

NEW YORK STATE OFFICE OF THE STATE COMPTROLLER

**H. Carl McCall
STATE COMPTROLLER**



**NEW YORK CITY DEPARTMENT OF HEALTH
AND MENTAL HYGIENE**

INSPECTION OF RADIOLOGICAL EQUIPMENT

2001-N-9

**DIVISION OF MANAGEMENT AUDIT AND
STATE FINANCIAL SERVICES**

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Report 2001-N-9

Thomas R. Frieden, M.D., M.P.H.
Commissioner
New York City Department of Health and Mental Hygiene
125 Worth Street
New York, New York 10013

Dear Dr. Frieden:

The following is our audit report addressing the practices used by the New York City Department of Health and Mental Hygiene in performing inspections of radiological equipment.

This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution; Article II, Section 8 of the State Finance Law; and Article III of the General Municipal Law. Major contributors to this report are listed in Appendix A.

*Office of the State Comptroller
Division of Management Audit
and State Financial Services*

November 20, 2002

EXECUTIVE SUMMARY

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

INSPECTION OF RADIOLOGICAL EQUIPMENT

SCOPE OF AUDIT

The New York City Department of Health and Mental Hygiene (DOHMH) registers and inspects facilities (hospitals, clinics, physicians' offices) that use radiological equipment such as x-ray units. The regulated facilities are to be inspected when they begin operation and periodically thereafter. The purpose of the inspections is to ensure that equipment operators are qualified and equipment is maintained in good operating condition so that patients and operators are protected against the hazards of radiation. The frequency of inspection ranges from annually to every five years, depending on the type of facility. In the year ended June 30, 2001, about 6,600 facilities were registered by DOHMH to use more than 15,000 radiological machines.

Our audit addressed the following questions about DOHMH inspections of radiological equipment for the period July 1, 1999 through December 31, 2001:

- Were the inspections timely, and were they adequately tracked by an information system?
- Were complaints and inspection violations addressed in an appropriate manner?
- Did inspections of hospitals include as many machines as required?
- Were facility quality assurance programs assessed by DOHMH?

AUDIT OBSERVATIONS AND CONCLUSIONS

We identified a number of serious weaknesses in DOHMH's radiological equipment inspection process. Consequently, patients and equipment operators face increased health risks from exposure to radiation.

While facilities using radiological equipment are to be inspected by DOHMH when they begin operation, about half the facilities in our population of newly registered facilities (35 of 71) were not inspected within their first four months of operation, and some were not inspected for as long as 14 months. We also found that the subsequent cyclical inspections were not always performed at the required intervals, and in some instances were 2.8 years behind schedule. Additionally, enhancements are needed in the information system used by DOHMH to track inspections. (See pp. 5-8)

When violations are found during an inspection, DOHMH is required by law to re-inspect the equipment or take other appropriate follow-up action within 60 days. However, we found that re-inspections were often delayed for several months, and in some instances, were delayed for more than two years. In addition, even though several re-inspections determined that the previous violations had not been corrected, there was no indication that further action was taken by DOHMH in any of these instances. (See pp. 8-9)

According to DOHMH policy, a certain portion of a hospital's radiological equipment is to be examined during an inspection. However, we found that the number of machines examined during inspections is sometimes lower than required and, contrary to DOHMH policy, the size of the sample is not expanded when violations are found. We also determined that some of the most frequently used radiological machines in hospitals may never be examined during inspections. (See pp. 10-12)

Many facilities were required by a 1993 amendment to the State Sanitary Code to implement a comprehensive quality assurance program for their radiological equipment. However, we found little evidence that DOHMH inspectors are reviewing these facilities' quality assurance programs to determine whether they comply with requirements. Improvements are also needed in DOHMH's complaint resolution process, as there were a number of instances in which DOHMH did not respond effectively or promptly to complaints about radiological equipment or equipment operators. (See pp. 15-17)

We made 12 recommendations to improve the practices used by DOHMH in performing inspections of radiological equipment.

Comments of Officials

DOHMH officials agree with some of the findings in the report and most of the recommendations. However, DOHMH officials do not agree that deficiencies in the processes for inspecting radiological equipment present a risk to the public. A complete copy of the Department's response is included as Appendix B. Appendix C contains State Comptroller's Notes, which address matters of disagreement included in the Department's response.

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INTRODUCTION

Background

The New York City Department of Health and Mental Hygiene (DOHMH) is required by the New York State Sanitary Code (State Sanitary Code) and the New York City Health Code (City Health Code) to regulate the operation of radiological (i.e., radiation-producing) equipment in New York City. The equipment subject to regulation includes diagnostic, fluoroscopic and x-ray units. DOHMH also regulates mammographic equipment through a contract with the U. S. Food and Drug Administration (FDA). The purpose of the regulation provided by DOHMH is to protect patients and equipment operators against the hazards that can result from exposure to radiation. DOHMH registers, licenses and inspects the facilities that possess and use radiological equipment in New York City, including hospitals, medical centers, clinics, physicians' offices, dental offices and veterinary offices. Except for dental, podiatrist and veterinary offices, these facilities are also subject to additional regulation, as they are required by the State Sanitary Code to maintain a quality assurance program for their radiological equipment.

