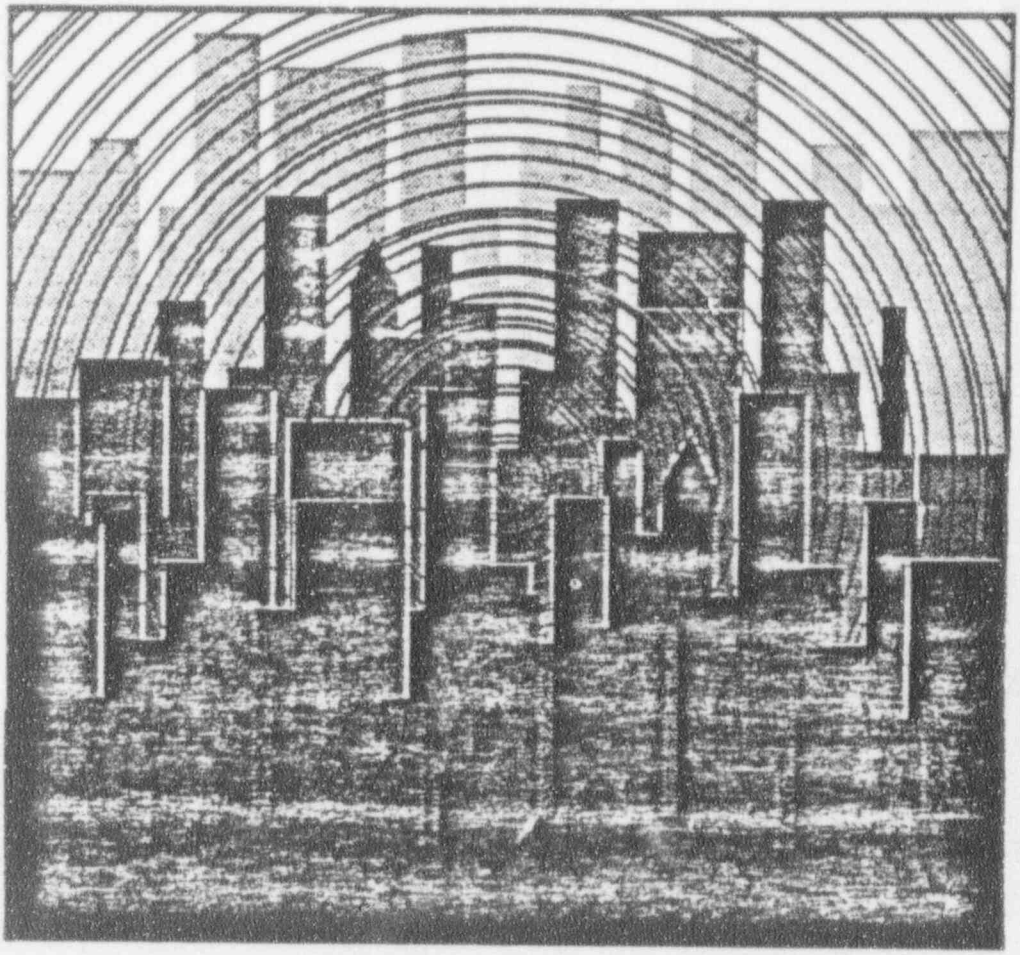
What you can't see could hurt you

The New York City Department of Health's Bureau of Radiological Health needs to improve enforcement of radiation safety laws



City of New York
Office of the Comptroller
Elizabeth Holtzman, Comptroller

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EXECUTIVE SUMMARY

The New York City Department of Health's ("DOH's") Bureau of Radiological Health ("BRH") apparently is not protecting the public from the potential dangers of medical radiation equipment and radioactive materials.

On January 9, 1992, the New York City Comptroller released a report on the Comptroller's study of DOH's X-ray equipment inspection program. That study, "Radiation Out of Control: The Department Of Health's Bureau for Radiation Control Is Not Inspecting All X-Ray Equipment In New York City," found that 40 percent of the facilities studied had not been inspected as frequently as required, and that many of the City's operating X-ray facilities had never been inspected by, or registered with, the City. The report also assessed DOH's implementation of so-called quality assurance programs which require medical facilities to help monitor their own X-ray equipment and its use.

This report follows up on the earlier report. It reviews whether, how, and when potentially serious problems with X-ray equipment that have been identified by BRH inspectors are rectified, and it studies BRH's oversight of three specific kinds of therapy equipment: Cobalt-60 teletherapy units,[1] Strontium-90 eye applicators,[2] and linear accelerators.[3]

One of BRH's principal functions is to ensure that medical radiation machinery is used and maintained properly in order to minimize patient and operator exposure to radiation and to help prevent diagnostic and treatment errors. Too much or too little radiation, or radiation administered to the wrong part of the body, can result in misdiagnosis and can impair important bodily functions, including reproduction, vision, and muscle development. Radiation increases risks for cancer, birth defects, and human cell mutation. Extreme overexposure to radiation can result in death.

Findings

BRH is mandated to license radioactive materials used in treating humans and to inspect radiologic therapy facilities on a regular basis to monitor compliance with safety laws. As indicated above, we reviewed BRH's regulatory treatment of three specific types of therapy equipment. We found:

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[1] The Cobalt-60 teletherapy unit is a very large machine. It weighs several tons and is used to treat diseases such as cancer by exposing the patient to a beam of gamma radiation generated by the radioisotope Cobalt-60.

[2] The Strontium-90 eye applicator is a small, portable device used to treat eye diseases through exposure to radiation generated by the radioisotope Strontium-90.

[3] Like the Cobalt-60 teletherapy unit, the linear accelerator is very large and must be used in a customized, well-shielded room. The linear accelerator is also used to treat malignant cancerous diseases, but unlike the Cobalt-60 teletherapy unit, the linear accelerator derives its power from the application of very high voltage that generates X-rays rather than gamma rays.

- Sixty-nine percent of the Cobalt-60 teletherapy facilities inspected by BRH were found to have serious violations that represented health hazards or potential health hazards, e.g., exposure to excessive levels of radiation.

- Forty-four percent of the City's licensed Cobalt-60 teletherapy unit facilities were not notified of health code violations found by BRH at the facility -- situations which may have jeopardized the public health -- until more than three months after the date of BRH's inspection. Two facilities were not issued violation reports until eight months after the inspection.

- BRH has records of only 10 facilities that house Strontium-90 eye applicator devices, but our survey located 24 such facilities in the City.[4] BRH is required to license and regularly inspect all facilities in the City that use a Strontium-90 eye applicator.

- BRH does not inspect linear accelerators despite laws mandating that it do so and does not know how many linear accelerators are in use in the City. BRH has never adopted regulations that set out standards for the use and maintenance of linear accelerators. Our survey identified 40 linear accelerators in use in the City and another 10 linear accelerators that hospitals were planning to purchase.

When an X-ray facility is cited by BRH for failing to meet the safety standards of the New York City Health Code, BRH is required by law to reinspect the facility within 60 days to ensure that all violations have been corrected. We found:

- BRH failed to reinspect over 36 percent of facilities with violations within the legally required 60-day period.[5] On average, overdue reinspections were performed in 95 days. One reinspection was not performed for 171 days.

- Over 42 percent of the facilities not reinspected on time had been cited for the most potentially dangerous violations.

- BRH records are inexact, incomplete, and do not adequately document steps taken to correct hazardous conditions.

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[4] These facilities were identified by surveying only the 39 facilities that, according to BRH, then had either a Cobalt-60 teletherapy unit and/or a Strontium-90 eye applicator. Therefore, 24 may be a low estimate of the number of facilities in the City that house Strontium-90 eye applicator devices.

[5] Records were collected from 227 dental, podiatric, and diagnostic radiology facilities, 70 of which were cited for violations. Comptroller's Office staff reviewed BRH's files on those 70 facilities.

Recommendations

- BRH should begin to inspect linear accelerators immediately.
- DOH should promulgate regulations that describe standards for the use and maintenance of linear accelerators.
- The City should offer unregistered radiology facilities a one-time three-month amnesty period from fines to maximize the number of facilities that are registered and inspected.
- BRH, in conjunction with State Health Department officials, should develop a comprehensive proposal for improving the BRH inspection program so that all licensing, inspections and reinspections are completed in the time specified by law.
- BRH should ensure that all reinspections are completed on time and that all violations are corrected quickly.
- BRH should ensure adherence to its self-imposed goal of reinspecting the worst violations first.
- DOH should computerize BRH's operations to expedite identification of sites at which inspections are needed and to maximize BRH productivity.
- BRH should create records that document clearly all enforcement actions taken by BRH personnel and all remedial actions taken by the facilities' operators.

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PART ONE

REINSPECTION OF DIAGNOSTIC X-RAY EQUIPMENT FACILITIES CITED FOR HEALTH CODE VIOLATIONS

A. INTRODUCTION

Medical X-rays account for an estimated 11 percent of a person's yearly exposure to all forms of radiation and over 60 percent of annual exposure to artificially created radiation.[6] Over the course of a lifetime, the average person receives hundreds of dental, chest, abdominal, back, head, foot and other X-ray diagnoses.

Variances in the quality of medical X-ray equipment and in the expertise of the machine operator can alter significantly the overall amount of radiation a patient unwittingly undergoes in everyday procedures. Many scientists believe that the risks of radiation exposure are cumulative (e.g., every X-ray increases a person's chances of developing cancer) and that, therefore, these variances are quite significant over a person's lifetime. A federal study of dental equipment found, for example, that nationally the average dose per dental X-ray was 33 percent higher than acceptable.[7] Another federal study found that patients' exposure to radiation from dental X-ray equipment varied by a factor of 80.[8] Because of the dangers inherent in medical radiation procedures, the City regulates radiation facilities and attempts to ensure that radiation is administered as safely as possible and at levels as low as reasonably achievable.

On January 9, 1992, the New York City Comptroller released a report on the Comptroller's study of the New York City Department of Health's ("DOH's") X-ray equipment inspection program. That study, "Radiation Out of Control: The Department Of Health's Bureau for Radiation Control Is Not Inspecting All X-Ray Equipment In New York City," sought to determine whether DOH was complying with established diagnostic X-ray equipment inspection cycles. It found that 40 percent of the facilities studied had not been inspected as frequently as required, and that many of the City's operating X-ray facilities had never been inspected by, or registered with, the City. The report also assessed DOH implementation of so-called quality assurance programs which require medical facilities to help monitor their own X-ray equipment and its use. This section of this report follows up on our earlier report by examining whether, how and when potentially serious problems with X-ray equipment that are identified by the DOH's Bureau of Radiological Health ("BRH") inspectors are rectified.

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[6] New York Times, November 20, 1987.

[7] *Report of State and Local Radiological Health Programs*. United States Department of Health and Human Services, Federal Drug Administration, Annual Report, December 31, 1984.

[8] J.R. Cameron, et al., "Reduction of Patient Exposure," *Journal of American Dental Association*, 96:977 (June, 1978).

BRH is divided into a Radiation Equipment Division and a Radioactive Materials Division. The former oversees the inspection of "any equipment or device which can emit radiation by virtue of the application thereto of high voltage,"[9] and the registration of the facilities at which such equipment is used. The Radioactive Materials Division licenses and inspects radioactive materials,[10] the machinery in which radioactive materials are used and the facilities that house such machinery.

B. BACKGROUND

1. The Law Requires BRH to Reinspect Facilities Cited For Violations Within 60 Days Of The Original Inspection.

New York State law mandates the registration and inspection of radiation installations, house X-ray equipment;[11] DOH is empowered to carry out these functions on behalf of the State.[12]

The State regulations administered by the City require X-ray equipment to be inspected and also require a "follow-up survey" of a radiation installation within 60 days of when City inspectors discover a violation of operating standards.[13] A "violation" includes any violation of New York City Health Code Article 175.[14] Neither the City nor the State interprets the requirement for a follow-up survey to necessitate an on-site reinspection.[15]

According to BRH officials, BRH field inspectors are supposed to notify installations in writing of all violations found during each inspection and indicate on the registrant's inspection report the period of time in which a reinspection will be performed. When a violation is minimal, however, BRH supervisors may direct, by written and/or oral communication, that an installation has corrected, or will correct, cited violations and that

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[9]24 R.C.N.Y. §175.02(16).

[10]Radioactive material is defined as "any material in any form that emits radiation spontaneously." 24 R.C.N.Y. §175.02(20).

[11]A radiation installation includes the X-ray equipment, as well as the physical surroundings of that equipment.

[12]Title 10 Part 16 of the New York State Sanitary Code comprises the regulations concerning radioactive materials and radiation installations.

[13]10 N.Y.C.R.R. 16.10(a)(1)(i).

[14]January 31, 1992 letter from Elizabeth Lang, Comptroller's Special Counsel--Investigations, to Karim Rimawi, Ph.D, Director, New York State Department of Health's Bureau of Environmental Radiation Protection; February 11, 1992 letter from Dr. Rimawi to Ms. Lang in response ("February 11, 1992 Rimawi letter"). Article 175 of the New York City Health Code comprises the regulations which govern the operation of radiologic facilities in New York City.

[15]February 11, 1992 Rimawi letter; January 22, 1992 letter from Elizabeth Lang to Robert Kulikowski, Ph.D., Acting Director, New York City Department of Health's Bureau of Radiological Health; and Dr. Kulikowski's February 6, 1992 response ("February 6, 1992 Kulikowski letter").

no on-site reinspection need take place.[16]

2. BRH Policy Calls For Severe Violations To Be Reinspected Sooner Than 60 Days.

BRH has categorized health code violations according to the severity of the health risk they pose to the patient and the equipment operator. Reinspection activities are supposed to be scheduled in accordance with these categories, that is, the violations posing the most severe risk are supposed to be reinspected first.

Violations are classified by BRH into three levels of severity:

- "Severity Level I Violations" are violations that if not corrected present a public health hazard. They include excessive levels of radiation exposure, no indication that the machine is limiting X-ray exposure to the targeted area, and insufficient filtration of the X-ray beam to stop unnecessary and harmful portions of the beam.

- "Severity Level II Violations" are violations that, if not promptly corrected, may lead to or contribute to a Severity Level I Violation. They include exposure switches that are operable outside of the area shielded from radiation, no means of numerically indicating that proper beam narrowing has been achieved, and failure to test properly the average exposure levels.

- "Severity Level III Violations" are violations that involve recordkeeping, documentation, postings and procedural matters that are easily corrected and have no direct impact on health and safety.

The City maintains that an initial survey which reveals only Severity Level III violations does not require an on-site follow-up survey.[17] The City deems that Severity Level I violations pose an exceptional threat, however, and generally requires follow-up in a "more stringent time frame" than the 60 days established by State regulation.[18] A January 17, 1992 DOH Memorandum summarized the steps for handling Severity Level I Violations as follows:

> If a facility is found to have any Severity I violations, a [notice of violation ("NOV")] must be issued. When an NOV is issued, all violations regardless of severity level must be included. This is in addition to the notification of the registrant/licensee of such violations by standard procedures. Other

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[16]April 28, 1992 Interview of Joseph Aufrichtig, Chief, Radiation Equipment Division, BRH, by Elizabeth Lang ("April 28, 1992 Aufrichtig interview").

