THE UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

IN THE MATTER OF:	)	
	)	
Pharmatopes, Incorporated	)	Byproduct Material
4545 43rd Street N.W.	)	License No. 08-18308-01MD
Washington, D.C. 20016	)	EA 81-03

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Pharmatopes, Incorporated, Washington, D.C. (the "licensee") is the holder of Byproduct Material License No. 08-18308-01MD (the "license") issued by the Nuclear Regulatory Commission (the "Commission") which authorizes the licensee to possess and distribute byproduct material to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR 35 or under equivalent licenses of Agreement States in accordance with the conditions specified therein. The license was issued on December 12, 1978, and has an expiration date of December 31, 1983.

II

A routine inspection was conducted of licensed activities under the license on August 29 and September 25, 1980. As a result of this inspection, it appeared that the licensee had not conducted its activities in full compliance with the conditions of the license and with the requirements of the Nuclear Regulatory Commission's "Standards for Protection Against Radiation", Part 20, "Rules of General Applicability to Domestic Licensing of Byproduct Material", Part 30,

and "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions," Part 71, Title 10, Code of Federal Regulations.

A written Notice of Violation was served upon the licensee by letter dated December 15, 1980, specifying the items of noncompliance in accordance with 10 CFR 2.201. A Notice of Proposed Imposition of Civil Penalties was served concurrently upon the licensee in accordance with Section 234 of the Atomic Energy Act of 1954, as amended (42 USC 2282), and 10 CFR 2.205, which incorporated by reference the Notice of Violation. An answer from the licensee to the Notice of Violation and the Notice of Proposed Imposition of Civil Penalties was received on January 12, 1981.

III

Upon consideration of the answers received and the statements of fact, explanation, and argument for deferral, compromise, mitigation, or cancellation contained therein, as set forth in Appendix A to this Order, the Director of the Office of Inspection and Enforcement has determined that the penalties proposed for the items of noncompliance, except for Item D, designated in the Notice of Violation should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 USC 2282), and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The licensee pay civil penalties in the total amount of Seven Thousand Fifty Dollars within twenty-five days of the date of this Order, by check, draft, or money order payable to the Treasurer of the United States and mailed to the Director of the Office of Inspection and Enforcement.

V

The licensee may, within twenty-five days of the date of this Order, request a hearing. A request for a hearing shall be addressed to the Director, Office of Inspection and Enforcement, U.S.N.R.C., Washington, D.C. 20555. A copy of the hearing request shall also be sent to the Executive Legal Director, U.S.N.R.C., Washington, D.C. 20555. If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. Upon failure of the licensee to request a hearing within twenty-five days of the date of this Order, the provisions of this Order shall be effective without further proceedings and, if payment has not been made by that time, the matter may be referred to the Attorney General for collection.

VI

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

a. whether the licensee was in noncompliance with the Commission's regulations and the conditions of the license as set forth in the Notice of Violation with the exception of Item D, referenced in Sections II and III above; and

b. whether on the basis of such items of noncompliance, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Victor Stello, Jr.
Director
Office of Inspection and Enforcement

Dated at Bethesda, Maryland
this 30th day of March 1981

Attachment:
Appendix A

APPENDIX A

EVALUATIONS AND CONCLUSIONS

For each item of noncompliance and associated civil penalty identified in the Notice of Violation, the original item of noncompliance is restated and the Office of Inspection and Enforcement's evaluation and conclusion regarding the licensee's response to each item contained in Exhibit A to Pharmatopes, Inc. letter dated January 6, 1981 is presented. The response to the licensee's general arguments in support of mitigation of the penalty are provided at the end of this Appendix after the discussion of the individual items of noncompliance.

1. STATEMENT OF NONCOMPLIANCE FOR ITEM A

10 CFR 20.101(a), "Radiation dose standards for individuals in restricted areas," limits the dose to hands and forearms, feet and ankles of an individual working in a restricted area to 18.75 rems per calendar quarter.