According to DOHMH, as of June 30, 2001, there were about 6,600 registered facilities in New York City containing more than 15,000 radiological equipment items. During the fiscal years ended June 30, 2000 and June 30, 2001, DOHMH reportedly inspected 1,500 and 1,897 of these items, respectively. These inspections were conducted by DOHMH's Bureau of Radiological Health, which deployed nine inspectors and two inspection supervisors (who also performed inspections) at the time of our audit. The purpose of the inspections is to ensure that the equipment is maintained in good operating condition and operators are qualified to use the equipment in a safe manner. Information relating to the inspections performed by DOHMH and the certificates issued by DOHMH is maintained on the Consumer Affairs Management Information System (CAMIS), which is a Citywide record keeping system used by various New York City agencies.

Article 175 of the City Health Code requires that facilities with radiological equipment be inspected when the facilities begin operations and periodically thereafter. According to DOHMH guidelines adopted in 1996, inspections after the initial inspection should be conducted cyclically in accordance with the following schedule: a sample of the equipment in hospitals and all equipment in radiologists' offices must be inspected every two years; all equipment in doctors', veterinarians' and chiropractors' offices must be inspected every three years; and all equipment in dentists' and podiatrists' offices must be inspected every five years. In addition, according to DOHMH's contract with the FDA, mammography facilities must be inspected annually. If an equipment item fails an inspection, the City Health Code requires that the item be re-inspected within 60 days to ensure that all violations have been corrected.

Audit Scope, Objectives and Methodology

We audited selected practices relating to DOHMH's inspections of radiological equipment for the period July 1, 1999 through December 31, 2001. The primary objectives of our performance audit were to determine whether DOHMH (1) has a system for identifying facilities that need to be inspected; (2) performs inspections in a timely manner; (3) addresses inspection violations and complaints about radiological equipment in an appropriate manner; (4) selects samples of hospital equipment for inspection in an appropriate manner; (5) assesses the adequacy of facility quality assurance programs; and (6) has an effective system for tracking inspections and inspection results. To accomplish our objectives, we interviewed DOHMH officials, reviewed DOHMH records, and analyzed information in the CAMIS database. Our audit focused on the two fiscal years ended June 30, 2001, but included certain actions taken by DOHMH through December 31, 2001.

As is our practice, at the outset of the audit we requested a representation letter from DOHMH management. The representation letter is intended to confirm oral representations made to the auditors and to reduce the likelihood of misunderstandings. Agency officials normally use the representation letter to assert that, to the best of their knowledge, all relevant financial and programmatic records and related data have been provided to the auditors. They affirm either that the agency has complied with all laws, rules, and

regulations applicable to their agency's operations that would have a significant effect on the operating practices being audited, or that any exceptions have been disclosed to the auditors.

However, officials of the Mayor's Office of Operations have informed us that, as a matter of policy, Mayoral agency officials do not provide representation letters in connection with our audits. As a result, we lack assurance from DOHMH officials that all relevant information was provided to us during this audit. We consider this refusal to provide a representation letter to be a limitation on the scope of our audit. Therefore, readers of this report should consider the potential effect of this scope limitation on the findings and conclusions presented in the report.

Except as discussed in the preceding paragraphs, we conducted our audit in accordance with generally accepted governmental auditing standards. Such standards require that we plan and perform our audit to adequately assess those procedures and operations of DOHMH that were included within our audit scope. Further, these standards require that we understand DOHMH's internal control structure and its compliance with those laws, rules and regulations that are relevant to the operations included in our audit scope. An audit includes examining, on a test basis, evidence that supports transactions recorded in the accounting and operating records and applying such other auditing procedures as we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments and decisions made by management. We believe our audit provides a reasonable basis for our findings, conclusions and recommendations.

We use a risk-based approach when selecting activities to be audited. This approach focuses our audit efforts on those operations identified through our preliminary survey as having the greatest probability for needing improvement. Consequently, by design, we use finite audit resources to identify where and how improvements can be made. Thus, we devote little audit effort to reviewing operations that may be relatively efficient or effective. As a result, our audit reports are prepared on an "exception basis." This report, therefore, highlights those areas needing improvement and does not address activities that may be functioning properly.

Response of DOHMH Officials to Audit

Draft copies of this report were provided to DOHMH officials for their review and comment. Their comments were considered in preparing this report and are included as Appendix B. Appendix C contains State Comptroller's Notes, which address matters of disagreement contained in the Department's comments.

Within 90 days after final release of this report, we request that the Commissioner of the New York City Department of Health and Mental Hygiene report to the State Comptroller, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.

INSPECTION OF RADIOLOGICAL EQUIPMENT

We found that significant improvements are needed in various aspects of the radiological equipment inspection process. For example, initial inspections may not be performed until months after facilities have begun operations, cyclical inspections may not be performed as frequently as required, and re-inspections to determine whether violations have been corrected often are not performed within the 60 days required by law. We also found that appropriate action is not taken when re-inspections determine that serious violations have not been corrected.

We further determined that hospitals are not always inspected as thoroughly as required, as the number of equipment items selected for inspection is sometimes lower than required and the size of the sample is not expanded when violations are found. We also determined that some of the radiological equipment in hospitals might never be selected for inspection. As a result of the various weaknesses in the inspection process, patients and equipment operators face increased health risks from exposure to radiation.