[17]November 7, 1991 and December 30, 1991 telephone interviews of Joseph Aufrichtig, Chief, Radiation Equipment Division, BRH. Despite the fact that the State regulation which requires a follow-up survey makes no such distinction, both State and City officials have taken the position that whether or not an on-site survey is required is left to the discretion of BRH.

[18]February 6, 1992 Kulikowski letter.

> escalated enforcement actions may also be invoked, including "stop" orders, sealing, seizure, or Commissioner's Orders or other appropriate actions as dictated by the situation. Follow-up action includes prompt reinspection, preparation for the Tribunal hearing and other activities as dictated by the course of escalated enforcement.

The Memorandum authorizes the Bureau Director to waive these enforcement guidelines in extenuating circumstances, but requires that written documentation of the reasons for such a waiver be kept on file for review during program evaluations.

3. Data Used For Analysis.

The Comptroller's staff collected 227 BRH inspection reports from 413 radiological, dental and podiatric facilities.[19] Thirty-one percent of those reports (70) cited facilities for one or more violation of the New York City Health Code. On April 28, 1992, the Comptroller's staff reviewed records on file at BRH for all 70 of the facilities that had been cited for violations. Analysis of the 70 inspection reports shows that, apparently, BRH is not reinspecting these installations as required by law or by BRH policy.

C. FINDINGS

1. BRH Exceeds 60-Day Legal Limit On Over 36 Percent Of Dated Follow-Up Surveys.

As noted, both the City and the State take the position that the "follow-up survey" required by State regulations need not always be an on-site reinspection. Even so, all facilities are supposed to be reviewed in some fashion within 60 days. BRH does not maintain this schedule.

Because of violations that remained uncorrected and required second reinspections, the 70 violation reports in our survey represented a need for a total of 81 reinspections. BRH records show that 78 of these reinspections were performed. BRH files, however, contain dates of completion for only 54 of the 78 reinspections. In reviewing the records relating to these reinspections for timeliness, we considered only 57 reinspections: those 54 that were dated and the three not completed. BRH files contain no documentation that the remaining 24 reinspections were completed on time, but they are not included in the tabulation of reinspection rates in order to avoid making any assumptions about the data.

Figure One below shows that over 36 percent (21) of these 57 inspections were not completed within 60 days.[20] On average, overdue reinspections were performed in 95 days.

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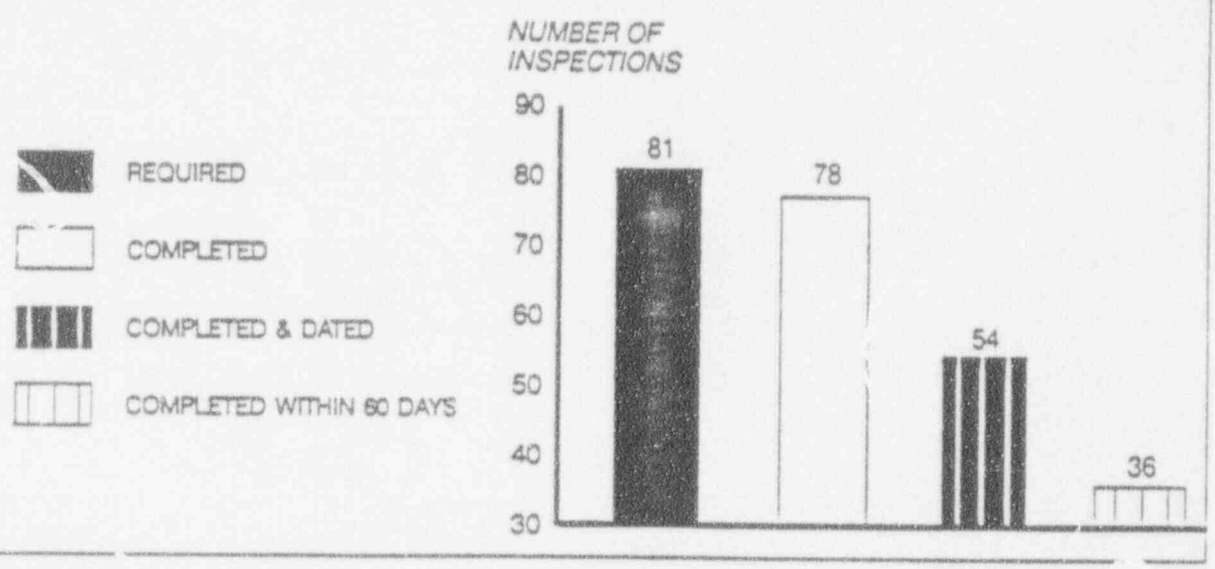
[19]There are approximately 7,200 X-ray installations in New York City.

[20]If it is assumed that the 24 inspection reports that are not dated were performed within 60 days, then BRH still failed to perform 26 percent of the reinspections on time. If it is assumed that all undated inspection reports relate to inspections performed more than 60 days after the initial inspection, BRH failed to perform

Twenty-eight percent of overdue reinspections were not performed within 100 days and the longest period between inspections was 171 days.[21]

Figure One

Reinspections Completed, According to BRC Files



It is also noteworthy that of the 78 follow-up surveys that reportedly were done, it appears that only 30 involved on-site reinspections. In all other cases, the facilities presumably were cleared in reliance on communications from the registrant that BRH did not verify through its staff's own observations.[22]

2. BRH Exceeds The 60-Day Limit On At Least 37 Percent Of Reinspections For Severity Level I Violations.

BRH's initial inspections of the 70 facilities identified at least one Severity Level I Violation at 31 facilities -- one Level I violation was found twice at the same facility.[23] According to BRH, Severity Level I violations are those of greatest urgency, and yet, as Figure Two below shows, follow-up surveys for over 37 percent of these violations (12) were not conducted within the State mandated 60-day period. Furthermore, despite BRH's protocol calling for a more stringent time-frame for the follow-up survey for these violations,

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56 percent of the reinspections on time.

[21] See Appendix A for information on dates on reinspections and severity of violations found.

[22] This determination was based on the presence or absence of an actual reinspection report. Where an original inspection report was marked cleared of violations, it was assumed that BRH did not perform a field reinspection unless other materials were in the file to indicate the contrary.

[23] Determination of the severity level of the violations was made using a schedule provided to the Comptroller's Office by BRH.

only one reinspecti[illegible] out of the 32 was performed within 30 days.

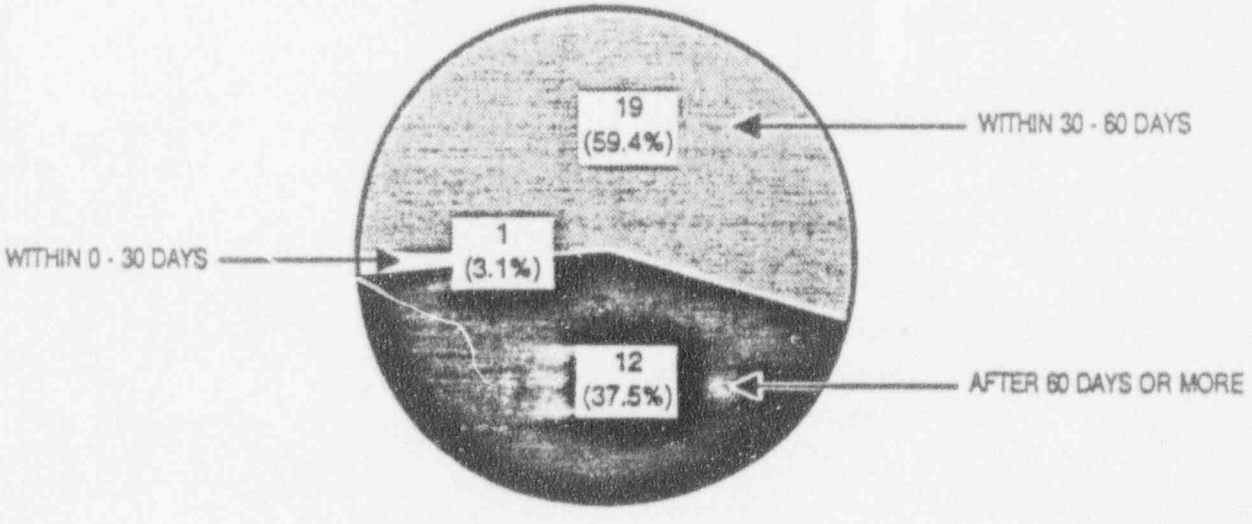
In almost every instance, BRH files which indicated that reinspections were not performed within 60 days or were never conducted, contain no representation that anyone in authority waived the or postponed the necessary reinspection.

3. Example 1: BRH's Apparently Ineffective Enforcement Activities.

A BRH inspector issued a Severity Level I violation to a facility operated by a dentist because the X-ray unit's beam size was not properly limited to the minimum necessary width and there was insufficient evidence of beam narrowing. Thirty-five days after citing this facility, BRH returned to reinspect. The reinspection disclosed that the problem had not been corrected. The dentist was allegedly having the machine repaired and he was granted a 30-day extension. The first reinspection report has a notation in the margin dated 32 days after the reinspection. It represents that a BRH representative had spoken with the doctor and granted him another extension of 93 days. No justification for this action is set forth. BRH did not reinspect, however, until 165 days later, at which time the inspector wrote that the "[doctors] are unable to accomplish and correct the violation cited. . .and unit is dismantled." Thus, the machine not only administered more radiation than necessary, it was beyond repair. Nevertheless, BRH apparently took no action to restrict use of the machine for 200 days. There is no indication in records obtained from BRH or from the facility that the equipment was not being used during that period.

Figure Two

Reinspections Completed for Severity Level I Violations, According to BRC Files



4. BRH Does Not Meet Its Goal Of Placing Highest Priority On Reinspecting The Most Severe Violations.

The reinspection data contradict BRH statements that the most serious violations will be given priority and will be reinspected sooner than the 60-day mandated limit.[24]

BRH inspectors wrote on 41 of the 81 reports reviewed that a reinspection would be conducted "in 30 days." However, only 24 of the 31 facilities cited for Severity Level I violations were advised that they would be reinspected on this expedited reinspection schedule. In addition, only eight of the 41 reinspections actually were completed within 30 days and only one of the eight was at a facility that had been cited for a Severity Level I Violation. The remaining seven inspections conducted within 30 days were at facilities where the highest level citation was a Severity Level II Violation.[25]

This pattern of apparently failing to reinspect the most threatening violations first is also true for reinspections not done within the required 60 days. As Table One shows, 21 of 57 facilities (36 percent) were not reinspected within 60 days; 42.9 percent (9 facilities) of these were cited for Severity Level I Violations. The remaining 57.1 percent (12 facilities) were facilities where the highest violation found was a Severity Level II.[26]

Table One
Reinspections Not Performed Within 60 Days,
By Type of Facility and Highest Severity Level of Violations Cited[27]

Severity Level	Radiologists	Podiatrists	Dentists	Total Overdue By Severity Of Violations
Level I	4	3	2	9 (42.3%)
Level II	10	1	1	12 (57.7%)
Level III	0	0	0	0 (0.0%)
Total Overdue By Type of Facility	14 (66.7%)	4 (19.0%)	3 (14.3%)	21

[24]See, e.g., February 6, 1992 Kulikowski letter.

[25]Facilities are often cited for more than one violation and only the most serious level of violation was counted in this tabulation.

[26]Since a full 30 percent of reinspections are marked completed but are not dated, however, it is important to consider the violations cited on these reports in order to draw accurate conclusions about which facilities BRH reinspects on time. Only 17 percent (4) of these undated reports cite Level I and/or Level II Violations while 83 percent (20) cite only Level III Violations. If it is assumed that undated reports are completed on time this reinforces the conclusion that severe violations go uncorrected. If it is assumed that these reports are not completed on time, the overall failure to reinspect on time rises.

[27]See text at page 3, supra, for a description of the three Severity Levels of violations.

General diagnostic radiation equipment is subject to annual inspections, whereas dentists and podiatrists are inspected triennially.[28] There are three reasons for this. First, the radiation dosage administered by the diagnostic X-ray machines used by general radiologists is significantly higher than it is for dental and podiatric equipment. The health problems diagnosed by physicians with radiation equipment tend to be more threatening and finally, general radiologists expose more sensitive body tissue to radiation. It is important, therefore, that radiologists' facilities be closely monitored. The purpose of developing a schedule of priorities is undermined if BRH does not apply those priorities in setting its reinspection schedule.

As Table One also shows, radiologists account for over 65 percent of overdue inspections. Of the 9 facilities with Severity Level I Violations that were not reinspected within 60 days, almost half were radiology facilities.

5. Example 2: BRH's Apparently Ineffective Enforcement Activities.

A hospital in our survey was cited for eight violations of the health code. Its chest X-ray machine was found to be emitting radiation beyond the maximum allowable limit, a Severity Level I Violation, and yet the facility was not reinspected by BRH for 161 days. Reinspection disclosed that the violation had not been corrected. The unit was sealed and a second reinspection was scheduled for 45 days later. Thus, BRH allowed a condition to go uncorrected, and apparently took no action for 161 days to prevent the use of a malfunctioning X-ray machine that would have overexposed patients to radiation if used. There is no indication in BRH's files that the equipment was not being used. Because this violation would not have resulted in immediately visible damage to the patient, the patient would have had no way of knowing that he or she had been overexposed. Similarly, because the damage done by overexposure is so difficult to quantify, the failure of BRH to enforce timely repairs does not attract the attention it warrants.

6. BRH Apparently Does Not Keep Adequate Records Relating To Off-Site Follow-Up Surveys.

BRH supervisors make handwritten, abbreviated notations in the margin of some inspection reports indicating that a follow-up survey has been completed.[29] There is no formal system for recording a Supervisor's decision not to order an on-site reinspection (i.e. there is no form to fill out for inclusion in BRH files or to send to facilities, no computer database to update and no place to record the supervisor's name and the date of the supervisor's decision). In addition, materials that are sent to BRH by a facility to document the facility's claims of corrective action are not necessarily included in the facility's BRH

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[28] 10 N.Y.C.R.R. §16.10(a)(1)(i).

[29] April 28, 1992 Aufrichtig interview. According to Mr. Aufrichtig, the following notations may be made on a field inspector's report by a BRH supervisor: "NCA" (no cause for action); "VCW" (violations complied with, to be reinspected "per schedule"); "VRRPS" (violations removed, to be reinspected "per schedule"); "Compliance" (on-site reinspection to be performed).

file.[30] Of the 78 reinspections marked completed in our sample, only 69 percent of them are dated.

In almost every case in which a reinspection is identified as completed, there is no indication of when the reinspection was deemed completed or that a supervisor authorized clearance of the violations cited.

As a result of the superficiality of BRH's files, and also owing to the lack of computerized recordkeeping, tracking down installations with existing violations is difficult and time consuming and BRH has no way of making a quick and accurate determination of an installation's history of radiation control violations.

7. BRH Must Alter Its Practices and Procedures Fundamentally In Order To Fulfill Its Regulatory Responsibilities.

In 1989, BRH reviewed and revised its fee structure so that "adequate and reasonable fees" could be charged "to recover the cost to the City of the inspection and licensing program."[31] Review of the materials BRH used to support its rate increases, however, supports the findings of the Comptroller's 1992 report that because BRH is unable to complete all inspections according to mandated cycles, simply increasing rates will not help BRH complete more inspections and BRH needs to develop a comprehensive strategy for improving its productivity.