Contrary to the above, an individual working in a restricted area received a dose of approximately 20.3 rem to the hand during the fourth calendar quarter of 1979.

This is an infraction. (Civil Penalty - $500)

EVALUATION OF LICENSEE'S RESPONSE TO ITEM A

The licensee admits noncompliance and, by way of explanation, states that the individual in question was hired on the basis of qualifications and education and that it was felt that he would function fairly well with minimal supervision. The licensee recognizes, however, that the individual's qualifications and education alone do not assure that overexposures will not occur. Greater attention to radiation safety requirements, such as those cited in the Notice of Violation, is necessary by the licensee in its conduct of licensed activities.

CONCLUSION

The item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

2. STATEMENT OF NONCOMPLIANCE FOR ITEM B

10 CFR 20.405, "Reports of overexposures and excessive levels and concentrations," requires the submission of a report to the Commission within 30 days of each exposure to radiation in excess of the limits of 10 CFR 20.101. 10 CFR 20.409, "Notifications and reports to individuals," requires notification within 30 days to individuals who received exposures which were the subject of reports submitted to the Commission under 10 CFR 20.405.

Contrary to the above, subsequent to the exposure of an individual's hand to a radiation dose in excess of the limits of 10 CFR 20.101 during the

fourth calendar quarter of 1979, neither the Commission nor the individual was notified within 30 days.

This is an infraction. (Civil Penalty - $500)

EVALUATION OF LICENSEE'S RESPONSE TO ITEM B

The licensee admits noncompliance in failure to report the overexposure to the Commission and denies noncompliance in not reporting the overexposure to the individual. The licensee explains that failure to report the overexposure to the Commission resulted from the false impression that the film badge supplier would notify the Commission. The licensee also states that the exposure was discussed with the employee before termination of his employment.

While the licensee denies noncompliance with regard to 10 CFR 20.409 because the individual was notified orally at the time of his termination, the regulation requires that the individual be notified in writing within 30 days of the exposure. Even the oral notification did not fall, apparently, within the 30 day period. This notification of the individual in writing was finally made in a letter dated December 29, 1980.

CONCLUSION

The item as stated is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

3. STATEMENT OF NONCOMPLIANCE FOR ITEMS C.1, C.2, and C.3

10 CFR 20.201, "Surveys," requires that such surveys be made as necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment and measurements of levels of radiation or contamination of radioactive material present.

1. Contrary to the above, the licensee failed to make such surveys as were necessary to assure compliance with 10 CFR 20.101, "Radiation dose standards for individuals in restricted areas." Specifically, on six occasions between January and July 1980, involving four individuals, TLD ring badges were issued but were not evaluated by the licensee.

   Further, the licensee failed to evaluate the exposure to the hands of one individual for a period when the individual's TLD ring badge was damaged and could not be read.

   This is an infraction. (Civil Penalty - $500)

2. Contrary to the above, surveys were not made to assure compliance with 10 CFR 20.103, "Exposure of individuals to concentrations of radioactive materials in air in restricted areas." Specifically, surveys of airborne radioactivity were not conducted during the routine handling of up to 50 millicurie quantities of iodine-131 in liquid form.

   This is an infraction. (Civil Penalty - $500)

3. Contrary to the above, as of September 25, 1980, surveys were not made to assure compliance with 10 CFR 20.106, "Radioactivity in effluents to unrestricted areas." Specifically, no surveys were made of the concentrations of radioactive materials in the effluent air discharged to unrestricted areas from a hood where up to 50 millicuries of iodine-131 in liquid form were routinely handled.

   This is an infraction. (Civil Penalty - $500)

EVALUATION OF LICENSEE'S RESPONSE TO ITEM C.1

The licensee admits the item of noncompliance and explains that administrative failures caused the item of noncompliance.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEMS C.2 AND C.3

The licensee admits both items of noncompliance, but explains that mechanical procedures for handling of I-131 solution were discussed during two previous NRC inspections.