Initial Inspections

A facility seeking to operate radiological equipment in New York City must apply to DOHMH for a certificate to do so. If the application is approved, a certificate is issued and the facility is registered by DOHMH. At this point, the equipment can be used by the facility. DOHMH is then required by the City Health Code to perform an initial inspection of the equipment (neither the City Health Code nor the DOHMH guidelines specify a timeframe for this inspection; the City Health Code simply states that the inspection should be performed “at the time a facility begins operations”). To identify the facilities that require an initial inspection, DOHMH inspection supervisors rely on the license application forms that have been approved by DOHMH.

To evaluate the adequacy of DOHMH’s process for scheduling initial inspections, we selected facilities that were recently registered by DOHMH. To select the facilities, we reviewed

DOHMH's CAMIS database as of June 30, 2001. Facilities are entered on the CAMIS when they are registered by DOHMH, and while the CAMIS does not indicate the registration date (deficiencies in the CAMIS are addressed in the section of this report entitled *Management and Performance Information*), it does indicate the date each facility was last inspected. Therefore, to identify facilities that were likely to be newly registered, we looked for facilities that lacked an inspection date. We identified 86 such facilities, and when we showed a list of these facilities to DOHMH officials, they confirmed that all 86 facilities were newly registered. To identify the registration date for these facilities, we asked DOHMH officials to provide us with the case folders for the facilities.

DOHMH officials told us they could not locate the case folders for 8 of the 86 facilities. When we examined the 78 folders that were located, we found that the registration date was indicated in 71 of these folders. We also determined that an initial inspection had been performed at many of the facilities, but the date of the inspection had yet to be entered on the CAMIS. We noted the dates these inspections were performed, and evaluated the timeliness of the initial inspection for the 71 facilities with registration dates. We found that, generally, the initial inspection was not performed in a timely manner for these 71 facilities, as follows:

- 16 case folders contained no evidence indicating that an initial inspection had been performed. At the time of our review, all 16 facilities had been registered for at least six months, and one facility had been registered for 14 months.
- 55 case folders showed that an initial inspection had been performed. These inspections were performed between 6 and 337 days after the facilities were registered, and on average, were performed 100 days after the facilities were registered. As is summarized in the following table, 39 of the 55 initial inspections were performed more than 60 days after the facilities were registered:

<i>Interval Between Registration and Initial Inspection</i>	
Range of Days	Number of Facilities
0 to 60	16
61 to 90	10
91 to 120	10
More than 120	19

When new facilities are inspected promptly, hazardous operating conditions can be identified and corrected before patients or equipment operators are exposed to unsafe amounts of radiation. However, when these inspections are delayed, unsafe conditions may persist and increase the risk of unhealthy radiation exposure. For example, if equipment is not properly calibrated, patients or equipment operators may be exposed to unnecessarily high doses of radiation. We note that, in 27 of the 55 initial inspections that were performed for our sample of newly registered facilities, the DOHMH inspector identified violations that could have created health risks if they were not corrected. After one of the inspections, DOHMH sealed the facility's equipment because the x-ray unit was defective and dangerous; after another inspection, DOHMH ordered the facility to cease operating the equipment, because it was too hazardous to use.

We therefore conclude that improvements are needed in the process used by DOHMH to schedule facilities for initial inspections. As is discussed in more detail in the section of this report entitled *Management and Performance Information*, we recommend that a formal tracking system be developed for this purpose, and facilities be included on the system from their day of registration. If a facility has been registered for a certain number of days, but still has not been inspected, it should be highlighted by the system. The system could also be used to schedule the subsequent cyclical inspections for the facility. We also recommend that DOHMH amend its guidelines to specify when initial inspections should be performed (e.g., before a facility opens or within a certain number of days of opening).

Cyclical Inspections

After the initial inspection, a facility should be inspected annually, every two years, every three years or every five years, depending on the type of facility. The date each facility

was last inspected by DOHMH is recorded on the CAMIS. To determine whether any facility was overdue for its next cyclical inspection, we analyzed the inspection dates recorded on the CAMIS. We found that, as of June 30, 2001, a total of 121 of the 6,584 facilities (1.8 percent) included on the CAMIS were overdue for their cyclical inspection, as follows:

- 17 of the 121 facilities (14 percent) requiring inspection every two years (hospitals and radiologists' offices) were overdue by as much as eight months.
- 21 facilities requiring inspection every three years (doctors', veterinarians' and chiropractors' offices) were overdue by as much as eight months.
- 83 facilities requiring inspection every five years (dentists' and podiatrists' offices) were overdue by as much as 2.8 years.

We therefore conclude that improvements are needed in the timeliness of DOHMH's cyclical inspections.

Re-Inspections

When violations are found during an inspection, DOHMH is required by the City Health Code to re-inspect the equipment or take other appropriate follow-up action within 60 days to ensure correction of any violations found. Violations are classified by DOHMH as either Category 1, Category 2 or Category 3. Category 1 violations are the most severe kind of violations, representing deficiencies in compliance with the NYC Health Code that warrant immediate action to obtain compliance. A facility with a Category 1 violation is issued a summons for the head of the facility to appear before a tribunal judge. The judge can impose penalties, including an order to close the facility. Category 2 and 3 violations are less severe.