In 1989, BRH estimated that its total operating costs for fiscal year 1990 would be $2.3 million. This figure included all operating costs for both the radiation equipment division and the radioactive materials division: salaries and wages, personnel benefits, environmental support, equipment costs, and building space costs. Using the proposed increased fees, BRH projected total revenue for fiscal 1990 to be $1.9 million.[32]

The proposed fees would thus just about cover anticipated operating costs for the number of inspections BRH actually completes per year. Part of the revenue gap is explained by the fact that about 15 percent of X-ray inspections (based on the number of tubes inspected) of municipal and other government owned equipment are completed free of charge.

In evaluating program costs and proposing increased rates, BRH failed to consider whether the number of inspections and license applications the Bureau actually completes and the productivity per BRH inspector hour are high enough.

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[30] April 28, 1992 Aufrichtig interview.

[31] Notice of Adoption of an Amendment to the New York City Health Code, NYC DOH, effective August 8, 1990.

[32] It does not appear that the biennial registration fee of $100.00 was included in the revenue projections. If there are about 7,200 radiation facilities Citywide and half re-registered every year, then this would amount to an annual revenue of $360,000.

Rough calculations using BRH figures for the total number of installations and the number of inspections completed shows that BRH completes about 50 percent of the required inspections.[33] Simply increasing the fee for an inspection will not help BRH complete more of its workload. The Bureau needs to evaluate the type of equipment used for data processing, the amount of equipment used for inspections, and the number of inspectors it needs. BRH will then be able to generate an estimate of how much it would cost to boost productivity and ensure that all activities required by the health code are completed.

Although BRH staff have made efforts to increase the number of inspectors and to begin a project to computerize data management, they appear not to have completed an overall analysis of the Bureau or to have developed recommendations for reorganizing their operations. Finally, even if there is a small, one-time added cost incurred to increase the Bureau's productivity, that cost should be more than compensated for by the revenue generated by added inspectors completing more work faster with better equipment.

D. CONCLUSION

BRH has failed to implement an inspection program that adequately protects public safety. The reinspection of X-ray facilities found to be in violation of the health code is not conducted within the legally prescribed period of time. In addition, some reinspections appear never to have been conducted, and the most severe violations do not appear to be given priority. Finally, decisions to certify correction of violations are apparently based on written and/or oral communication that is not recorded systematically or thoroughly. The BRH program thus suffers both from poor organization and a lack of quality control.

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[33]This was calculated as follows. In its 1989 analysis BRH reported 814 facilities requiring annual inspection, 1,700 requiring biennial inspection, and 4,451 requiring triennial inspection. BRH also reported completing in 1989 336 annual, 452 biennial, and 881 triennial inspections. Assuming that the number of biennial and triennial inspections to be completed per year is divided evenly, we can compare the number of inspections done with those needed: (336 + 452 + 881)/(814 + 850 + 1514) = 1669/3178 = 53%.

PART TWO

LICENSING, REGISTRATION AND INSPECTION OF RADIATION THERAPY MACHINERY: STRONTIUM-90 EYE APPLICATORS, COBALT-60 TELETHERAPY UNITS, AND LINEAR ACCELERATORS

A. INTRODUCTION

BRH is responsible for licensing, registration and regular inspection of all medical facilities with machinery that uses radioactive materials. We reviewed BRH's oversight of three types of therapy machinery -- the Strontium-90 Eye Applicator ("eye applicator"), the Cobalt-60 Teletherapy Unit ("teletherapy unit "), and the linear accelerator. These machines are described in more detail below.

The eye applicator and the teletherapy unit present a more immediate risk of injury to the patient than do conventional diagnostic X-ray machines, yet BRH fails to inspect them on schedule, fails to provide medical facilities with inspection reports quickly, and fails to keep accurate and complete records on the numbers of these machines being operated in the City.

There are at least 40 linear accelerators currently in use in the City and it appears that they are becoming increasingly popular. The health code requires all installations using radiation equipment, including linear accelerators, to register with the City, and stipulates that all radiation equipment will be inspected by the City, unless otherwise provided. Linear accelerators are not exempted from these requirements, but the City has no program in place to inspect linear accelerators and does not inspect them.

If radiologic facilities and radioactive materials are not registered and/or licensed, BRH does not schedule the regular required inspections. If radiation machinery is not inspected regularly, there is no assurance that it is operating properly, and BRH has failed to protect members of the public who are exposed to radiation in order to diagnose or treat disease.

B. EYE APPLICATORS AND TELETHERAPY UNITS

1. Background.

a. Descriptions And Uses.

The teletherapy unit and the eye applicator are therapeutic machines that are used to treat cancer and other diseases. Because they must produce a biological change in the cells being targeted, these machines need to deliver significantly higher radiation doses than do dental, podiatric, and other diagnostic X-ray machines (that is, the equipment described in

Part One of this Report). These machines are highly sophisticated and serve as very valuable medical tools if they are well maintained and properly used. However, the danger to the patient from malfunctioning or improperly used therapeutic equipment is much greater than with diagnostic equipment. Improper administration of radiation therapy can cause radiation burns, unnecessarily expose radiosensitive tissues (such as the reproductive organs), or increase the risk to the patient of developing cancer. Radiation increases risks for cancer, birth defects, and human cell mutation.[34] In extreme cases, death could result from a treatment error.

Teletherapy is a cancer-fighting technique in which a patient receives an external dose of radiation rather than the insertion of radioactive material into the body. A teletherapy unit is very large and must be properly installed in a well-shielded, customized room, with thick walls of concrete, metal and glass. The health code requires specific controls to prevent overexposure of the patient or the technician who operates the equipment. For example, the radiation beam must shut off automatically if the entrance door to the teletherapy room is unlocked.[35] The health code also requires that the machine operator have constant visual access to the patient and also continuous access to a radiation monitor that notifies the operator if the radioactive material is exposed or partially exposed at any time.[36]

The eye applicator is a small, portable device used to combat eye diseases. The applicator delivers the maximum strength of radiation to the conjunctiva, or the part of the cornea being treated, and the minimum dose to the lens of the eye. Overexposure can result in damaging the lens of the eye and can cause a cataract to develop. In extreme cases, it could result in blindness. Treatment with the eye applicator is often given in conjunction with surgery.

Because of its small size, an important factor in preventing the misuse of the eye applicator is keeping an accurate account of the number and locations of the machines to ensure that their use is controlled.

b. Law Mandates Licensing And Regular Inspection Of Radiotherapy Materials And Installations.

Regulation of the eye applicator and the teletherapy unit is managed by BRH's Radioactive Materials Division. A facility using the teletherapy unit or an eye applicator must be licensed and inspected by BRH at regular intervals. In addition, the New York City Health Code states that "no person shall transfer, receive, possess or use any radioactive material for medical purposes except in accordance with a specific license issued pursuant to the [health code]."[37]

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[34]Upton, Arthur C. "Health Effects of Low-Level Ionizing Radiation," *Physics Today*, 34-39; August, 1991.
[35]24 R.C.N.Y. §175.108(i)(5)(ii).
[36]24 R.C.N.Y. §175.108(i)(7)(ii) and (8)(i).
[37]24 R.C.N.Y. §175.108(a)(3)(i).

The type of radioactive materials license issued by BRH varies according to the amount and type of radioactive material and the purpose for which it will be used. This report concerns three types of licenses: a specific license for teletherapy units; a specific medical license in which the amounts, types, and form of radioactive materials are set; and a broad medical license in which the amount and type of radioactive material is set, but the form of the material may vary.[38] Training and qualifications requirements for radiotherapists vary according to the perceived risk of radiation overexposure of the equipment operator and the patient and according to whether the material is to be used for human medical purposes.

c. Licensing And Inspection Fees.

A teletherapy unit license costs $1,365.00 and an additional $1,165.00 to renew every five years.[39] A teletherapy inspection costs $320.00 and must be conducted annually.

An eye applicator may be covered under two types of licenses, both of which must be renewed every five years, and both of which may cover the eye applicator as well as other radioactive materials. A "specific medical license" is $1,350.00 and $1,150.00 to renew and a "broad medical license" is $3,135.00 and $1,520.00 to renew. Inspections of specific medical licenses are conducted every three years at a cost to the licensee of $610.00 for the first location and $140.00 for each additional site at which is located the licensed material. Inspections of broad medical licensees are triennial and BRH charges $3,515.00 for the basic inspection and $140.00 for each additional site inspected.

d. Data Used For Analysis.

On April 29, 1991, the Comptroller's Office requested from BRH a copy of the most recent inspection report for every eye applicator and teletherapy unit facility in the City. BRH responded on June 4 with a list including 39 facilities. On January 14, 1992, the Comptroller's Office wrote again to BRH requesting an explanation of violations cited on inspection forms and an updated count of the number of eye applicators and teletherapy units in the City. BRH responded on January 17 and 24, 1992. The Comptroller's Office then contacted directly the 39 facilities listed to request information about BRH inspections.

Analysis of the facilities' inspection reports shows that the BRH program is not fulfilling its mandate to license and inspect all eye applicators and teletherapy units in the City.

2. Findings On Eye Applicators.

According to a list of medical facilities with eye applicators and teletherapy units supplied by BRH, there were 37 teletherapy units and six eye applicators located in a total of 39 facilities in the City as of June 1991. In response to a January, 1992 request for an

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[38] A teletherapy unit can only be used with a specific teletherapy license, not a specific or broad medical license. See 24 R.C.N.Y. §175.102 for a detailed discussion of license types.

[39] 24 R.C.N.Y. §5.07.

updated list, BRH provided a new list and stated that "other than several teletherapy decommissionings, this is a relatively stable population of licensees so the list is similar to the one provided you in June 1991."[40] Nevertheless, the number of eye applicators listed by DOH went up from 6 to 10.

Our survey of the 39 facilities identified by BRH as having one or more teletherapy unit and/or one or more eye applicator revealed that eye applicators were being used at 24 of these facilities. BRH was aware of these machines at only 10, or 42%, of these facilities. Given that the eye applicator is small and transportable, there is a significant possibility that this machine could be used by an unlicensed operator, or that someone could inadvertently be exposed to the radioactive source material.

3. Findings On Teletherapy Units.

It is important that BRH issue inspection reports as quickly as possible so that the facilities will be on notice of the hazards identified and be able to minimize the risks associated with the violations as soon as possible. This is even more important when the violations BRH inspectors identify are serious.

According to BRH, a facility is notified of violations "either [by] a narrative report completed by the inspector on form 148E and left at the completion of the inspection or a formal letter containing the results of the inspection (i.e. inspection report) transmitted to the registrant/licensee from [the BRH] office."[41] All of the teletherapy unit installation files reviewed contained inspection reports; none contained form 148E reports.

Using BRH violation guidelines, 27 of 39 inspection reports (69 percent) were determined to contain Severity Level I and/or Severity Level II Violations. Because these violations represent health hazards or potential health hazards, the facility should be notified of them as quickly as possible. Often, these facilities are not notified quickly.

Table Two
Time BRH Took To Issue Inspection Reports Citing Severity Level I And/Or Severity Level II Violations

Number Of Reports	12	1	2	6	2	1	1	2	27
Issuance (Months After Inspection)	1	2	3	4	5	6	7	8	

4. Example 3: BRH's Apparently Ineffective Enforcement Activities.

In one case we studied, a hospital was cited for allowing radioactive materials to be

[40]January 24, 1992 letter from Robert Kulikowski to Elizabeth Lang.
[41]Letter from Robert Kulikowski to Meave O'Marah, February 25, 1993.

used for therapeutic purposes when a doctor was not supervising the machine operator. Proper supervision is a critical element of radiation safety standards, yet the hospital was not issued the report listing this violation -- and others -- for eight months.

In 1992, the New York State Department of Health's Center for Environmental Health reported that the four known recent cases of persistent treatment error ("over periods of months to years"), which impacted 77 patients, were due to a person "who functioned with minimal or no supervision."[42] BRH's failure to give timely notification to the hospital of this lapse in supervision put the public at unnecessary risk of radiation misadministration.

Of the 27 facilities cited for serious violations, only 33 percent (9) were issued their inspection reports within 30 days. Over 40 percent of the facilities were not issued their reports for more than three months and two facilities were not issued their reports for more than eight months (Table Two). BRH's failure to notify facilities immediately of their violations creates an unacceptable risk.

5. Example 4: BRH's Apparently Ineffective Enforcement Activities.

On September 7, 1990, BRH inspectors cited a doctor for certain problems with a teletherapy unit and for possessing an eye applicator as well as radium without a license. Three months later, on December 4, 1990, BRH issued its inspection report which instructed the doctor to notify BRH of his corrective plans within 30 days.

On December 14, 1990, BRH reinspected the facility and found the same violations.[43] BRH issued their second inspection report on May 6, 1991. Alarmingly, the May report to the doctor also stated that "during [the December 4] inspection, you [i.e. the doctor] indicated that you did not know what some of the unlabeled radioactive materials were. Because these may be old radium-226 sealed sources, it is recommended that they be tested for leakage and the areas in which they are stored be tested for concentrations of airborne radon gas. Kindly forward a copy of the results of such tests to this Section for review." The doctor responded on July 1, 1991 and indicated that he was applying for a license.[44]

On July 8, 1991, ten months after the original inspection, BRH's only response to the facility it knew to be in possession of unlicensed radioactive materials was a letter stating that the doctor's July 1, 1991 letter had been received, that "this correspondence [would] be incorporated into [BRH's] records for further review at the time of the next inspection," and that "[a]ll notices of violations found during the. . .inspection, and posted pursuant to. . .the New York City Health Code, are no longer required to remain posted."

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[42]February 25, 1992 notice from Rita Aldrich, Chief, Radioactive Materials Section, Bureau of Environmental Radiation Protection, to New York State Department of Health Radioactive Materials Licensees.

[43]The teletherapy unit was not reinspected.

[44]The doctor also maintained in this letter that he had written to BRH previously though he could not locate a copy of that letter.

According to a report prepared by an independent, certified health physicist who reviewed these inspection reports for the Comptroller's Office, "radium, as a naturally occurring material, has never been regulated except at local levels. This means that the Nuclear Regulatory Commission in their oversight of the City's program would not criticize the handling of Radium. . . .Radium is extremely hazardous and these old sources have a well known history of leaking and contaminating a whole building. DOH only suggests they should be checked for radon gas, with no other caution. This is akin to finding a strong poison in a restaurant and suggesting that the owner take care not to break the bottle."[45]

6. Conclusion.

The data presented in this report indicate serious flaws in BRH's Radioactive Materials Division. The combination of BRH's failure to inspect facilities on schedule with its failure to notify radioactive materials installations promptly of violations means that conditions that BRH has defined as posing a threat to the public health are allowed to remain uncorrected for too long. In addition, BRH's apparent lack of awareness of most of the eye applicators in the City poses a serious public health threat.

Patients who receive important therapeutic treatment from these machines have little or no way of knowing whether BRH has inspected the medical facility and its equipment, or even whether the facility is licensed by the Department of Health. Given the potential for serious harm from this equipment if it is used improperly, or if it is not functioning correctly, BRH must take immediate steps to license and regularly inspect this equipment.