NRC inspections are audits in nature and do not include examining every aspect of a licensee's activities. The failure to find noncompliance does not bar the finding of noncompliance during some future inspection or the imposition of civil penalties when noncompliance is found.

CONCLUSION

The items, as stated, are items of noncompliance. The information given does not provide a basis for modification of this enforcement action.

4. STATEMENT OF NONCOMPLIANCE FOR ITEM D

10 CFR 19.12, "Instructions to Workers," requires that all individuals working in restricted areas be instructed in the precautions or procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses for the protection of personnel from exposure to radiation or radioactive materials.

Contrary to the above, on August 29 and September 25, 1980, individuals working in a restricted area apparently were not instructed in the precautions and procedures to minimize exposure to radioactive materials and the requirements of the license, including the requirements to use protective devices (syringe shields, lab coats and gloves) and perform tests for monitoring hand contamination.

This is an infraction. (Civil Penalty - $500)

EVALUATION OF LICENSEE'S RESPONSE TO ITEM D

The licensee denies the item of noncompliance and states that the individuals were trained although they did not perform in conformance with the instruction given. The licensee intends to place greater emphasis on monitoring individual compliance.

Although the licensee's response indicated training was provided to employees, the pharmacist's failure to follow procedures listed in the Notice of Violation (see item F) and lack of knowledge of some procedures indicated that the training program was apparently not entirely effective to ensure personnel adherence to procedures. However, in view of the fact that the licensee had provided training and intends to place greater emphasis on monitoring individual compliance, we are remitting the penalty for item D in its entirety. In this regard, we intend to examine the licensee's training program and its effectiveness in more detail during future inspections.

CONCLUSION

The penalty for this item of noncompliance is remitted in its entirety.

5. STATEMENT OF NONCOMPLIANCE FOR ITEM E

10 CFR 71.5, "Transportation of licensed material," requires that transportation of licensed material be made in accordance with the applicable requirements of the Department of Transportation in 49 CFR 170-189, insofar as such regulations relate to the packaging of byproduct, source or special nuclear material, marking and labeling of the packages, loading and storage of packages, placarding of the transportation vehicles, monitoring requirements and accident reporting.

49 CFR 173.393, "General packaging and shipment requirements," requires that, prior to each shipment of any package, the shipper insure by examination or appropriate test that the packaging is in an unimpaired physical condition, each closure device of the packaging is properly installed and secured, and external radiation and contamination levels are within allowable limits.

Contrary to the above, on August 29, 1980, prior to shipping packages containing radioactive materials, the licensee failed to survey the packages for external radiation and contamination levels, failed to assure that each package was in an unimpaired physical condition, and failed to ensure that each package was properly sealed and secured.

This is an infraction. (Civil Penalty - $500)

EVALUATION OF LICENSEE'S RESPONSE TO ITEM E

The licensee admits the failure to survey the packages for external radiation and contamination levels, but denies the failure to assure that each package was in an unimpaired physical condition and that each package was properly sealed and secured. The licensee states that the syringe containers are hand-packed and closed in a positive locking latch type attache case and that little more can be done to ensure that they are in an unimpaired physical condition and are properly sealed and secured.

The licensee also states that previous NRC inspections failed to identify a problem in surveying cases and therefore, the licensee assumed that its procedures were adequate.

Once again, it should be noted that inspections are essentially audits of the licensee's activities, not complete reviews of every aspect of the licensee's operations. The fact that a particular inspection results in no findings of noncompliance does not constitute a finding that the licensee's activities are wholly in compliance with all requirements.

With respect to the failure of previous inspections to identify such noncompliances, the licensee should note that NRC inspectors do not ordinarily examine every facet of a licensee's activities. Licensees are expected to comply with all NRC requirements, regardless of whether all of the licensee's activities are examined during each inspection.

The licensee's reply to the failure to assure that each package was in an unimpaired physical condition, and was properly sealed and secured, indicates a possible misunderstanding of the citation.