DOHMH maintains a log for Category 1 violations. We reviewed this log to select all the facilities that had Category 1 violations during the two years ended June 30, 2001. We selected a total of 181 facilities. We reviewed the case folders for these 181 facilities to determine whether appropriate follow-up action had been taken by DOHMH in response to the violations. We found that, as of December 19, 2001, appropriate follow-up action had not been taken at many of the 181 facilities, as follows:

- There was no evidence that 12 of the 181 facilities (7 percent) had been re-inspected to determine whether the hazardous conditions were corrected. As of December 19, 2001, it had been at least 8 months (257 days) and as long as 28 months (863 days) since hazardous conditions had been identified at the 12 facilities.
- For 20 facilities that had been re-inspected, there was no evidence that the facilities had corrected the conditions that caused the Category 1 violations. Moreover, there was no evidence in the case files demonstrating that DOHMH had taken action (such as summoning the head of the facility to appear before a tribunal council) against any of the 20 facilities. As of December 19, 2001, it had been at least 173 days and as long as 897 days (almost 2½ years) since DOHMH's inspections cited the Category 1 violations that had not been corrected, and an average of 537 days had elapsed since the re-inspections.
- Contrary to the City Health Code, 55 of the re-inspections were performed more than 60 days after the original inspection. These 55 re-inspections were performed up to 161 days after the original inspection, and on average, were performed 92 days (almost three months) after the original inspection.
- Of 23 facilities that received Category 1 violations for lack of registration or registration renewal, 9 were still not registered or renewed as of July 11, 2002, yet DOHMH had not re-inspected these facilities as required.

We conclude that improvements are urgently needed in DOHMH's re-inspection process. Too many re-inspections are performed far too long after the hazardous conditions were first identified, and violators are not penalized if DOHMH discovers that they have failed to correct these hazardous conditions. If appropriate action is not taken in response to serious violations identified during the inspection process, the regulatory process is undermined and the safety of the public is jeopardized.

Hospital Inspections

The radiological equipment at hospitals must be inspected every two years. According to DOHMH officials, hospitals are inspected more frequently than other types of facilities, because they have more radiological equipment and treat more patients than other types of facilities. However, we found that hospitals often are not inspected as thoroughly as required by DOHMH policy, and some of the radiological equipment at some hospitals may never be inspected. As a result of these weaknesses in DOHMH's inspection process, patients and equipment operators at New York City hospitals are not fully protected against radiation hazards.

Since hospitals often have many radiological machines, DOHMH does not examine all of a hospital's machines during each inspection. Rather, according to DOHMH policy, the number of radiological machines to be examined during an inspection depends on the total number of radiological machines in operation at the hospital, as follows:

Total Number of Machines in Operation	Number of Machines To Be Inspected
1 – 20	4
21 – 30	5
31 – 40	7
41 – 50	9
51 – 60	11
61 – 70	13
71 – 80	15
81 – 90	17
91 – 100	19
More Than 100	20

A total of 88 hospitals are inspected by DOHMH. We reviewed the case folders for these hospitals to determine how many radiological machines were in operation at each hospital and how many were examined in the most recent DOHMH inspection of the hospital. Since 18 of the case folders did not contain information about the number of machines in operation at the hospital and another 17 folders did not contain the most recent inspection report, we excluded those 35 hospitals from our review.

For the remaining 53 hospitals, we compared the number of machines examined during the last inspection to the number that should have been examined according to DOHMH policy. As is shown in the following table, the required number of machines was not examined at 18 of the 53 hospitals (34 percent):

Size of Hospital	Number of Machines in Operation	Hospitals Reviewed		Machines Inspected at The 18 Hospitals	
		In Total	Required Number of Machines Not Examined	Required Number	Actually Inspected
Large	More than 40	17	10	141	117
Medium	21 – 40	13	3	21	15
Small	1 – 20	23	5	20	13
Total		53	18	182	145

As is shown by the table, a total of at least 182 radiological machines should have been inspected at these 18 hospitals, but only 145 machines were actually inspected, a difference of 37 machines.

In addition, according to DOHMH policy, if an inspector finds two or more Category 1 violations during an inspection of a hospital, the inspector is required to examine additional machines at that hospital. However, this additional work was not done for four the hospitals we reviewed; even though DOHMH inspectors found two or more Category 1 violations at these hospitals. There was no evidence in the case folders documenting that the inspectors examined additional machines at these hospitals.

When performing hospital inspections, DOHMH inspectors are to select a sample of radiological machines for examination. While DOHMH policy indicates how many machines should be selected for examination, it does not indicate the method that should be used in making the selections (e.g., random, systematic, judgmental). DOHMH officials told us that inspectors should first obtain a list of radiological machines from the hospital and then select a random sample from the list.

However, the officials also told us this is not done; rather, the inspectors use their judgment to select a sample from the machines made available to them at the time of their visit. If a machine is being used while the inspector is at the hospital, it is considered unavailable for inspection.

As a result of this practice, some of the radiological machines used most frequently may never be selected for inspection, particularly the x-ray machines in special procedures rooms, cardiac catherization rooms and operating rooms. DOHMH officials acknowledged that their inspectors have not been getting into these rooms during inspections because the equipment is generally being used. We believe this gap in DOHMH's inspection coverage exposes patients and equipment operators to serious risk; for example, if a fluoroscopic unit is not properly maintained, it emits excessive radiation that could result in both internal and external burns to the patient. We therefore recommend that a sampling methodology be developed that will give all the machines in a hospital a reasonable chance of being selected for inspection over a period of time.