C. LINEAR ACCELERATORS

1. Description And Uses.

A linear accelerator produces X-rays when an electrical charge is passed over a stream of electrons that are directed at a solid target; the stream's collision with the target results in the emission of the X-rays. The higher the voltage applied to the electron stream, the higher the X-ray dosage available for medical use. Conventional diagnostic X-rays are usually produced in the 20,000 to 150,000 voltage range. The linear accelerator generates X-rays from the application of between 2 to 35 million volts. Higher radiation dosages penetrate deeper into the body, making it possible to treat with a linear accelerator cancers that are not treatable by surgery or by surgery alone.

The linear accelerator is used to treat many of the same diseases as the teletherapy unit -- but it has two advantages. First, because the linear accelerator is an X-ray machine, it does not require radioactive source material. This means fewer regulations for the medical facility to be worried about and also no risk of exposing the operator or patient to

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[45]Report prepared by Michael O'Brien, Certified Health Physicist, for the Office of the Comptroller on November 14, 1991.

radioactive materials by mistake. At the same time, the linear accelerator is more complicated mechanically and may require more expert maintenance.

The second advantage is that the linear accelerator can produce a narrower field of radiation than the teletherapy unit. In addition, the way X-rays are distributed to the tissues between the skin and the target within the body is different than the distribution of the gamma rays produced by the teletherapy unit. The linear accelerator's X-ray beam gives off most of its strength deeper into the body than does the teletherapy unit.[46] As a result of the depth distribution and narrowing beam, the linear accelerator can sometimes apply radiation more directly to the targeted cells, with less chance of damage to healthy tissue.

2. State And City Health Codes Apply To Linear Accelerators.

Both the State and City health codes apply to all radiation equipment and all radioactive materials except as otherwise provided, and there are no State or City exemptions for the linear accelerator machine.[47]

The City health code also has, however, specific sections on many types of radiation equipment that regulate the use and define the frequency and nature of inspections for each type of equipment. There is no such section on linear accelerators. Such a section would provide important standards for those who maintain and operate linear accelerators.

3. Findings.

a. BRH Apparently Has Never Inspected Linear Accelerators.

Despite health code regulations requiring regulation of all radiation equipment, the City apparently does not inspect these machines.

On June 1, 1992, about two months after our survey of hospitals concerning linear accelerators, BRH mailed a letter to medical radiation facilities stating that BRH was planning "to increase its involvement in the regulatory and inspectional aspects of medical particle accelerator use."[48] The letter went on to say that "the health and safety ramifications of this equipment for patient, operator, members of the public and the

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[46]Conversely, the maximum dose of diagnostic X-rays (e.g., by a dental X-ray machine) is given off at the skin.

[47]24 R.C.N.Y. §175, Introductory Notes, states that "all radiation sources in the City must be obtained under either a permit or license or be specifically exempt." 24 R.C.N.Y. §175.53, Exemptions of Radiation Equipment, does not exempt the linear accelerator. Similarly, 10 N.Y.C.R.R. §16.4 details radiation equipment exempted by the State and, again, the linear accelerator is not exempted.

Coverage of linear accelerators under general provisions of the State and City Health Codes was confirmed by interview with Mary Anne Harvey, NYS DOH, on January 19, 1993.

[48]June 1, 1992 letter from Robert Kulikowski to hospital radiology departments, radiation safety officers, radiologists, linear accelerator facilities, and teletherapy unit facilities. Medical particle accelerator is another name for linear accelerator.

environs is well established and the Bureau needs to play a more active role in overseeing the protection of public health and safety in this area."

On June 8, 1992, DOH stated in a letter of response to an inquiry about linear accelerator regulation that:

> While the Bureau's regulatory program for accelerators has been less than optimal, several positive steps have been taken to remedy this situation. These include: preparing amendments to the Health Code placing specific requirements on accelerator facilities to ensure that the machines meet current standards of practice; requiring that facilities submit shielding diagrams, radiation protection survey reports, and calibration reports to the Bureau; as well as implementing a basic inspection program to the extent currently provided for by the Health Code.[49]

BRH has reportedly made efforts to complete the above steps, but does not appear to be significantly closer to actually implementing a program. When all hospitals in the City were surveyed by the Comptroller's Office, not a single one reported having had a BRH inspection of its linear accelerator and a number of respondents commented that it was their belief that City health code regulations did not extend to linear accelerators.

In a February, 1993 letter from BRH to the Comptroller's Office, the current status of the linear accelerator program was described as follows:

- "Draft regulations were developed and submitted to the New York State Department of Health for comment. . . .[BRH] plans to submit regulations for linear accelerators to the [City] Board of Health by this summer [1993]."

- "While the survey on the use of linear accelerators was sent in June 1992, a summer intern was assigned work on this project. Prior to completing all the data analysis, the intern had to return to school. Much time was spent following up on facilities which did not respond or did not respond with all requested information. . . .A preliminary review indicates that there are less than 100 linear accelerators in both institutional and private office settings, with institutional machines accounting for most."

- "BRH did submit a new needs package for additional staffing to implement the linear accelerator program. This could not receive final approval until such time regulations were in place to authorize "licensing" these machines, collect fees for this activity and inspections."[50]

Since no new staff will be approved for the linear accelerator program until the

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[49]Letter from Margaret Hamburg, Commissioner, NYC DOH, June 8, 1992.
[50]Letter from Robert Kulikowski to Meave O'Marah, February 25, 1993.

regulations have been approved, BRH must rely on summer interns to move the initiative forward, and the linear accelerator program is unlikely to be in place for at least one year, probably more. Steps must be taken sooner to prepare BRH for a fully operational linear accelerator program.[51]

b. At Least 40 Linear Accelerators Are Being Used In New York City.

On March 16, 1992, the Comptroller's Office wrote to 66 New York City hospitals to determine the number of linear accelerators in operation in the City and whether they had ever been inspected by the Department of Health. Forty hospitals responded. Twenty-two of them reported a total of 40 linear accelerators then in use. If respondents have followed through on their reported plans to purchase more linear accelerators, there would have been a total of 50 machines in use at 28 facilities at the close of 1992.

c. Difference in Supervision of Hospital Radiology Programs v. Private Radiology Programs.

Although our survey of linear accelerator use did not extend beyond hospitals, it appears that the number of linear accelerators is growing even more rapidly in private physicians' offices than in hospitals.[52] The number of linear accelerators in the City has been growing since they were first introduced in the 1950's, but it appears that their number has grown more dramatically in the past ten years. The oldest linear accelerator reported to the Comptroller's Office as still in use was installed in 1973.

The Comptroller's Office survey of all hospitals turned up 40 linear accelerators. BRH has guessed that there are under 100 and that most of these are in hospitals. Our survey included all hospitals, however, so either there are many fewer than 100 linear accelerators or there are quite a few of these machines in private radiologists' offices. According the State DOH, about half of the linear accelerators registered with the State are in hospitals

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[51]According to a February 25, 1992 interview of Mary Anne Harvey, NYS DOH, by Comptroller's Office staff, the State DOH is also planning to amend its regulations to include a section on linear accelerators. According to NYS DOH State those regulations will be based on guidelines now being prepared by the American Association of Physicists in Medicine (AAPM). By using AAPM guidelines, the State DOH hopes to standardize requirements and also to capitalize on the AAPM's expertise in this field. According to the AAPM, however, the guidelines they are developing will not be ready for about six months to a year. It is unlikely that the City will get State approval for its regulations before the State has developed its own.

[52]February 3, 1993 telephone interview of Mary Anne Harvey, NYS DOH, by Comptroller's staff. Ms. Harvey estimated, based on the State's registration data, that the number of linear accelerators in use outside of New York City is split about evenly between hospitals and private physicians offices. She also stated the this proportion is likely to be the same in the City, but said that she could not confirm this guess as only the City would have the registration information.

Linear accelerators are very expensive -- anywhere from about $500,000 to $2 million to purchase and install. They are also mechanically complex and it may be that until recently, only hospitals had sufficient resources to purchase and properly use and maintain linear accelerators.

and about half are in private practices.[53] The same may be true for the City. This is significant because private radiologists undergo less supervision of their activities, a potentially serious problem if BRH does not regulate linear accelerators at all.

Four important factors distinguish hospitals from private radiologists. First, hospitals have accreditation requirements that private facilities do not; hospitals, therefore, have quality control programs in place to monitor linear accelerators. Second, until 1992 only hospitals and mammography facilities were required to have quality control programs -- methods of self-inspection for proper use and maintenance of equipment. Because hospital programs have been in place longer, they are more likely to have stronger internal controls.

Third, hospitals also must have prior approval from the State to significantly increase or alter the medical services they are providing.[54] This provision includes adding a linear accelerator when the facility previously was providing limited or no radiotherapy, but does not include replacing a teletherapy unit with a linear accelerator.[55] This provision means that the State should know of many of the linear accelerators located in hospitals.

There apparently is no reason for use of linear accelerators to be restricted to hospitals, but precautions should be taken to ensure that private programs undergo the same amount of supervision internally and externally as hospitals programs do. Finally, the Comptroller's 1992 report found that BRH inspects hospitals more regularly than they inspect private radiologists: 70 percent of hospitals surveyed had been inspected in the past year as required, but the same was true only of 49 percent of private radiologists had been.

The lack of BRH involvement in the regulation and oversight of linear accelerators could pose a hazard, particularly given the training needed for linear accelerator operation and given that outside supervision is already weaker in private physicians' offices. The State Department of Health's Center for Environmental Health recently reported that their "experience to date in investigating the causes of radiation therapy errors in New York State indicates that the most important single cause has been lack of technical knowledge on the part of the persons performing treatment planning, especially with respect to computer-assisted treatment planning systems."[56] As already mentioned, the State DOH also found that persistent cases of therapy misadministration were consistently attributable to a lack of supervision by qualified personnel.

Because the City does not inspect linear accelerators, and because the State requires

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[53]January 19, 1992 telephone interview of Mary Anne Harvey by Comptroller's Office staff. This opinion is also shared by two physicists interviewed by the Comptroller's Office.

[54]10 N.Y.C.R.R. §710.

[55]10 N.Y.C.R.R. §710.1(c)(2)(i)(1). Under these planning requirements, the State DOH charges hospitals a fee of .004 percent of the total capital cost value of a project, including purchase and installation costs. A $1.5 million linear accelerator facility would thus cost the hospital an additional $6,000.00.

[56]February 25, 1992 notice from Rita Aldrich, Chief, Radioactive Materials Section, Bureau of Environmental Radiation Protection to New York State Department of Health Radioactive Materials Licensees.

only hospitals to obtain permission to install radiotherapy equipment, neither the City nor the State knows exactly how many linear accelerators are being used by private physicians in the City. This is a hazardous condition that must be corrected.

4. Conclusion.

Although BRH has maintained that it is preparing revisions to its program to increase its involvement in the regulation of linear accelerators, there are few indications that it is moving at a pace that can accomplish this goal in a reasonable amount of time.

Linear accelerators have been in use in the City since the 1950's, and although machines up to 20 years old are still in use, the City still does not have protocols for their inspection. This failure contravenes health code regulations and places the public at an ever increasing risk of radiation injury.

Given the backlog that already exists in current BRH programs,[57] it is unlikely that BRH can implement a linear accelerator inspection program without major departmental reforms.

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[57]See Comptroller's report, "Radiation Out of Control." In addition, the "City of New York Financial Plan Fiscal Years 1993-1996," Vol. II, p. 115, Jan. 29, 1993 (proposed budget), states that "currently there is a backlog of license applications and a two-year waiting period for renewals" in the Radioactive Materials Division.

APPENDIX A: REINSPECTION DATA FOR DIAGNOSTIC RADIOLOGISTS

Sample Number	Severity Level I Violation[a]	Severity Level II Violation	Severity Level III Violation	Marked For 30-Day Follow-Up	Inspection Date	Follow-Up Date	Days In Between
RADIOLOGISTS							
106		x	x	y	4/5/90	6/5/90	61
129		x x	x x	y	9/25/90	10/26/90*[b] 10/31/90 VCW[c]	31 5
191		x	x	y	8/14/91	8/22/91 VCW	8
217	x			y	8/28/90	10/12/90	45
222	x	x		y	6/22/89	9/21/89	91
223		x x		n	7/19/91	7/30/90* 8/8/91 VCW	11 9
245	x	x	x	y	4/23/91	10/1/91	161
265		x	x	y	3/14/91	4/3/91	47
267		x		y	4/21/89	6/2/89	43
292	x	x	x x	y	9/26/90	11/2/90* VRRPS[d]	37 --
293		x		y	1/15/91	2/22/91	38
299		x	x	y	6/20/90	10/11/90	113
303	x	x x x		y	10/9/90	1/9/91* 2/15/91* -----[e]	92 37 --

[a] "Severity Level I Violations," if not corrected, present a public health risk. They include excessive levels of radiation exposure and filtration of the X-ray beam that is not sufficient to stop unnecessary and harmful portions of the beam. A "Severity Level II Violation," if not promptly corrected, may lead to or contribute to a Severity Level I Violation. They include exposure switches that are operable outside of the area shielded from radiation, no means of numerically indicating that proper beam collimation has been achieved, and failure to test properly the average exposure levels. "Severity Level III Violations" involve recordkeeping, documentation, postings and procedural matters that are easily corrected and have no direct impact on health and safety.

[b] A "*" notation designates a facility cited for further/remaining violations that required another inspection.

[c] VCW is BRH notation for "violations complied with." Unless otherwise indicated, this means no on-site reinspection occurred.

[d] VRRPS is BRH notation for "violations have been removed, reinspect per schedule." Unless otherwise indicated, VRRPS means that no on-site reinspection has been completed. When no date accompanies this notation it is because the BRH files contained no date and there is thus no way of determining when the follow-up survey was done.

[e] No record of reinspection.