On August 25, 1980, the inspectors observed that one attache case used for shipping of radioactive materials had a sizeable hole in the corner. In addition, the inspectors also noted that one package was shipped while missing the required security seal. These observations indicated that the licensee had not assured that each package was in an unimpaired physical condition and was properly sealed and secured.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of the enforcement action.

6. STATEMENT OF NONCOMPLIANCE FOR ITEMS F.1, F.2, F.3, F.4, F.5, F.6, AND F.7

Condition 20 of License No. 08-18308-01MD requires that licensed materials be possessed and used in accordance with the statements, representations and procedures contained in the license application dated October 5, 1979 and November 27, 1978.

1. "Laboratory Rules for the Use of Radioactive Material," attached as Item No. 15 to the license application, requires that individuals working in the restricted area wear personnel monitoring devices (film badges and TLD ring badges).

   Contrary to the above, on August 29, 1980, an individual was observed working in a restricted area and was not wearing a personnel monitoring device (a film badge or a TLD ring badge).

   This is an infraction. (Civil Penalty - $500)

2. "Laboratory Rules for the Use of Radioactive Material," attached as Item No. 15 to the license application, requires that individuals use syringe shields when preparing samples of radioactive material.

   Contrary to the above, on August 29, 1980, an individual was observed withdrawing a sample of technetium-99m into a syringe without using a syringe shield.

   This is an infraction. (Civil Penalty - $750)

   This item of noncompliance had also been identified during a previous inspection conducted on September 13, 1979.

3. "Laboratory Rules for the Use of Radioactive Material," attached as Item No. 15 to the license application, requires that individuals monitor their hands and clothing for contamination before leaving an area where radioactive materials are used.

   Contrary to the above, on August 29, 1980 and September 25, 1980, individuals were observed not monitoring their hands and clothing for contamination before leaving an area where radioactive materials were used.

   This is an infraction. (Civil Penalty - $500)

4. Item 1 of The Laboratory Rules requires that individuals wear laboratory coats at all times in areas where radioactive materials are used.

   Contrary to the above, on August 29, 1980 and September 25, 1980, individuals were observed working in areas where radioactive materials were used and were not wearing laboratory coats.

   This is an infraction. (Civil Penalty - $500)

5. Item 10 of the license application states that you will follow the procedures described in Appendix D, Section 2 of NUREG 0338 (Rev. 1) for calibration of the dose calibrator.

   Items C and I of Appendix D, Section 2, require performance of a daily constancy check on each dose calibrator. Item I.9 requires that higher than normal background levels be investigated and eliminated.

   Contrary to the above requirements, on August 29, 1980, it was observed that a constancy check was not performed on one dose calibrator and a high background reading was not investigated on another dose calibrator. Both calibrators were used for assaying patient doses that day.

   This is an infraction. (Civil Penalty - $500)

6. Item 17.D.3 of the license application states that the method for performing wipe tests be sufficiently sensitive to detect 100 disintegrations per minute.

   Contrary to the above, as of September 25, 1980, the procedures used for analyzing wipe test samples was not sufficient to detect 100 disintegrations per minute.

   This is an infraction. (Civil Penalty - $500)

7. Item 2 of the "Procedures for Opening Packages Containing Radioactive Materials" requires that the exposure levels measured at three (3) feet from each incoming package be recorded.

   Contrary to the above, as of September 25, 1980, the exposure levels for incoming molybdenum-99/technetium-99m generators were not recorded.

   This is a deficiency. (Civil Penalty - $50)

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.1

The licensee admits that this item of noncompliance occurred.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of the enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.2

The licensee admits this item of noncompliance and states, in explanation, that the individual was made nervous by the inspection. The licensee further states that it had understood, prior to the September 13, 1979 inspection, that syringe shields were required only for the preparation of reagent kits to be used for patient doses rather than for the preparation of all patient doses. As the licensee acknowledges, NRC inspectors informed the licensee during an exit interview on September 13, 1979, that syringe shields are required for preparation of all patient doses.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.3

The licensee admits that this item of noncompliance occurred on August 29, 1980 but denies that it occurred on September 25, 1980. The licensee explains that, on September 25, 1980, the pharmacist left the preparation area but did do so with his hands folded in front of his chest to avoid possible contamination. The licensee also states that the frisker room monitor and two G-M monitors were being calibrated and/or repaired at the time of the inspection. Only one GM monitor was available and this was being used in the dispatcher area to survey packages on September 25, 1980.