We further determined that some of the radiological machines in hospitals (and other facilities) may never be inspected because DOHMH may never learn of their existence. DOHMH has no other process for identifying such machines. We therefore recommend that DOHMH develop processes for identifying such machines. For example, DOHMH could periodically compare the list of machines provided by the hospital to the machines actually in use at the hospital. Further, DOHMH could search facility listings (such as the yellow pages or trade publications) to identify unregistered facilities.

Recommendations

1. Amend the DOHMH guidelines to specify a timeframe for initial inspections, and perform initial inspections within this timeframe.
2. Perform cyclical inspections and re-inspections within the timeframes prescribed by the DOHMH guidelines.

Recommendations (Cont'd)

3. Take appropriate action when re-inspections determine that the conditions causing Category 1 violations have not been corrected.
4. During inspections of hospitals, examine the number of radiological machines required by DOHMH policies, and adhere to the policy that requires the sample size to be increased when violations are found.
5. Develop a sampling methodology that gives all the radiological equipment in a hospital a reasonable chance of inspectors to use this methodology, and monitor the inspectors to ensure that the methodology is used.
6. Develop processes for identifying radiological machines that have not been inspected.
7. Improve record keeping practices so that facility case folders are complete and can be located.

MANAGEMENT OF THE INSPECTION PROCESS

D OH reduced its inspection coverage when facilities were required to implement an internal quality assurance program for their radiological equipment. However, we found that DOHMH may not be adequately monitoring the effectiveness of these quality assurance programs. If the programs are not implemented as required or are not as effective as intended, the reduction in inspection coverage may not be justifiable. We also found that DOHMH could respond more effectively and more promptly to complaints about radiological equipment and equipment operators, and could make a number of improvements in the information system used to manage the inspection process.

Mandated Facility Quality Assurance Program

The DOHMH guidelines adopted in 1996 extended the inspection cycles for facilities with radiological equipment. Prior to these guidelines, which became effective January 1, 1996, hospitals and radiologists had to be inspected annually; dentists, podiatrists and veterinarians had to be inspected every three years; and all other facilities or offices had to be inspected every two years. In 1995, the last year the old inspection cycle was in effect, about 3,000 facilities were inspected by DOHMH. In 1996, the first year the new inspection cycle was in effect, about half as many facilities (1,500) were inspected.

Officials at the New York State Department of Health, the agency which extended the inspection cycle in New York City, told us that the cycle could be extended without jeopardizing public health because the larger facilities in New York State are now required to perform their own inspections as part of a comprehensive quality assurance program mandated by a 1993 amendment to the State Sanitary Code. We reviewed the amendment and determined that, as part of this quality assurance program, facilities are required to employ a qualified expert, such as a physicist, to perform periodic tests of the radiological equipment used by the facility. The facilities are required to maintain reports of the test results to show that they have complied with the inspection requirement, and DOHMH

inspectors are required to review these reports as part of the facility inspection. According to DOHMH officials, the checklist used by DOHMH inspectors during an inspection addresses certain aspects of these expert reports.

To determine whether DOHMH was reviewing facility quality assurance programs as required, we examined the case folders for all 88 hospitals and for a random sample of 25 of the 190 radiologist offices performing mammographies as of June 30, 2001. We found that, even though all 113 facilities are required to test their radiological equipment as part of the mandated quality assurance program, only 2 of the 113 folders contained evidence that DOHMH inspectors had reviewed these tests (these two folders contained copies of the facilities' expert quality assurance reports). In the absence of documentation indicating that facility quality assurance programs have been reviewed by DOHMH inspectors, DOHMH officials cannot be reasonably assured that the programs have in fact been reviewed. To provide greater assurance that the programs are reviewed by DOHMH inspectors, we recommend that the facilities be required to submit their expert quality assurance reports to DOHMH.

If facility quality assurance programs are not implemented as required or are not as effective as intended, public health could be jeopardized. We note there are indications that the programs may not be as effective as intended, as a total of 234 Category 1 violations, at 181 different facilities, were cited by DOHMH inspectors during the two years ended June 30, 2001. These violations included equipment that was in poor repair and maintenance as well as equipment operators who were unqualified. In addition, several of the mammography units inspected by DOHMH had problems that could compromise the quality of the x-ray images produced by the units. Such problems could result in incorrect diagnoses of the patients served by the units. If the quality assurance programs have not been as effective as intended at ensuring high-quality imaging or in minimizing radiation hazards, DOHMH's extension of its inspection cycles may not have been in the public interest. Accordingly, we recommend that DOHMH evaluate the effectiveness of the quality assurance programs in New York City and, on the basis of this evaluation, determine whether City facilities should be inspected more frequently.

Response to Complaints

According to DOHMH policy, complaints about radiological equipment or equipment operators should be addressed as soon as they are received. In addition, both the complaint and the action taken to address the complaint should be recorded on a standard form (a complaint sheet). According to the complaint sheets on file for the two years ended June 30, 2001, DOHMH received a total of 39 complaints during this period. However, DOHMH does not maintain a log to record complaints when they are received. As a result, DOHMH management has less assurance that all complaints have been accounted for. To increase this assurance and to enhance management's control over the complaint resolution process, we recommend that such a log be maintained.

To determine whether DOHMH responded to complaints in a timely manner, and whether the responses effectively addressed the issues identified in the complaints, we reviewed all 39 complaint sheets on file for the two years ended June 30, 2001. We determined that DOHMH responded to the complaints between 1 and 35 days after they were received, and an average of 12.8 days after they were received. Since it took nearly two weeks, on average, for DOHMH to respond to the complaints, we conclude that improvements are needed in the timeliness of the process.