Sample Number	Severity Level I Violation	Severity Level II Violation	Severity Level III Violation	Marked For 30-Day Follow-Up	Inspection Date	Follow-Up Date	Days In Between
311		x x		y	3/20/90	7/26/90* 10/11/90	128 77
367	x		x	y	8/21/91	10/3/91	51
392		x	x	y	9/27/90	12/7/90	71
399		x		y	4/5/90	4/9/90 VRRPS	4
406		x	x	y	8/27/91	10/4/91	38
415		x	x	y	1/15/91	3/11/91	55
417	x	x x	x	y	9/11/91	10/31/91* VRRPS	49 --
432	x	x	x	y	3/6/90	5/31/90	86
456		x	x	y	10/5/90	-----	--
490		x		y	11/15/90	1/25/91	71
495	x	x		y	4/19/90	5/1/90 VRRPS	12
532		x	x	y	1/16/91	3/18/91	61
542		x	x	y	4/2/91	8/26/91	146
DENTISTS							
527		x	x	n	10/31/90	12/17/90	47
652	x			n	11/1/90	12/20/90	49
837	x			n	10/8/90	11/8/90	31
1525	x			n	5/24/90	7/6/90	42
1630			x	n	4/26/91	VRRPS	--
1639			x	n	11/19/90	VRRPS	--
2111		x x x	x	n	8/12/91	10/15/91* 11/22/91* 12/6/91	64 38 15
2156			x	n	10/29/90	VRRPS	--
2860			x	n	10/7/91	VRRPS	--
3048	x	x	x	y	3/6/90	5/31/90	86
3863	x	x	x	y	4/18/91	5/29/91	41
3882			x	n	1/2/91	VRRPS	--
4199			x	n	12/18/90	VRRPS	--
4352			x	n	4/30/91	VRRPS	--

Sample Number	Severity Level I Violation	Severity Level II Violation	Severity Level III Violation	Marked For 30-Day Follow-Up	Inspection Date	Follow-Up Date	Days In Between
4763	x			n	11/7/88	VRRPS	--
4911	x			n	10/12/88	VRRPS	--
5093			x	n	8/15/91	VRRPS	--
5139	x			y	6/18/91	8/15/91	58
5409	x	x x	x	y	8/16/91	9/30/91* 11/22/91	45 22
5460	x x			y	6/22/89	7/27/89* 1/8/90	35 165
5477			x	n	4/2/91	VRRPS	--
5627			x	n	7/24/91	VRRPS	--
PODIATRISTS							
026			x	n	7/23/91	VRRPS	--
042			x	n	8/28/91	VRRPS	--
047	x			y	7/28/87	-----	--
118			x	n	8/28/91	VRRPS	--
260			x	n	1/23/91	VRRPS	--
274	x		x	y	11/16/87	1/28/88	73
293	x		x	y	12/26/90	1/30/91	35
331	x			y	3/13/90	4/25/90	43
406			x	n	4/16/90	VRRPS	--
449	x	x		y	8/11/91	11/13/91	94
451	x			y	9/4/91	10/11/91	37
553	x	x		y	3/26/90	5/4/90	39
560	x		x	n	3/8/91	4/12/91	35
701			x	n	8/29/91	VRRPS	--
705	x			y	3/11/91	5/9/91	59
708			x	n	3/7/91	VRRPS	--
738		x		y	6/30/89	8/30/89	61
822	x		x	y	6/24/91	8/16/91	53
879			x	n	2/1/91	VRRPS	--
916			x	n	2/7/91	VRRPS	--

Sample Number	Severity Level I Violation	Severity Level II Violation	Severity Level III Violation	Marked For 30-Day Follow-Up	Inspection Date	Follow-Up Date	Days In Between
462	x		x	n	10/9/91	VRRPS	--
960	x			y	5/7/91	7/3/91	57

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 23, 1993

Mr. Eugene J. Gleason
Deputy Commissioner for Operations
New York State Energy Office
Empire State Plaza, Building 2
Albany, NY 12223

Dear Mr. Gleason:

This is to confirm the discussion held with you and officials of the four New York radiation control agencies on November 24, 1992 concerning our recent review of the State's Agreement State program.

As a result of our review of the State's total program and the exchange of information between the Nuclear Regulatory Commission and the agencies in New York that conduct the program, the staff believes that the State program as a whole is adequate to protect public health and safety. However, we are unable to make a finding of compatibility at this time due to the status of agency regulations.

Status and Compatibility of Regulations is a Category I indicator. During our previous review, we deferred a finding of compatibility due to the status of regulations and although the Departments have made progress toward adoption, we cannot offer a finding of compatibility until the regulations are effective. The Department of Environmental Conservation regulations regarding low-level waste were determined to be compatible with NRC regulations. We have the latest draft of the proposed State Department of Health changes and will be forwarding our comments shortly. We understand that the City Department of Health plans a comprehensive revision to the Health Code in 1993 and we look forward to reviewing a draft when available. The Department of Labor is proposing to update its regulations to cover financial assurance requirements for decommissioning.

Status of Inspection Program is a Category I indicator. At the time of the review, the City Department of Health had 48 licenses overdue for inspection by a period of greater than 50% of the inspection interval. We were pleased to note that, subsequent to the review, the Department staff prepared an action plan to address the backlog. We would encourage the Department to be more alert to program developments as they occur and prepare such action plans as backlogs begin to develop.

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ATTACHMENT 2

An explanation of our policies and practices for reviewing Agreement State programs is attached as Enclosure 1. Enclosure 2 contains further details on the above comments. Enclosure 3 contains detailed comments and recommendations on each of the four individual programs. We would appreciate your review of, and written response to, these comments and recommendations. We are enclosing a second copy of this letter for placement in the State's public document room or otherwise to be made available for public review.

I would like to express my appreciation for the courtesy and cooperation extended to all of the NRC staff who participated in the review effort by each of the agencies' representatives during the review. I especially appreciate the effort made by you and your staff in arranging for our entrance and exit meetings. I believe that these meetings were fruitful and contributed to the effectiveness of the review process. I am looking forward to the responses to our recommendations. Once we have had an opportunity to review your responses we would be prepared to conduct a follow-up review to address our areas of concern. At the conclusion of that review, we would be prepared to update our findings of adequacy and compatibility.

Sincerely,

Carlton Kammerer

Carlton Kammerer, Director
Office of State Programs

Enclosures:
As stated

cc: see next page

cc:
Langdon Marsh
Executive Deputy Commissioner
Department of Environmental Conservation

William Staziuk, P.E., Ph.D., Director
Center for Environmental Health
New York State Department of Health

Robert F. Gollnick
Deputy Commissioner for Worker Protection
Department of Labor

Margaret A. Hamburg, M.D.
Commissioner of Health
New York City Department of Health

J. M. Taylor, Executive Director for Operations, NRC
T. Martin, Regional Administrator, NRC Region I
NRC Public Document Room
State Public Document Room

Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs," were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories.

Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need of improvement in particular program areas is critical. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period. The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Act, as amended.

ENCLOSURE 1

SUMMARY OF REVIEW AND COMMENTS
NEW YORK RADIATION CONTROL PROGRAM
AUGUST TO SEPTEMBER 1992

Scope of Review

This was a consolidated program review of the four regulatory agencies with Agreement State responsibility in the State of New York. These agencies are the State Departments of Health (SDOH), Labor (DOL), and Environmental Conservation (DEC), and the New York City Department of Health (CDOH). The review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs, which was published in the Federal Register on May 28, 1992, and the internal procedures established by the NRC Office of State Programs, Agreement State Program. The State's program was reviewed against the 30 program indicators provided in the guidelines. The review included discussions with program management and staff, technical evaluation of selected licenses and permits, as well as compliance files, the evaluation of the four agencies' responses to an NRC questionnaire that was sent to the Departments in preparation for the review, and field evaluations of State inspectors.

This regulatory program review consisted of on-site office visits to the New York State Department of Environmental Conservation during the week of August 18-22, 1992, the State Department of Labor during the week of August 31 - September 4, 1992, the State Department of Health during the week of September 21-25, 1992, and the City Department of Health during the week of October 5-9, 1992.

Conclusion

As a result of our review of the State's program, the staff believes that the State program as a whole is adequate to protect public health and safety. However, we are unable to make a finding of compatibility at this time due to the status of agency regulations.

Current Review Comments and Recommendations

The following comments and recommendations were discussed during the management close out meeting with State officials on November 24, 1992 and were the principle bases for our overall findings regarding the State program.

ENCLOSURE 2

I. LEGISLATION AND REGULATIONS

Status and Compatibility of Regulations is a Category I indicator. The following comment and recommendation is of major significance with regard to compatibility.

Comment

The Department of Environmental Conservation has completed its work on the development of regulations regarding low-level radioactive waste. These regulations were reviewed by NRC and determined to be compatible with NRC regulations. Although the public comment period has expired and comments have been taken into account, we cannot offer a formal finding of compatibility until the regulations become effective. The State Department of Health has also worked diligently in preparing a revision to its regulations. We have the latest draft of the proposed changes and will be forwarding our comments shortly. The City Department of Health plans a comprehensive revision to its Health Code in 1993 and we look forward to reviewing a draft when available. There are a number of changes to NRC regulations which the City has not adopted within the three year time period given to Agreement State programs to effect such changes. The Department of Labor needs to amend its regulations to cover financial assurance for decommissioning.

Recommendation

We encourage the State to continue to move forward with its schedules to adopt changes to the Departments' regulations.

II. COMPLIANCE

Status of Inspection Program is a Category I indicator.

Comment

At the time of the review, the City Department of Health had 48 licenses overdue for inspection by a period of greater than 50% of the inspection interval. We were pleased to note that, subsequent to the review, the Department staff prepared an action plan to address the backlog. This plan included a goal of bringing the inspection program up-to-date within six weeks.

Recommendation

In light of the Department plan, we do not intend to defer a finding of adequacy at this time, however, we intend to follow the Department's progress in implementing the action plan and if sufficient progress is not made, perform a follow-up review to review the subject further. We would encourage the Department to be more alert to program developments as they occur and prepare such action plans as backlogs begin to develop.

Summary Discussion with State Representatives

A summary meeting to present the results of the regulatory program review was held on November 23, 1992 in Albany at the offices of the New York State Energy Office. The NRC staff was represented by William Kane, Deputy Regional Administrator, Region I, and John McGrath, Region I State Agreements Officer. The State Energy Office was represented by Eugene Gleason, Deputy Commissioner for Operations and Donna Ross, Staff Assistant to Mr. Gleason. The State Department of Environmental Conservation was represented by N.G. Kaul, Director, Division of Hazardous Substances Regulation, and Paul Merges, Chief, Bureau of Radiation. The State Department of Health was represented by William Staziuk, Director, Center for Environmental Health, Karim Rimawi, Director, Bureau for Environmental Radiation Protection, and Rita Aldrich, Chief, Radioactive Materials Section. The State Department of Labor was represented by Thomas McCormick, Special Assistant to the Deputy Commissioner for Worker Protection, Maria Colavito, Director, Division of Safety and Health, and George Kasyk, Acting Chief, Radiological Health Unit. The New York City Department of Health was represented by Gerald Flanders, Acting Deputy Commissioner for Environmental Health Services and Robert Kulikowski, Chief, Radioactive Materials Division.

NEW YORK CITY DEPARTMENT OF HEALTH
BUREAU OF RADIOLOGICAL HEALTH
RADIATION CONTROL PROGRAM
SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE PERIOD OCTOBER 1990 TO AUGUST 1992

Scope of Review

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs, Agreement State Program. The Department's program was reviewed against the 30 program indicators provided in the guidelines. The review included discussions with program management and staff, technical evaluation of selected permit and compliance files, the evaluation of the Department's responses to an NRC questionnaire that was sent to the Bureau of Radiological Health (BRH) in preparation for the review, and a field evaluation of three BRH inspectors.

This review is part of a comprehensive review of the New York Agreement State program. The in-briefing was held October 5, 1992 in New York City, New York. The Department was represented by Dr. Richard R. Kulikowski, Director, Bureau of Radiological Health. NRC was represented James Myers, State Agreements Program, Office of State Programs, NRC Headquarters and John McGrath, Regional State Agreements Officer. A field accompaniment of BRH inspectors at Columbia-Presbyterian Medical Center, a broad scope, human use licensee was conducted on October 8, 1992 by Mr. Myers. A field evaluation of a BRH inspector at the Cabrini Medical Center was conducted on October 7, 1992 by Mr. McGrath. A review of selected licensing and compliance actions was conducted by Messrs. Myers and McGrath on October 5-7, 1992. A closeout meeting with Enid Carruth, M.P.H., Deputy Commissioner, Environmental Health Services, New York Department of Health and Dr. Kulikowski was held on October 9, 1992.

Conclusion

The staff believes that the Department's program is adequate to protect public health and safety, however, we are withholding a finding on compatibility due to the status of the Department's regulations. A statement of compatibility was also withheld following the 1990 program review. The BRH program has made progress on some regulatory changes since the 1990 comments, however, not all necessary changes were adopted and additional regulations have come due in the meantime.

Status of Program Related to Previous NRC Findings

Comments and recommendations from NRC's previous review were sent to the State in a letter dated March 7, 1991. The State's response to NRC was dated June 7, 1991. We are pleased to see that BRH has made progress in several of the comment areas. However, several of the issues remain unresolved; specifically, the issues of the status and compatibility of regulations, the purchase of a Ge-Li spectroscopy system, the establishment of a written policy for conducting unannounced inspections, and the lack of adequate documentation in inspection reports.

The BRH has taken corrective action in response to our previous comments as follows:

1. Quality of Emergency Planning (Category I)

The BRH has reviewed and implemented a revised emergency response plan following recommendations made on the last review. NYCH Emergency Plans were updated in December 1991 and are similar to NRC's. The plan appears to work well as exhibited by BRH's response to recent emergencies.

2. Confirmatory Measurements (Category II)

BRH inspectors were observed confirming licensee measurements during the accompaniments. Results were being recorded in the inspector's checklists for use in the inspection report.

CURRENT REVIEW COMMENTS AND RECOMMENDATIONS

All 30 program indicators were reviewed. The City fully satisfies 21 of these indicators. Specific comments and recommendations for the remaining 8 indicators are as follows:

I. LEGISLATION AND REGULATIONS

Status and Compatibility of Regulations is a Category I indicator.

Comment

For those regulations adopted by NRC which are deemed to be a matter of strict compatibility, the State regulations should be amended to conform as soon as practicable, usually within three years. Normally, this time interval begins when the rule becomes effective. Although BRH has moved to adopt some needed compatible rules, there are a number of rules that are still in the developmental stage. BRH will need to adopt the following regulations to maintain compatibility:

"Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees" (10 CFR Parts 30, 40, and 70); April 7, 1993.

"Standards for Protection Against Radiation", (10 CFR Part 20); January 1, 1994.

"NVLAP Certification of Dosimetry Processors" (10 CFR Part 20); February 12, 1991.

"Bankruptcy Notification" (10 CFR Parts 30, 40, 61, 70); February 11, 1990.

"Decommissioning" (10 CFR Parts 30, 40 and 70); July 27, 1991.

"Notification of Incidents" (10 CFR Part 20, 30, 31, 34, 39, 40, .and 70); October 15, 1994.

"Quality Management Program and Misadministration" (10 CFR Part 35); January 27, 1995.

Recommendation

It is recommended that BRH continue to work toward adopting the regulations that are directly related to health and safety as soon as possible.

II. MANAGEMENT AND ADMINISTRATION

1. Laboratory Support is a Category II indicator.

Comment

The Bureau's present Ge-Li gamma spectroscopy unit has been out of service for some time. The Bureau has ordered a unit, but has not taken delivery. During the inspector accompaniments it was discovered that BRH was using a licensee's equipment to count wipe tests taken during an inspection. BRH recently received a service contract on their present counter. At the time of the review, the unit had just been repaired and was being put back into regular service. The practice of using licensee's equipment to perform the Bureau's wipe tests is questionable.

Recommendation

We recommend that the Bureau make every effort to obtain the counting capability necessary to effectively run the program and to not rely on licensee's equipment.

2. Administrative Procedures is a Category II indicator.

Comment

Although BRH has done a very good job at improving their licensing and compliance files, work remains to be done on improving the quality of each docket file. Administrative procedures appear not to be routinely followed. Almost every licensing or compliance file reviewed was found to have missing, misplaced or misfiled documents. Although the "job" is getting done, the disordered and incomplete docket files do not promote a high degree of confidence in the Bureau's ability to efficiently carry out its licensing, inspection and compliance responsibilities or to respond to questions from licensees or the public.

Recommendation

The management should review BRH written internal procedures with the staff to provide a higher degree of uniformity and continuity in administrative practices.

