Committee, the Licensee did not ensure the attendance of that person. As a result, the nursing representative did not attend any meetings of the Radiation Safety Committee following the appointment. Therefore, no mitigation for good past performance is warranted.

Conclusion on Mitigation

The NRC staff has concluded that the information provided in the Licensee's response provides an adequate basis for partial mitigation of the civil penalty. Accordingly, a reduction of the civil penalty in the amount of $1,250 is warranted.

III. NRC Conclusion

The information provided by the Licensee in its Reply and Answer to a Notice of Violation, dated April 5, 1993, described extenuating circumstances for Violations M, O, and P contending that an NRC inspector told the Licensee to discontinue the activities associated with those violations. Such advice was provided to the Licensee regarding Violations M and O. The information provided was erroneous, but the Licensee apparently acted in good faith and discontinued the regulatory actions associated with Violations M, O, and P. Consequently, Violations M, O, and P have been withdrawn. As explained above, withdrawal of Violations M, O, and P does not affect the overall Severity Level III problem associated with the breakdown of the management oversight of licensed activities. However, based on reconsideration of the factor for Prior Opportunity to Identify, a reduction of $1,250 in the amount of the proposed civil penalty is warranted.

In summary, the Licensee's Reply and Answer to a Notice of Violation, including the extenuating circumstances surrounding Violations M, O, and P, did not provide an adequate basis for reduction of the severity level. However, a reduction of $1,250 in amount of the proposed civil penalty is warranted. Consequently, a civil penalty in the amount of $5,625 should be imposed.

AUG 11 1993

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