We also found that DOHMH's response to six of the complaints did not effectively address the issues identified in the complaints. For example, one complaint questioned the qualifications of a technician performing a mammography examination. In response to this complaint, the DOHMH inspector determined that the technician whose qualifications were questioned was licensed as a radiology technologist. However, according to the Federal Mammography Quality Standard Act, licensed technologists must meet additional requirements to take mammographies, and the inspector did not determine whether the technologist met these additional requirements.

If complaints are not promptly and effectively resolved, patients and equipment operators may be exposed to radiation hazards. We recommend that improvements be made in DOHMH's complaint resolution process.

Management and Performance Information

The CAMIS database lists only the most recent DOHMH inspection of each facility. Neither the CAMIS nor any other information system maintained by DOHMH provides information about all the inspections performed at a facility. As a result, DOHMH managers cannot readily assess a facility's inspection history. While past inspection reports may be maintained in a facility's case folder, case folders are not always available for review (as was previously noted in this report). The New York State Department of Health issued a report in 2000 in which it was noted that DOHMH does not fully utilize the CAMIS. We recommend that the CAMIS be enhanced, or an alternative information system be developed, to provide a comprehensive history of facility inspection results.

We also note that DOHMH does not track inspection violations, and more generally, does not summarize and maintain a database of inspection findings. If violations were maintained on an automated information system, it would be easier for DOHMH to ensure that re-inspections were performed within 60 days and appropriate action was taken when serious violations were not corrected. A comprehensive database of inspection findings could help managers analyze overall conditions and identify recurrent problems that need to be addressed. This database could include:

- The date each facility was registered
- The number and type of radiation equipment at each facility
- The date each equipment item was inspected
- The inspection findings reported by inspectors
- The number and subjects of complaints received against facilities
- The number and types of violations issued against each facility

As is discussed earlier in this report, such a comprehensive database could also be used to schedule inspections. We recommend that either the CAMIS be enhanced to accommodate this data or an alternative system be developed.

Recommendations

8. Review facility quality assurance programs as required during inspections, and document this review in facility case folders.
9. Require all facilities with mandated quality assurance programs to submit their expert quality assurance reports to DOHMH.
10. Evaluate the effectiveness of the facility quality assurance programs and, on the basis of this evaluation, determine whether facilities should be inspected more frequently.
11. Maintain a log of the complaints received about radiological equipment or equipment operators, and respond promptly to the issues identified in the complaints.
12. Enhance the CAMIS or develop an alternative database system to provide a comprehensive history of facility inspection results and related inspection information. Track facilities on this system from their day of registration, and use the system to schedule inspections for facilities.

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THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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September 23, 2002

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Audit Director
Office of the State Comptroller
110 State Street
Albany, New York 12236

Subject: Draft Audit Report on Inspection of Radiological Equipment; Report No. 2001-N-9

Dear Mr. McClune:

We have reviewed the draft audit report and appreciate your consideration of our comments on the findings and recommendations.

The Department does not agree with the major conclusions and implications of this report: that certain deficiencies noted present a risk to the public. The executive summary of the report, for instance, states that "patients and operators face increased health risks from exposure to radiation," as a result of the "weaknesses" in the Department's inspection process. The audit report cannot support such a statement. The history of the Department's Radiological Equipment Inspection Program, as well as separate audits conducted by the New York State Department of Health, confirm that the Department is effective in minimizing the risk of injury to the public from malfunctioning or misused radiological equipment.

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Note 1

While the Department agrees with some of the findings in the draft report, many of the issues raised by the audit team appear to result from a lack of technical understanding or mistaken assumptions. For instance, many comments about risk appear to reflect an unfamiliarity with the many redundant levels of protection in the radiological equipment oversight system. The auditors also mistakenly concluded that a "Category 1" violation issued by the Department always indicated the presence of a serious health risk to the public. As our detailed response makes clear, this is inaccurate.

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Note 1

The auditors allege that there is no evidence that we review operator quality assurance reports. In fact, our inspection reports include extensive documentation of our detailed review of these reports. This conclusion is inconsistent with a scrutiny of our files.

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Note 2

While our current method of scheduling initial inspections does not represent a risk, the auditors have identified several areas that the Department agrees can be improved. Several other suggestions concerning improved scheduling and documentation appear to be valid.

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Note 3

* See State Comptroller's Notes, Appendix C

We do not agree with several other findings, including those relating to complaints, the timing of cyclical inspections, and the proper handling of reinspections. When we researched specific examples presented in the draft report, we determined that the auditors overstated the risks presented by specific cases or inaccurately described our own activities. Our response presents our view of these issues. We either append copies of the relevant documentation or have made the documentation available should the auditors wish to review it.

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Note
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We appreciate the courtesy and consideration of your audit staff in the performance of this audit. If you have any questions or need further information, please contact Charles Troob, Assistant Commissioner, Business Systems Improvement at (212) 442-8413/8436.