III. LICENSING

Licensing Procedures is a Category II indicator

Comment

The technical quality of the Bureau's licensing actions appears to be adequate. No unusual licensing problems were uncovered during the review. As previously stated, the quality of the licensing actions is, however, somewhat diminished by the poor documentation, misfiled documents, and lost documents. Management or peer review of the actions either were not documented or were very poorly documented in the files.

Recommendation

We recommend that the Bureau staff endeavor to document all contacts with licensees, file all documents correctly, and record all peer and management reviews in the docket file.

IV. COMPLIANCE

1. Status of Inspection Program is a Category I indicator.

Comment

Data provided by the BRH shows that the program had 48 licenses that are overdue for inspection. Of these, one is a priority I license that is overdue by more than 50 percent of the normal inspection interval. The remainder are priority II and III licenses ranging from three to 93 months overdue. The BRH submitted a draft plan for inspection of the overdue licenses during the program review. A final plan was forwarded to NRC the week following the review. The six week plan would bring the inspections up-to-date. It is noted that regularly scheduled inspections were not delayed as a result of this "get well" plan, but were conducted at their appointed times. The Bureau Director will review the progress of the inspection plan on a weekly basis. Additionally, a tracking system in dbase IV has been developed to assist management in following the progress of the "get well" plan and to track future inspections and compliance activities.

Recommendation

With submission of the draft plan during the visit, BRH satisfied the requirement to develop a management plan addressing this deficient indicator. Since the review, the BRH appears to be on schedule with the "get well" plan, having completed 24 of the 48 overdue inspections. BRH should continue to use the tracking system they have recently developed to assure that the inspection backlog is eliminated according to plan.

2. Inspection Procedures is a Category II indicator.

Comment

BRH inspection procedures parallel those of NRC and appear to be consistent with NRC present policies. Although the Bureau does not have an established policy for unannounced inspections, BRH does in practice conduct some inspections on an unannounced basis when required. It was not clear from the compliance or licensing files that an effective feedback system exists for communicating significant inspection information to the license reviewers.

Recommendation

It is again recommended that BRH develop and implement a formal policy to conduct unannounced inspections and have the policy reviewed by legal counsel as soon as possible. This comment was also made after the 1989 and 1990 reviews. We also recommend that the program develop a procedure to

provide for better feedback between the inspection staff and the licensing staff. Refine the "feedback" system from inspections to notify licensing of problems with a particular licensee.

3. Inspection Reports is a Category II indicator.

Comment

During the review of inspection files, it was noted that the documentation of inspection results needed to be improved. Some of the problems noted involved docket files missing essential information. We also noted inconsistency in the application of procedures, such as a failure to cite for an unauthorized disposal, reporting of spills, and citations not supported by information in the inspection reports. There was also a lack of follow-up in the areas of possible escalated enforcement actions in at least two situations. In general, there appears to be a lack of "follow up" on enforcement actions. In several other situations, there were long delays in issuing enforcement letters; there was no follow up to lack of licensee response; and there was no follow up on corrective actions at subsequent inspections. The number of overdues, however, indicates that a system is needed to keep on top of the inspections schedule.

Recommendation

The BRH should use its new tracking system to follow all aspects of the inspection process. Carefully document all aspects of the inspection process to include management review of the inspection.

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION
RADIATION CONTROL PROGRAM
SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE PERIOD OCTOBER 1990 TO AUGUST 1992

Scope of Review

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs, Agreement State Program. The Department's program was reviewed against the 30 program indicators provided in the guidelines. The review included discussions with program management and staff, technical evaluation of selected permit and compliance files, the evaluation of the Department's responses to an NRC questionnaire that was sent to the State in preparation for the review, and a field evaluation of a Department inspector. In addition to the indicators, the NRC staff focused on the coordination of DEC with the other New York Agreement State agencies.

This review is part of a comprehensive review of the New York Agreement State program. The DEC meeting was held during the period August 17-21, 1992 in Albany, New York. The Department was represented by Dr. Paul Merges, Director, Bureau of Radiation. NRC was represented by John McGrath, Regional State Agreements Officer. A field accompaniment of a DEC inspector at Rensselaer Polytechnic Institute, an incinerator permittee, was conducted on August 20, 1992 by Mr. McGrath. A review of selected permit and compliance actions was conducted by Mr. McGrath on August 17-20, 1992. A closeout meeting with N.G. Kaul, Director, Division of Hazardous Substances Regulation and Paul Merges was held on August 21, 1992.

Status of Program Related to Previous NRC Findings

Comments and recommendations from NRC's previous review were sent to the State Energy Office in a letter dated March 7, 1991. The State responded to NRC on June 7, 1991. The Department has made some progress in several of the areas, however, several of the issues raised during the previous review have not been resolved.

I. LEGISLATION AND REGULATIONS

Comment

During our last review of the DEC program we noted that DEC is the lead agency in the State with regard to regulation of low-level waste and would have key responsibilities regarding the regulation of a State low-level waste disposal facility. As such, NRC policy is that Agreement States who are also declared host States for such a facility need to have regulations that are

compatible with 10 CFR Part 61 in place three years subsequent to the effective date of 10 CFR Part 61, i.e. by January 26, 1986. We recognize that DEC has made significant progress in the development of its regulations, and that it is working to complete the regulations necessary for licensing a low-level waste disposal facility. During the review we received a preliminary draft copy of the remaining Part 383 rules needed for this licensing action. Once we have reviewed all of the necessary pieces of the regulations we will determine if there are any sections of Part 61 that need to be addressed by DEC or DOL.

Recommendation

We encourage the State to continue to move forward in accordance with its schedule. Regulations covering financial assurance, post-closure activities and other necessary requirements still need to be adopted by the State.

State Response

The Department recognizes the need to adopt the remaining portions of its regulations for low-level radioactive waste (LLRW) disposal facilities. As NRC is aware, the New York State LLRW Management Act mandated the development of regulations addressing disposal technologies not contemplated by 10 CFR Part 61, and this has contributed to the need for far more complex regulations than those in Part 61. DEC will continue its efforts to promulgate the appropriate regulations. Adoption of regulations on financial assurance requirements is now scheduled, and we hope to have them promulgated before the NRC's next inspection of our program. The remaining regulations related to the permit application, operation, closure, post-closure, and institutional control requirements for LLRW disposal facilities, are scheduled to be issued as proposed rules in 1991, with final adoption expected in 1992. It should also be noted that the regulations for the first two stages of New York State's process for development of the LLRW facility are already in place, and the remaining regulations are scheduled for adoption well in advance of the stage in the approval process that they will govern.

Current Status

The final draft amendments to DEC regulation on LLRW, Part 383, have been prepared and submitted to NRC for review. This, in addition to changes already in place in Part 381 (Permit and Manifest System), Part 382 (facility siting requirements), and Subpart 383-6 (Financial Assurance Requirements), as well as the existing provision of Industrial Code Rule 38 form the New York

equivalent to 10 CFR Part 61. A determination has been made that the regulations are compatible with 10 CFR Part 61. A number of changes have been made as a result of the public comment period and these changes are currently being evaluated by NRC.

II. ORGANIZATION

Comment

The radiation control program is completing the preparation of a Memorandum of Understanding (MOU) between DOL and DEC to define respective agency roles and responsibilities relating to licensing a LLRW disposal facility. Discussion with staff at the Departments of Labor and Environmental Conservation indicate that staff in each agency is fully cooperating and striving to keep each other informed of respective activities. Also, a number of interagency committees have been established which are serving to effect coordination and exchange of information, principally in the LLRW area. Such discussion and review of files, however, indicate a need to clearly defined in the MOU or companion implementing documents, specific details on how respective agency responsibilities will be implemented by staff on a day-to-day basis including a broader range of activities. The MOU or companion implementing documents should include activities regarding the West Valley site, future activities in licensing a LLRW disposal facility and other major activities subject to regulatory purview of each agency. During the last review, NRC recommended as part of the development of the regulatory program for low-level radioactive waste, that the Department finalize the MOU with the State Department of Labor concerning division of regulatory responsibilities over low-level waste.

Recommendation

The Departments of Labor and Environmental Conservation should complete the MOU and include sufficient detail in the MOU, or develop companion implementing documents to provide clear guidance and instruction to staff on how respective agencies' responsibilities will be carried out for specific activities such as West Valley and licensing of a LLRW disposal facility and other major activities subject to regulatory purview of each agency.

State Response

NRC recommends that DEC and DOL finalize the proposed MOU on regulation of LLRW facilities. DEC will give finalization of that MOU a high priority. Once the MOU is signed, we will review the need for companion or implementing documents for regulation of the LLRW facility. NRC also recommends that the two agencies include in the MOU or companion documents a description of the

respective agencies' responsibilities for West Valley. This does not appear to be necessary. NRC has not cited, nor are we awareof, any current overlaps or gaps between the two agencies' regulatory program for West Valley.

Current Status

The Department's Counsel's Office has taken over negotiation of all MOUs with other State agencies. The specific MOU with DOL is on hold pending the reorganization of DOL into the Department of Health.

Comment

It is not clear at what point in the materials program that DEC implements their regulatory authority. During the review of both the licensing and compliance files, it appears that DEC depends on the licensing agencies to review and approve licensees (permittees) environmental sampling methods and training of the personnel gathering the samples. Discussions with the lead NRC reviewers for the DOH and DOL reviews indicate that these agencies are depending on DEC to perform these analyses.

Recommendation

DEC needs to identify their responsibility and develop an MOU with the other New York licensing agencies to insure that the environmental release program in the State of New York is covering all aspects of the 274b authority.

State Response

DEC disagrees with NRC's comment on the apparent lack of review of environmental sampling methods. This is not the case. The information required to be submitted in an application for a DEC permit includes a description of effluent monitoring systems and equipment. NRC is correct in its comment that DEC does not review, the qualifications and training of permittees' staff. DEC is currently reviewing the need to promulgate regulations addressing specific training and qualification requirements.

NRC recommends that DEC identify its responsibility and develop an MOU with the other New York licensing agencies on the regulation of environmental releases. DEC does not believe that an MOU is needed at this time. The New York State Committee on Licensing has created a subcommittee to coordinate the New York agencies' adoption of the new Part 20. As part of that process, the agencies will be more clearly defining each agency's area of authority.

Current Status

The Bureau recently received an opinion regarding DEC jurisdiction in New York City which affirmed the view that DEC does have regulatory jurisdiction. DEC management favors pursuing an MOU with the City and the Counsel's office will be handling the negotiations.

Comment

DEC presently has an MOU with the Department of Health signed in 1982 to implement the DEC environmental monitoring authority and program. As part of the review, NRC reviewed the reports from 1982-1987 from SDOH. In discussions with the NYDEC staff, they indicated that preliminary information was available to DEC if requested from DOH. However there was no routine exchange of information or a procedure in place to notify DEC if any significant result occurred. During the last review, NRC recommended that the Department review its arrangement with the Department of Health for environmental monitoring with the objective of assuring the results of the monitoring are provided to the Department on a timely basis.

Recommendation

We again recommend that DEC and SDOH review the existing MOU and establish a procedure for notifying DEC on a timely fashion of results of environmental monitoring around DEC permittees.

State Response

NRC recommends that DEC and SDOH review and consider amending the existing MOU on the environmental monitoring program. DEC and SDOH have discussed this issue, and have agreed that no revision of the MOU is necessary at this time. SDOH will continue to review the monitoring results and promptly notify DEC of any unusual results in the vicinity of DEC permittees.

Current Status

Since both agencies believe that there is no problem with the existing program, this items is considered closed.

Comment

New DEC staff involved in the Bureau of Radiation West Valley program has effectively developed a working knowledge about past operations and activities, have initiated planning for future DEC activities leading to requiring submission of a final closure and stabilization plan for the site, and are effectively discharging day-to-day oversight responsibilities. A revised permit is in

preparation and recent inspection activities have been effective in identifying areas needing corrective action by NYSERDA. Lead responsibility within DEC for the LLRW site has been assigned to the Bureau of Hazardous Waste Facility Management within the Division and it is unclear how NYS responsibilities under the agreement for radiation matters at this site will be handled in the future. The reassignment was made due to mixed waste considerations involved in the pumping and treatment of liquids from trenches and future needs to address site closure through the DEC RCRA program.

Recommendation

The program should ensure that the Bureau of Radiation, which NRC understands is the DEC organization responsible for carrying out New York State responsibilities under the NYS Agreement, has effective lead responsibility for activities at the site involving radiation matters. Since the West Valley site was licensed as a low-level radioactive waste disposal facility, not a hazardous waste disposal facility, consideration should be given to assigning lead responsibility for radiation protection activities at the site to the Bureau of Radiation. We recommend that the Department coordinate with NRC to ensure that the activities under Section 274b are adequately addressed.

State Response

These are matters strictly within the jurisdiction of this Agency and this Division, and therefore, not an NRC matter. The decision has been made to have the hazardous waste program be lead.

Current Status

No further recommendations were made on this issue. The Bureau of Radiation is still very active in reviewing activities at West Valley and is working very closely with the hazardous waste division.

III. MANAGEMENT AND ADMINISTRATION

Comment

The program lacks adequate facilities to store and prepare environmental samples taken for analysis and to set up and operate instrumentation purchased by the DEC for analysis of such samples. In addition, the reviewers received a copy of a February 8, 1990 memorandum which instructed the staff to cease any activities which will produce environmental samples. Also the DEC was instructed not to set up the equipment to analyze their samples.

Recommendation

We recommend that the DEC's Division of Hazardous Substances Regulation conduct a review to assure that resources are sufficient to enable the program to effectively carry out all responsibilities including the ability to utilize the available equipment.

State Response

The DEC's Division of Hazardous Substances Regulation has concerns over the lack of adequate laboratory space available to the radiation program. The Department is hopeful that the Governor's proposed budget will be enacted by the State legislature.

Current Status

The Bureau continues to use the DEC central lab and SUNY-Albany. SUNY-Albany recently gave DEC space at its laboratory facility and DEC is beginning to set up its equipment there. Once in operation, this facility, run by DEC staff, should be able to handle all DEC lab needs.

Comment

DEC does not presently have written administrative procedures for the following areas: receipt, assignment and tracking of permittees application inspections, assignments, announcements of inspection, termination of permittees, coordination of decommissioning of permittees, responding to press inquiries exchange of information with NRC and Agreement States and distribution of All Agreement State Letters and Information Notices.

Recommendation

We recommend that the staff develop administrative procedures covering the above mentioned areas.

State Response

Since October 1990, DEC has made major changes to the administration of permit applications. As the result of an intra-departmental Memorandum of Understanding signed in December 1990, radiation permits for releases of radioactive material to surface and groundwater have been integrated into the Department's permit management system and are now subject to the administrative procedures of the Division of Regulatory Affairs. The applications are submitted to the Department's regional office and promptly entered into the Department's permit management database for tracking. The review of the permit is governed by the State Uniform Procedures Act and its implementing regulations. The progress of the review is tracked by the regional office, to ensure that the Department acts on the applications in the required time periods. The Department plans to bring the bulk of the remaining radiation permits, those for releases to air, into the same system by the end of 1991. In the interim, the Radiation Control Program is applying the Uniform Procedures regulations to those permits and is developing internal procedures for application receipt, tracking, and review.