With respect to the September 25, 1980 inspection, it should be noted that during the inspection, the inspectors observed that the drivers did not monitor themselves for contamination prior to leaving the pharmacy, which is a restricted area. These drivers had handled potentially contaminated shielded containers while they loaded the attache cases used to carry the radioactive material. These are the actions that constituted the noncompliance. The citation was not made for the pharmacist's actions that were observed during the September 25, 1980 inspection. Inspectors did observe that the pharmacist did not perform the required monitoring during the August 19, 1980 inspection.

CONCLUSION

This item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.4

The licensee admits that this item of noncompliance occurred on August 29, 1980 but denies that it occurred on September 25, 1980. The September 25, 1980 item referred to the failure of the licensee's drivers to wear lab coats. The licensee explains that it understood that drivers were not users of radioactive materials and therefore were not required to wear laboratory coats. The licensee also states that previous inspections had not alluded to drivers as being users of radioactive material.

With respect to the September 25, 1980 response, as noted above, the drivers were observed handling potentially contaminated shielded containers while they loaded the attache cases used to carry the radioactive material. The drivers were not wearing lab coats. Lab coats are required to be worn by all individuals handling radioactive materials, not just pharmacists and technicians.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.5

The licensee admits the failure to perform the daily constancy check but denies the failure to investigate and eliminate higher than normal background levels. The licensee states that the individual was aware of the background level and utilized a feature of the dose calibrator which substracts out background levels to give true readings. The licensee states that the individual indicated the high background was due to a needle cap which fell next to the ionization chamber.

The license requires that higher than normal backgrounds be investigated and eliminated. During the August 25, 1980 inspection, the pharmacist stated that in the past, such readings were due to contaminated vials and needle caps which sometimes fell between the sample chamber and shield. The pharmacist had made no investigation which would have shown whether or not his assumption was accurate. No investigation of this higher than normal background reading was undertaken until the pharmacist was questioned by the inspectors.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.6

The licensee denies this item of noncompliance and explains that previous inspections had evaluated operating procedures for wipe testing and therefore they were assumed acceptable. In support of mitigation of the penalty, the licensee says that the inspection report erroneously states that the sodium iodide counting system had not been calibrated for several years and explains that it had been calibrated duri. its 18 months of operation.

The statement in the report about the counting system calibration was intended to place a lower limit on the system's sensitivity. No detector efficiency was in the records available to the inspectors. Even assuming a maximum efficiency of 100%, the counting technique used by the licensee was incapable of achieving the required sensitivity of 100 disintegrations per minute. The item of noncompliance was not based on the time since the last calibration, but rather the sensitivity of the method.

The licensee's response indicates a lack of understanding of the item of noncompliance. The licensee's procedures require that the licensee be able to detect 100 disintegrations per minute on the wipe sample. The procedure employed by the licensee on the day of the inspection was incapable of detecting this level of contamination. Additional shielding and relocation of the detector is unlikely to achieve the required sensitivity so long as a six-second counting time is employed.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM F.7

The licensee admits this item of noncompliance and states that it had mistakenly assumed that compliance with only the requirements of 10 CFR 20.205 was acceptable.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the license does not provide a basis for modification of this enforcement action.

7. STATEMENT OF NONCOMPLIANCE FOR ITEM G

10 CFR 30.41, "Transfer of Byproduct Material," requires that, prior to transferring licensed material, the licensee verify that the transferee's license authorizes the receipt of the type, form and quantity of byproduct material to be transferred.

Contrary to the above, on two occasions in 1980, byproduct material was transferred to persons without verifying that those persons were authorized to receive the material.