Sincerely,

Thomas R. Frieden, M.D., M.P.H.
Commissioner

TRF/mc

* See State Comptroller's Notes, Appendix C



THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg
Mayor

Thomas R. Frieden, M.D., M.P.H.
Commissioner

nyc.gov/health

Inspection of Radiological Equipment

New York City Department of Health and Mental Hygiene

Draft Audit Report 2001-N-9

New York State Office of the Comptroller

RESPONSE BY OFFICE OF RADIOLOGICAL HEALTH

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

September 23, 2002

The Radiological Equipment Inspection Program ("the Program") is designed to ensure rigorous technical and safety inspections of radiological equipment facilities in New York City. It consists of nine trained and experienced assistant scientists and two senior scientists responsible for oversight of over 6,500 permitted radiological equipment operators and facilities. In the period addressed by the audit team (July 1, 1999 through December 31, 2001) the program inspected approximately 3,500 facilities, one of the highest productivity rates for any radiation equipment inspection program in New York State. The history of the program demonstrates its effectiveness in minimizing the risk of injury to the public from malfunctioning or misused radiological equipment.

In a 2001 Program Review, the New York State Department of Health, Bureau of Environmental Radiological Radiation Protection found "The New York City Bureau of Radiological Health is satisfactory in meeting its obligations under the Municipal Public Health Services Plan. The quality of the inspections performed by BRH inspectors is adequate to protect the public health and safety." These conclusions contrast with the findings of the State Comptroller's auditors (none of whom were trained in radiation physics) who cite "serious weaknesses" in the radiological equipment inspection program. This response document will show that, while some of its findings have merit, many issues raised by the audit team result from a lack of technical understanding or mistaken assumptions. This response document will clarify these issues and, where legitimate weaknesses are identified, describe corresponding changes in Program procedures as a response.

This response will address auditor issues (in quotes) in the order that they appear (beginning on page 5 of the subject report).

INITIAL INSPECTIONS

"...improvements are needed in the process used by DOHMH to schedule facilities for initial inspections."

Although the Program concurs with the audit findings relative to initial inspections, it should be noted that many of the new facilities cited were either dental offices, where the risk from radiological equipment is low, or were change of ownership situations, where the equipment had been previously inspected. On page 7 of the subject report the auditors state that the Program, after an initial inspection, sealed equipment at one facility because the X-ray unit was "defective and dangerous." This is incorrect. The new unit was sealed at the request of the operator in order that it not be inspected at that time. The auditors state on the same page that another facility was ordered to cease operating certain equipment because it was "too hazardous" to use. The facility was, in fact, a podiatrist office where the Program inspector found the collimator beam was slightly larger than the X-ray film and issued a stop order instead of requiring the facility to make an adjustment to the unit. This stop order was removed upon review by a Program supervisor, as this is not considered a hazardous situation. Auditor descriptions such as "defective", "dangerous" or "hazardous" do not apply to these situations.

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Note
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Installation of new equipment involves numerous redundant safeguards, including manufacturer inspection to US Food and Drug Administration (FDA) standards, quality assurance survey and calibration by a qualified health physicist, and FDA registration. Because no equipment can be considered risk-free, the Program concurs that initial inspections be given priority over routine work. New protocols have been implemented that ensure inspection of all equipment prior to operation (i.e., prior to use on patients). These protocols will be documented in Section 7 of the new equipment application form (RC 53) as follows:

ATTENTION: X-RAY EQUIPMENT SHALL NOT BE USED FOR PATIENT PROCEDURES PRIOR TO INSPECTION BY THE OFFICE OF RADIOLOGICAL HEALTH. FAILURE TO SCHEDULE A PRE-OPERATION INSPECTION WILL RESULT IN CIVIL PENALTY. CALL ORH FOR APPOINTMENT (212)676-1580, 1577, 1582.

CYCLICAL INSPECTIONS

"...a total of 121 of the 6,584 facilities, 1.8%, included on the CAMIS were overdue for their cyclical inspection"

The Program adheres to the guidelines set forth by the US Nuclear Regulatory Commission (NRC). Item 10.05 of the NRC Inspection Manual states, "the frequency of inspection for a licensee should not fall outside the following points: for inspection of licensees in Priorities 1, 2, 3- Interval between inspections may vary by plus or minus 25%. For inspections of licensees in Priorities 4 and 5- Interval between inspections may vary by plus or minus 1 year." According to NRC guidance, priority 2 inspections (i.e., facilities inspected on a two year cycle) have an acceptable range of plus or minus 183 days from their scheduled inspection date before they are considered not timely. For priority 3 inspections (i.e., facilities inspected on a three year cycle) the range is 274 days. For priority 5 inspections (i.e., facilities inspected on a 5 year cycle) the range is 365 days. Program analysis of the 6,584 facilities cited in the audit revealed that only 3 facilities (less than one tenth of one percent) would be considered not timely under NRC guidance criteria.

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Note
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RE-INSPECTIONS

"Category 1 violations are the most severe kind of violations, creating a direct or imminent hazard to public health."

Category 1 violations do represent deficiencies in compliance with the NYC Health Code that warrant immediate action to obtain compliance. However, most Category 1 violations do not represent a hazard to the public or the operator. A review of Program records for the audit period revealed a majority of Category 1 violations (72) to be sensitometry issues. A Category 1 sensitometry violation is not a direct or imminent health hazard. It involves processor quality assurance for photographic film and involves no X-rays. 62 Category 1 violations were issued for no permit, 20 for other processor QA violations, 20 violations were issued to facilities that subsequently went out of business and 7 Category 1 violations were dismissed at Administrative Tribunal.