The Department will develop administrative procedures for the other areas listed by NRC as time and staffing level permits. During the October inspection of DEC's program, the NRC staff recommended that DEC refer to the procedures of other Agreement States and the NRC for guidance and suggestions; the NRC staff offered to send some recommended procedures to DEC. We hope to receive those from NRC soon.

Current Status

The Bureau has developed a permit tracking system which adequately addresses the staff needs.

IV. PERSONNEL

Comment

DEC has not filled a vacant supervisory position in the program having responsibility for LLRW disposal licensing, and LLRW transport permits. This position would also round out the requirements for the essential personnel with a civil engineering background as discussed in the proposed guidelines.

Recommendation

Given increased activities at West Valley and increased activities involving decontamination and decommissioning of sites in New York State and need to continue activities preparatory for LLRW disposal facility licensing, it is important that DEC take action to fill this vacant position.

State Response

Again, this is a Department decision. No positions are presently being filled due to the State's budget constraints. Two State items have been deleted from the budget.

Current Status

The Bureau has been organized in a way which has eliminated the specific position identified during the last review, but adequate staffing is available to address LLRW needs.

Comment

The reviewer noted that DEC has been establishing a cadre of staff after a period of lack of support in the mid 1980s. There is no written procedure discussing training of new staff.

Recommendation

We recommend that DEC establish a written procedure addressing training of new staff for the various responsibilities under the 274b agreement. This procedure should include attendance at certain NRC core courses, accompaniments with senior staff and accompaniments with SDOH or DOL inspectors to the various types of licensees over which DEC also has jurisdiction.

State Response

DEC concurs with the NRC's comment regarding the need for procedures on training of new staff. As time and staffing permit, we will begin to develop such procedures. This task would be greatly expedited if NRC would advise the Department on the minimum training NRC expects of Agreement State personnel.

Current Status

Most of the current staff have gone through appropriate NRC training courses. The Bureau has an informal training plan, but nothing has been written.

V. LICENSING

Comment

During the review of permittee files, several problems were identified. The date of issuance in several instances was several months later than the effective date on the permit. There was one instance of the tie down condition being incorrect, inaccurate description of permittees activities and lack of documentation telephone inquires. It is also not clear which New York regulatory agency reviews environmental sampling programs and the training of the personnel carrying out this function.

Recommendation

It was noted that the reviewers are using checklists and there is supervisory sign-off on the checklist. We recommend both reviewers and management pay closer attention to the licensing processes. We also recommend that training and the reviews of the environmental program of the permittee also be reviewed.

State Response

DEC has already taken steps to correct these problems and prevent their recurrence. The permit that had the error in the tie down has been corrected, and Bureau staff have been reminded of the importance of tie downs. Telephone conversations are not documented on a conversation record form similar to that used by the NRC. Supervisory reviews of permitting actions have been intensified. Permits are now given a more detailed and careful review, including the supervisor's use of a checklist in reviewing draft permits. Among other things, the checklist prompts a review of both the appropriateness of the tie downs and the accuracy of the citations. As was stated in the response to Item II 2, DEC is reviewing whether it will promulgate regulations addressing specific training and qualification requirements.

Current Status

Previously identified permit problems have been addressed. The Bureau has developed checklists for all categories of permits in addition to a checklist for supervisory review of permitting actions.

Comment

We note that the staff is still developing proposed checklists for four types of permittees. The procedures that have been developed and are in use are an excellent beginning. This comment was made during the last review.

Recommendation

These procedures need to be finalized and distributed to all permit reviewers so that questions on coordination with other State agencies can be addressed.

State Response

DEC will continue to develop the recommended procedures, as time and staff limitations permit.

Current Status

As indicated above, the Bureau has developed checklists for all categories of permits in addition to a checklist for supervisory review of permitting actions.

VI. COMPLIANCE

Comment

A review of the compliance file and discussions with the DEC indicate that there is not a specific enforcement policy for the Bureau of Radiation. Although DEC has a enforcement policy for issuing orders, a specific policy addressing the Agreement Program has been requested from the DEC legal counsel and has not yet been developed. There does not appear to be a standard period of time for issuance of compliance letters or the manner of handling items of noncompliance. During the last review NRC recommended that the Bureau institute a procedure to track enforcement actions. There is still no formal procedure to track enforcement.

Recommendation

A written enforcement procedure should be available describing the various levels of enforcement available to the inspector. Also a standard time period for issuance of enforcement letters needs to be established. Also the State should institute a procedure to track enforcement actions.

State Response

DEC is developing an enforcement guidance memorandum (EGM) which will address the policies and procedures the Department will use to promote compliance with DEC regulations and the Environmental Conservation Law. The EGM will address the Department's response to violations of 6 NYCRR Part 380 and more particularly contain guidelines for determining civil penalty amounts, explanation of severity levels for violations and assignment of enforcement responsibility. We will also be developing guidance documents

governing enforcement referrals. A first draft has been prepared and is undergoing internal review. We expect to have these efforts finalized by the end of this year.

Current Status

The draft enforcement guidance memorandum has been approved by the Attorney General's office and is undergoing internal Bureau review.

Comment

During the accompaniment of the State inspector and review of the inspection reports revealed that on a routine basis the DEC inspectors are not taking survey instruments with them into licensed facilities. When discussed with the inspectors, they indicated that it was noted in the inspection procedures but the use of survey instruments had lapsed.

Recommendation

The inspection procedures should be strengthened to include the use of survey instruments and documentation of the survey results. The staff should be instructed to always take appropriate, calibrated, operable survey instruments prior to entering a permittee facility.

State Response

The inspection report form has been amended to include the documentation of surveys. The information recorded on the form includes the instrument used, its calibration date, the check sources used, the instrument's response to the check source, background readings, and the results of the survey of the facility and the property.

Current Status

Survey instrumentation is now being utilized on all Bureau inspections.

Comment

The Bureau staff appears to collect independent samples from permittees. If the samples are taken on licensees facilities before release to the environment, there is some question whether the Bureau has the necessary authority to possess the licensed material.

Recommendation

The program needs to determine if it needs to apply for and obtain a license for radioactive samples collected during inspections and State investigations. It would benefit the Bureau to have an in house radiation program and clarify the legal question over the possession of radioactive samples collected from licensees and in the environment.

State Response

The program is not currently allowed to bring radiation samples into the Bureau's offices. Without the ability to properly secure radioactive material, we will not apply for a radioactive materials license.

Current Status

As stated earlier, SUNY-Albany has donated space to the Bureau for a radiation lab. The Bureau is currently in the process of setting up the lab.

Comment

Only one velometer was available for inspections and was out of calibration during the time of the review.

Recommendation

With four inspectors, a second instrument should be purchased to enable more than one staff to be on an inspection and also be available when instruments are calibrated.

State Response

Last fall, the Bureau had ordered a second velometer, but all purchases were stopped due to the State's fiscal crisis. We will attempt to purchase the instrument in this fiscal year.

Current Status

The Bureau continues to include this instrumentation in budget requests.

Current Review Comments and Recommendations

All 30 program indicators were reviewed and the Bureau fully satisfies 24 of these indicators. Specific comments and recommendations for the remaining 5 indicators are as follows:

I. LEGISLATION AND REGULATIONS

Status and Compatibility of Regulations is a Category I indicator.

Comment

The Department has completed work on the development of regulations equivalent to 10 CFR Part 61 and NRC has made a determination that the State's regulations are compatible with Part 61. DEC needs to adopt the following other regulations to become compatible:

"Standards for Protection Against Radiation", (10 CFR Part 20); January 1, 1994.

"Bankruptcy Notification" (10 CFR Parts 30, 40, 61, 70); February 11, 1990.

Recommendation

Subsequent to public review, further changes were made to the Department's regulations. These changes are currently undergoing NRC review. Provided none of the changes affects our previous determination that the regulations were compatible with 10 CFR Part 61, we should be in a position to offer a finding of compatibility upon the effective date of the adoption of these regulations.

V. LICENSING

Technical quality of Licensing Actions is a Category I indicator. The following comment and recommendations are of minor significance.

Comment

The technical quality of the permitting actions has improved significantly over the past review period. Permits reviewed during this review showed a much greater degree of consistency in application of regulatory requirements. During our last review, we addressed the issue of program coordination, particularly with regard to the permitting program and other aspects of the DEC program where interface with the other licensing agencies is necessary. Specifically with regard to permitting, DEC still has not exercised its regulatory authority over licensees in New York City.

Recommendation

Now that the permitting program is on track, we recommend that DEC explore addressing the licensees in the New York City area that require DEC permitting.

VI. COMPLIANCE

1. Enforcement Procedures is a Category I indicator.

Comment

For the last few reviews, NRC has been recommending that the Bureau develop formal enforcement policies and procedures. DEC is developing an enforcement guidance memorandum (EGM) which will address the needed policies and procedures, however, the current draft is still undergoing internal review. During the current review, we learned that the draft enforcement guidance memorandum has been approved by the Attorney General's office, but is undergoing some further internal Bureau review.

Recommendation

We recommend that the Bureau complete its review of the draft enforcement guidance memorandum as soon as possible and implement the final version.

2. Inspector's Performance and Capability is a Category I indicator.

Comment

NRC guidelines point out that the program compliance supervisor or other management representative should conduct annual field evaluations of each inspector to assist performance and assure application of appropriate and consistent policies and guides. During the review period, which covers almost two years, not all Bureau inspectors have been accompanied by management on inspections.

Recommendation

We understand that the Bureau plans to complete the inspection accompaniments by November 1992, however, we recommend that the Bureau place a higher priority on assuring that inspection accompaniments be performed in a timely fashion.

3. Confirmatory Measurements is a Category II indicator.

Comment

During our previous review, we noted that only one velometer was available for use by the inspection staff. Last year, the Bureau ordered a second velometer, but all purchases were stopped due to the State's fiscal crisis. Although theBureau continues to include this instrumentation in budget requests, no progress has been made.

Recommendation

As we have recommended in the past, a second instrument should be purchased to enable more than one staff to be on an inspection and also be available when instruments are calibrated.

Summary Discussion with State Representatives

A summary meeting to present the results of the regulatory program review was held with N.G. Kaul, Director, Division of Hazardous Substances Regulation and Paul Merges on August 21, 1992. The NRC representative indicated that the Department had made significant progress in several areas since the previous review, particularly with regard to the development of standard procedures in the permitting program. However, the NRC staff indicated that Bureau still needs to address the areas mentioned during the review. No recommendation on adequacy or compatibility was offered at the summary meeting.

SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE NEW YORK STATE DEPARTMENT OF LABOR
RADIATION CONTROL PROGRAM
OCTOBER 19, 1990 TO SEPTEMBER 4, 1992

SCOPE OF REVIEW

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs. The Department's program was reviewed against the 30 program indicators provided in the Guidelines. The review included discussions with program management and staff, technical evaluation of selected license and compliance files, and the evaluation of the responses to an NRC questionnaire that was sent to the Department's Division of Safety and Health, Radiological Health Unit, in preparation for the review.

The 27th regulatory program review meeting with Department representatives was held during the period October 31 - September 4, 1992, in the Department offices in Brooklyn, New York. The State was represented by Mr. George Kasyk, Acting Principle Radiophysicist.

Selected license and compliance files were reviewed by John McGrath, Regional State Agreements Officer, Region I, assisted by Richard Blanton, Office of State Programs. A summary meeting regarding the results of the review was held with Maria Colavita, Director, Division of Safety and Health on September 22, 1992. A similar meeting was held with Mr. Kasyk and his staff on September 4, 1992.

CONCLUSION

The program for control of agreement materials is adequate to protect the public health and safety and is compatible with the regulatory programs of the NRC. The finding of compatibility, however, is contingent upon the adoption by the Department of the amendment to Code Rule 38 on Financial Assurance for Decommissioning.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in a letter to Eugene Gleason (State Liaison Officer) dated March 7, 1991. All comments made at that time were reviewed and found to have been satisfactorily resolved and closed out prior to this meeting, except the following:

1. Legislation and Regulations is a Category I Indicator.

   The Department has adopted all of the rules and amendments that were overdue at the time of the last review. However, one rule which must be adopted, the Financial Assurance for Decommissioning rule, came due for adoption since the last review. An amendment to adopt this rule has been drafted and is under review by the Department's Legal Counsel.

2. Staffing Level is a Category II Indicator.

   A new Associate Radiophysicist position for the Low-Level Waste Program has been approved, but not funded. The workload of the Department in the Low-Level Waste area, however, is increasing. At the same time, the position of the Principle Radiophysicist has been vacant since March. Partly as a result of this, a backlog of overdue inspections noted during the last review has decreased but has not been eliminated, and a backlog of requested licensing actions is increasing.

3. Status of the Inspection Program is a Category I Indicator.

   After the 1990 review, the Department submitted a plan to eliminate the backlog of overdue inspections by the end of 1990. However, a reduced backlog still existed during this review, and the staff then planned to eliminate it by the end of October 1992. Details of the planned action were not available, however the bulk of the current backlog involves licensees in a limited geographic area of the State. We are concerned, however, that unless the Principle Radiophysicist position is filled it may not be possible to achieve this plan.

CURRENT REVIEW COMMENTS AND RECOMMENDATIONS

All 30 program indicators were reviewed and the State fully satisfies 25 of these indicators. Specific comments and recommendations for the remaining four indicators are as follows:

I. <u>LEGISLATION AND REGULATIONS</u>

Status and Compatibility of Regulations is a Category I Indicator.

<u>Comment</u>

The Department's regulations in Code Rule 38 are compatible with NRC regulations except for the following rules:

"Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees" (10 CFR Parts 30, 40, and 70); April 7, 1993.

"Decommissioning" (10 CFR Parts 30, 40 and 70); July 27, 1991.

The financial Assurance for Decommissioning rule is in the process of being adopted. An amendment to the rule on decommissioning is under review by the Department's legal staff. The Department has implemented the requirements of the emergency planning rule administratively, through the licensing process, for each licensee to which the rule would apply.

Recommendation

The Department should proceed with the adoption of the decommissioning rule and the emergency planning rule as quickly as practicable. The adoption of the emergency planning rule would assure that its provisions are uniform applied to all licensees.

II. PERSONNEL

Staff Supervision is a Category II Indicator.

Comment

Since the retirement of the Principal Radiophysicist, the Radiological Health Unit has not been in a position to provide adequate supervision of the staff. The duties of both the Principal Radiophysicist and the Supervision Radiophysicist have been performed by the same person. This has led to the inadequate supervision of the inspection staff and an increase in the licensing backlog.

Recommendation

The Department should fill the Principle Radiophysicist position as soon as possible.

III. COMPLIANCE

1. Inspector's Performance and Capability is a Category I Indicator.

Comment

NRC guidelines on the performance of inspectors states that each inspector should be accompanied on at least one inspection each year by program management. During the review period, only one such accompaniment was made. The lack of accompaniments is due in part to the redistributed workload resulting from staff vacancies.

Recommendation

To assure the continued adequate performance of inspectors, the Radiological Health Unit supervisory staff needs to commit to performing annual accompaniments of its inspectors.