This is an infraction. (Civil Penalty - $750)

This item of noncompliance had also been identified during a previous inspection conducted on September 13, 1979.

EVALUATION OF LICENSEE'S RESPONSE TO ITEM G

The licensee admits this item of noncompliance and states that an attempt had been made by phone and letter to obtain a letter of timely renewal or new license and that the licensee had been orally assured that their customer had a valid license. While the licensee indicated that oral verification by the customers had been made, 10 CFR 30.41 requires that any oral verification be confirmed in writing within 10 days. Written verification had not been completed.

CONCLUSION

The item, as stated, is an item of noncompliance. The information presented by the licensee does not provide a basis for modification of this enforcement action.

Evaluation of Licensee's Protest of Imposition of Civil Penalties

In Exhibit B of Pharmatopes, Inc., January 6, 1981 letter, the licensee protests the imposition of civil penalties based on "...explanations of items of noncompliance, as well as a demonstration of extenuating circumstances." In addition to the two arguments discussed below, the licensee argued that incorrect assumptions by the NRC in finding noncompliance and differing interpretations of license requirements should be considered as a basis for mitigating the civil penalties. These contentions have been addressed in the NRC's evaluation of the licensee's response to the specific items of noncompliance. The licensee also states that there are several "discrepancies" in the NRC's inspection report. The Notice of Violation was based on the inspection findings. The cited "discrepancies" do not affect the findings used as a basis for the cited items of noncompliance.

1. Organizational Problems

The licensee contends that the circumstances at the Washington, D.C. facility are not common to the Company and resulted from a recent managerial change, an increased volume of new business, and difficulties in recruiting and training new personnel.

NRC Evaluation

The NRC acknowledges that the licensee's managerial problems contributed to the items of noncompliance. In fact, the NRC's concerns about the licensee's radiation safety program are based in large part on this apparent breakdown in management controls. This does not, however form the basis for remitting or mitigating any portion of the proposed civil penalties.

While the licensee may understandably experience organizational difficulties during a change in management or a period of business expansion, such difficulties cannot be allowed to interfere with strict adherence and attention to the requirements for the safe handling and use of radioactive materials. Utmost care and caution in the conduct of licensee activities must be exercised at all times. Imposition of civil penalties is important to emphasize to licensees that the Commission expects scrupulous adherence to its requirements. In this particular case, civil penalties are necessary to bring forcefully to the licensee's attention that the breakdown in control of licensed activities revealed in the items of noncompliance is unacceptable and to deter future violations.

2. Failure of Previous NRC Inspections to Identify Items of Noncompliance

The licensee states, both in Exhibit B and in the replies to several specific items of noncompliance, that previous NRC inspections had failed to identify items which were cited during this inspection. The licensee makes the argument that it should "...have the opportunity to comment on these items and institute corrective measures prior to the imposition of civil penalty."

NRC Evaluation

An NRC licensee is responsible for ensuring that all licensed activities are conducted in accordance with NRC regulations and the conditions of the license. There is no allowance for a licensee to be in noncompliance until the item is identified during an inspection. Escalated enforcement through the imposition of civil penalties may be, and often is, required for items of noncompliance identified for the first time. The determination as to whether civil penalties are appropriate involves consideration of a number of factors, including the nature and number of items of noncompliance as well as the recurrence of items of noncompliance. In this case, our

inspections revealed a number of failures to adhere to radiation safety requirements, which demonstrated an overall weakness in Pharmatopes' control of licensed activities. In such circumstances, civil penalties are appropriate. We have considered the fact that some of the items have been cited for the first time, and have incorporated this factor in our determinations, by assessing these items with a civil penalty at the lower end of the scale that is used in making the assessment. Greater weight may be accorded for recurrent items in determining whether civil penalties should be imposed, and, as here, a higher amount on the scale for recurring items of noncompliance may be appropriate. The fact that several items were not cited during previous inspections does not form a basis for remitting or mitigating proposed civil penalties.