2. Inspection Reports is a Category II Indicator.

Comment

The review of the compliance files revealed a limited number of deficiencies of types that could, under the proper circumstances, become significant. These included delays in getting the reports of inspections into the compliance files, poorly worded citations of observed violations, marginal or insufficient documentation to back up citations and the use of an inspection result notice form to cite violations in a case where a stronger, more formal notice of violation was indicated. It is noted that the Department staff plans to phase out the use of the form to cite violations.

Recommendation

The Department should focus greater attention on the quality of inspection reports. Considering current staffing levels, it may not be best to discontinue the use of the form entirely since letter type notices of violations are more time consuming to prepare. The Department may wish to consider revising it's inspection priority schedule which currently calls for substantially more frequent inspections than the NRC schedule in several categories.

NEW YORK STATE DEPARTMENT OF HEALTH
RADIATION CONTROL PROGRAM
SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE PERIOD OCTOBER 1990 TO SEPTEMBER 1992

Scope of Review

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs, Agreement State Program. The Department's program was reviewed against the 30 program indicators provided in the guidelines. The review included discussions with program management and staff, technical evaluation of selected permit and compliance files, the evaluation of the Department's responses to an NRC questionnaire that was sent to the State in preparation for the review, and field evaluations of Department inspectors.

This review is part of a comprehensive review of the New York Agreement State program. The Department of Health meeting was held during the period September 21-25, 1992 in Albany, New York. The Department was represented by Dr. Karim Rimawi, Director, and Rita Aldrich, Bureau of Environmental Radiation Protection. NRC was represented by John McGrath, Regional State Agreements Officer and Lloyd Bolling, State Programs. Field accompaniments of Department of Health inspectors were conducted on September 21-22, 1992 by Lloyd Bolling. A review of selected licensing and compliance actions was conducted by Messrs. McGrath and Bolling on September 23-24, 1992. A closeout meeting with William Staziuk, Director, Center for Environmental Health and Ronald Tramontano, Director, Division of Environmental Protection was held on September 25, 1992.

Status of Program Related to Previous NRC Findings

Comments and recommendations from NRC's previous review were sent to the State Energy Office in a letter dated March 7, 1991. The State responded to NRC on June 7, 1991. The Department has made progress in all of the areas, however, the Department's regulation remains to be formally adopted.

I. STATUS AND COMPATIBILITY OF REGULATIONS (Category I)

Comment

For regulations deemed to be a matter of compatibility by the NRC, State regulations should be amended as soon as practicable, but no later than three years. The effective date of the last amendment to the Department's regulations for maintaining compatibility was July 1979. In June 1990, however, the Department completed its third draft of Part 16 and is presently awaiting comments from it's legal office and the NRC. The revision addresses all of the regulatory changes adopted by the

NRC since 1974 that are applicable to the Department's program except the following:

"Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees" (10 CFR Parts 30, 40, and 70); April 7, 1993.

"Decommissioning" (10 CFR Parts 30, 40 and 70); July 27, 1991.

The Decommissioning Rule is not included in the draft revision because of the lack of formal guidance by the NRC on the contamination levels that are acceptable for release of a facility for unrestricted use. The Department contends that it would be premature to issue a Decommissioning Rule without these guidelines. The Radiological Emergency Rule is not included because the Department has no licensee to whom this rule applies. The Department is using a license condition to preclude broad scope licensees from exceeding possession limits which would require a contingency plan.

Recommendation

We encourage the Department to continue its efforts in revising Part 16. The Decommissioning Rule and the Radiological Emergency Plan must be included in the revision, however, in order to achieve compatibility with NRC regulations. We recommend that the Department include the Decommissioning Rule in its current Part 16 revision. We recommend that the Department amend its regulations by April 1993 to include the Radiological Emergency Rule. The Department should keep our Region I office informed of the status of the draft revision to Part 16.

State Response

The revision of Part 16 has been reviewed by the Division of Legal Affairs and is on its way back to us for minor changes. After the changes are made, it will be presented to the Public Health Council and published in the State Register for comment. We expect to have the revision in effect by the end of 1991.

To date, we have not received NRC's comments on the draft submitted to them in June 1990.

Current Status

The Department has prepared a revised draft (dated 1/10/92) based on comments which they have received so far. The Department published the draft regulations for public comment, responses were prepared, and the Public Health Council is expected to hold

a public meeting and approved the regulations sometime in November of this year. The 1/10/92 draft is currently in Headquarters for review.

Comment

The Department maintains monthly statistics on the licensing and inspection workload. As of September 1990, there were 146 licensing requests in-house awaiting initial review. Over two-thirds of these were applications for license renewal. Most were recent submittals, but several date back to 1985-86.

Recommendation

We recommend that 1) the management staff determine the cause(s) of the licensing backlog and 2) develop and implement a plan for reducing the backlog. Priority attention should be given to those applications which were submitted prior to 1988.

State Response

The license renewal backlog developed as a result of increasing complexity of licensing action and staffing shortages, which reflect difficulty in recruiting staff with a health physics background. The Department has instituted a trainee position in an effort to develop qualified staff and uses a combination of in-house training and attendance at NRC courses to accomplish this. Currently, both license reviewer positions are filled; one with a fully trained senior staff person and one with a trainee who will spend about four months in training this year.

The few remaining license renewal applications submitted prior to 1988 are either in the process of final review or have been renewed. Final action on the remaining 1988 applications for renewal is expected to be completed by the end of 1991, and a significant number of 1989 renewal applications are expected to be processed by that time also. With two fully trained staff in 1992, the backlog should be caught up by year's end.

However, we will continue to give priority to applications for amendment of licenses and new license applications, since delays here might cause hardship to both applicants and the public. We have managed to maintain a short turnaround time on these applications while sustaining a high standard of quality and will continue to do so.

Current Status

The backlog of licensing actions has been reduced to about 200. There are only 1 or 2 major renewals submitted prior to 1988

still under review. The licensing staff is now fully trained and should be able to contribute significantly to reducing the workload.

II. OFFICE EQUIPMENT AND SUPPORT SERVICES (Category II)

Comment

During our visits to field offices, it was noted that licenses, amendments and other correspondence in several files were missing or out of order. NRC guidelines indicate that the radiation control program should have adequate secretarial and clerical support. There is no secretarial or clerical support for the Department's radioactive material inspectors in the New Rochelle Office. All typing and filing are the responsibilities of the inspectors. A secretary is available to the staff in the Syracuse office, however, the inspectors are responsible for filing all correspondence. This shortage of clerical support is most reflective in the maintenance of the license files.

Recommendation

We recommend that the State review the relative allocation of technical and administrative resources to assure that field office files are adequately maintained while ensuring the most efficient and productive use of the Department's technical staff.

State Response

Clerical support for field offices is being addressed in several ways. New licenses issued by the central office are now being sent to the regions in folders ready for filing, and alphabetical lists of active licenses have been generated from our new computer database for each field office to assist them in determining whether their files are up-to-date. Clerical staff from the central office will also visit short-staffed offices periodically to assist in filing.

Current Status

The State's actions to address the clerical problems have been successful.

TECHNICAL QUALITY OF LICENSING ACTIONS (Category I)

Comment

The Radiation Control Program should assure that essential elements of applications have been submitted which meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures

sufficient to establish the basis for licensing actions. At the time of the review, the Department's licensing staff was not evaluating applicant's or licensee's radiation safety precautions for activities associated with the operation of incinerators, e.g., procedures for collecting, handling and disposing of ash residue; precautions used in performing maintenance or other work on incinerator components; the adequacy of the location and security of the storage area for combustible radioactive waste prior to incineration; the adequacy of the training of personnel loading waste into the incinerator, handling the ash, replacing filters, etc. This oversight appears to have been the result of the Department's belief that these areas were initially evaluated by the State Department of Environmental Conservation (DEC) since incineration is prohibited without a permit from DEC. Departmental inspectors, however, conduct a comprehensive evaluation of a licensee's program for use of radioactive materials, including those activities associated with incinerator operations.

Since the review, the Department has developed draft guidelines for licensing of activities associated with incinerator operations. These guidelines are based on NRC Policy and Guidance Directive 84-21. The Department has requested DEC to review the guidelines.

Recommendation

We recommend that the Department evaluate an applicant or licensee's (if renewal application is submitted) radiation safety precautions associated with the operation of an incinerator. We encourage the use of licensing guidelines similar to those (currently in draft) developed by the Department.

State Response

The Department does not agree that we have neglected to evaluate applicants' or licensees' radiation safety programs for incineration of radioactive materials. Incinerator permits are only held by our large licensees who conduct complex programs. Review of their applications always includes a detailed review of procedures for handling unsealed sources of radioactive material; training to be given to all licensee staff; waste storage, handling, processing and monitoring for radiation levels; and radioactive contamination. Enclosed is a 1987 memorandum sent to our Rochester Field Office and copied to our other field offices, which points out some aspects of incinerator programs to be reviewed during inspection. It concludes with a statement that the safety considerations for waste handling and incineration are the same as those for handling any unsealed sources of radioactive material.

It appears that since the word "incinerator" was not specifically included in applicants' and licensees' procedures, that NRC assumes commitments made for radiation safety in handling unsealed radioactive materials do not apply to incineration.

We also note that NRC staff who reviewed our licensing and inspection files found no instances where the alleged failure to evaluate "radiation safety precautions for activities associated with the operation of incinerators" resulted in the finding of deficient procedures relating to incinerator operations at the time of inspection. Since the reviewers also found that inspectors conduct a comprehensive evaluation of licensees' programs, including incinerator operations, any such deficiencies would have been noted. Given these observations by the NRC staff who reviewed the Department's program there appears to be no factual support for NRC's repeated assertions in the March 7, 1990 letter that there is a "regulatory gap" in this area.

However, following NRC's review of our program we did prepare draft guidelines for information to be submitted by licensees specifically for incineration. These were sent to DEC for comment on October 23, 1990 and a copy was provided to NRC at the November 1990 All Agreement States Meeting.

The Department's guidelines were finalized in December 1990 and sent to each licensee holding a permit for incineration in January 1991. A copy of the finalized guidelines and the cover letter requiring licensees to submit procedures in responses are currently under review.

The March 7, 1991 letter states that NRC is still reviewing the guidelines and intends to provide comments. Comments would, of course, be welcome and will be kept on file for future revisions.

Current Status

The Bureau has developed and is using a licensing guide for incinerators. The guide was reviewed by Region I and no suggestions for improvement were made. We believe that this issue is now closed.

STATUS OF INSPECTION PROGRAM (Category I)

Comment

The Radiation Control Program should maintain an inspection program adequate to assess licensee compliance with regulations and license condition. As of October 1990, the Department had 58 overdue inspections of Priority I, II, and III licensees. Eight of these were overdue by more than 50% of their inspection frequency. This is a comment of minor significance because the

Department has developed a plan for alleviating this backlog by the end of the year.

Recommendation

We recommend that the Department implement its inspection plan for eliminating the inspection backlog by the end of 1990. Priority attention should be given to Priority I licensees and to those which are overdue by more than 50% of their inspection frequency.

State Response

NRC's March 7, 1991 letter states that at the time of the October 1990 review the Department had 58 overdue inspections, and that 8 of these were overdue by more than 50% of their inspection interval.

Actually, at the time of the review there were 27 overdue inspections, and 8 of these were overdue by more than 50% of the inspection interval, It appears that the list of inspections that were found to be overdue during our 1988 NRC review (58) were inadvertently used in preparing this letter. (We note that NRC found that our inspection program satisfied NRC guidelines following the 1988 review, but found that we had a "significant backlog" during this review even though there were half the number of overdue inspections.)

Most of the 27 overdue inspections were in the Albany region and resulted from the loss of a trained Radiological Health Specialist from that field office. Budget constraints made it impossible to fill the vacated item, and we have subsequently lost another Associate Radiological Health Specialist from our New Rochelle field office. However, the Department developed a plan to accomplish overdue inspections while rotating Specialists to prevent the same person from consecutively inspecting the same facility, and at the same time providing opportunities for trainees to accompany experienced Specialists on inspections. Accomplishing these multiple goals within existing resources necessitated a plan that allows some inspections to become further overdue. However, by the end of 1990 all overdue inspections had been performed according to plan.

Current Status

Notwithstanding the loss of two positions in the New Rochelle office, the staff from other regions have contributed to the effort in the New Rochelle region and have kept up with the inspection workload. There is currently no significant backlog in the inspection area.

Current Review Comments and Recommendations

All 30 program indicators were reviewed and the Bureau fully satisfies 24 of these indicators. Specific comments and recommendations for the remaining 5 indicators are as follows:

I. LEGISLATION AND REGULATIONS

Status and Compatibility of Regulations is a Category I indicator.

Comment

The Department's radiation control regulations were last amended in July 1979. However, the Department recently completed a draft revision of Part 16 which addresses all of the regulatory changes adopted by the NRC since 1974 that are applicable to the Department's program including the decommissioning rule. The most recent draft (dated 1/10/92) was published for public comment, responses were prepared, and the Public Health Council is expected to hold a public meeting and approve the regulations sometime in November of this year.

Recommendation

We encourage the Department to continue its efforts in revising Part 16. We recommend that the Department include the Decommissioning Rule in its current Part 16 revision. The Department should keep our Region I office informed of the status of the draft revision to Part 16.

II. ORGANIZATION

Internal Organization is a Category II indicator.

Comment

At the current time, there is one individual assigned in the southeast region of the State. Because of the inspection workload in that region, staff from other regions of the State have been conducting inspections in that area. This has involved quite a bit of travel.

Recommendation

In order to best utilize staff resources, it may be appropriate to reorganize the staff to provide more effective coverage for the southeast region.

VI. COMPLIANCE

1. Enforcement Procedures is a Category I indicator.

Comment

During our review of compliance actions, one case was noted where enforcement action was held up for a significant period of time. Other cases were noted where licensees' responses were not evident many months after the enforcement letter. In many cases, responses to enforcement letters were not in the Albany files. It was assumed by the State staff that the responses were in the regional files, and in some cases this was verified.

Recommendation

It appears that a more effective tickler system should be implemented so that the staff is aware of cases where licensees have not responded to compliance letters in a timely fashion. A revised form for use by regional staff has been drafted and we recommend that this be implemented as soon as possible. In addition, it is important that the Albany files be maintained in an up-to-date condition.

2. Inspection Reports is a Category II indicator.

Comment

In one enforcement case, the lack of complete information in the file was a significant deficiency. In a memorandum, the inspector indicated that a named individual had instructed a second individual to alter an important record. The Bureau staff indicated that this was later found to be incorrect. There was nothing in the file, however, to establish this. The compliance supervisor was able to produce a handwritten note which addressed the deficiency, but the fact that the "official" record was not accurate is significant.

Recommendation

In addition to the need to assure that up-to-date information is in the files, the Bureau needs to assure that statements that could be considered defamatory are, if not true, stricken from the official record of a licensee.

Summary Discussion with State Representatives

A summary meeting to present the results of the regulatory program review was held with William Staziuk, Director, Center

for Environmental Health and Ronald Tramontano, Director, Division of Environmental Protection on September 25, 1992. Dr. Karim Rimawi and Rita Aldrich were also present. The NRC representatives indicated that the Department had made progress in several areas since the previous review, particularly with regard to the elimination of the inspection backlog. However, the NRC staff indicated that the Department still needs to finalize the revisions to the regulations before the NRC can offer a finding of compatibility.