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Note
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"There was no evidence that 12 of the 181 facilities (7 percent) had been re-inspected."

Program review found 10 of the cited facilities were reinspected with documentation that all violations were corrected.

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Note
7

"For 26 facilities that had been re-inspected, there was no evidence that the facilities had corrected the conditions that caused the Category 1 violations"

Program review contradicts this finding. This may be a case where the audit team either did not understand documentation terminology or did not read the entire inspection report. Program review of 21 of the cited re-inspection reports revealed that initial violations had either been corrected or equipment was sealed. For example:

1. The offices of [name provided upon request] were re-inspected on 3/29/00 for violations noted during a previous facility inspection. The re-inspection report indicates that violations previously noted had been corrected with several exceptions. The report states that documentation of correction for the remaining uncorrected violations was to be mailed to Program offices within 30 days. Such documentation was received on 4/11/00.
2. The offices of [name provided upon request] were inspected on 9/22/00 and violations noted with equipment in Rooms 1, 3, and 7. A re-inspection performed on 10/31/00 found violations in Rooms 1 and 3 had been corrected, but violation conditions remained for the Ritter Unit in Room 7. The re-inspection report documents that this unit was immediately sealed.

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Note
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Nineteen other cases from this group revealed similar types of actions taken by the Program. Time constraints did not allow for the review of the remaining 5 cases cited.

"Contrary to the City Health Code, 55 of the re-inspections were performed more than 60 days after the original inspection."

The Program agrees that in a minority of instances, re-inspections were not performed within a 60 day period.

" Of 23 facilities that received Category 1 violations for lack of registration or registration renewal, 9 were still not registered or renewed as of July 11, 2002, yet DOHMH had not re-inspected these facilities as required."

Some of these facilities went out of business and ceased operations. Others were cited for lack of permit. The Program would typically not reinspect a facility for a lack of permit but would instead transmit application forms and monitor each non-permitted facility to ensure proper registration.

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**Note
9**

Any equipment identified during an inspection to represent a direct or imminent hazard is immediately sealed and taken out of service until the identified problems are corrected. 51 facilities were sealed during the audit period for cause. Similarly, the Program monitors every registration violation until the facility is registered, its equipment sealed or the facility ceases operations permanently. In some cases cited by the audit team, a facility had registered and entered violation status in the following period. The audit team misinterpreted this violation status as failure to respond to the original violation.

HOSPITAL INSPECTIONS

"18 case folders did not contain information about number of machines in operation at the hospital, and another 17 folders did not contain the most recent inspection report"

Program review contradicts this finding. A review of the 35 reports cited above revealed that all included the most recent inspection report. Files for hospitals recently inspected are typically in preparation for several weeks following the inspection and therefore located with supervisors and not in file cabinets. The number of machines in operation is listed as "Number of tubes" on the face sheet of the 8 page large facility QA form (RC 37). The auditors were apparently not familiar with this fact.

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**Note
10**

"The required number of machines was not examined at 18 of the 53 hospitals."

The Program agrees that in a minority of instances, the maximum number of tube inspections were not performed. The number of tubes required for inspection is determined by the table cited in the subject report. However, current procedures require Program supervision to determine in advance the number of tubes to be inspected based on those present at the facility at

the time of the last inspection. If a hospital acquires additional equipment during that time, the number of tubes inspected would be lower than the table recommends and conversely, if a facility reduces existing equipment, the number of tubes inspected would be higher. Program review finds an insignificant difference in hospital tubes from one cycle to the next. In addition, all X-ray equipment at hospital facilities are required to be checked on a quarterly, semi-annual and annual basis by a qualified health physicist. As a response to the audit recommendations, however, effective immediately Program inspectors will determine on-site the number of tubes to be inspected based on those present at the facility at the time of the inspection.

"If an inspector finds a category 1 violation or 2 or more lesser violations, during an inspection of a hospital, the inspector is required to examine additional machines, at that hospital....No evidence in the case folders documenting that the inspectors examined additional machines at any of these 48 hospitals."

The audit team misinterprets Program policy. During hospital inspections, current Program procedures require that additional inspections of equipment be performed if **two or more Category 1 violations are found**. No additional tube inspections are required for any combination of lesser violations noted during the inspection.

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Note
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"Inspectors should first obtain a list of radiological machines from the hospital, and then select a random sample from the list. However, the officials also told us this is not done; rather, the inspectors use their judgement to select a sample from the machines made available to them, at the time of their visit..... As a result of this practice, some of the radiological machines used most frequently may never be selected for inspection, particularly the x-ray machines in special procedures, cardiac catheterization and operating rooms."

The Program concurs that the random determination of X-ray tubes to be inspected in hospitals can be improved. Beginning with the next scheduled cyclic inspection for each hospital, Program inspectors will utilize a new RC 54 form that documents the type and location of every tube in the hospital. This RC 54 will be on-site during future inspections to allow the inspector to choose tubes not inspected during previous cycles. However, each inspection will include inspections of equipment in the OR, ER and Special Procedures rooms. Also effective immediately, Program procedures require inspectors to make all necessary arrangements to inspect frequently used rooms, which are typically difficult to access.

"We further determined that some of the radiological machines in hospital, (and other facilities) may never be inspected because DOHMH may never learn of their existence."

At the beginning of each inspection, the hospital provides to the Program inspector a listing of all X-ray equipment at the facility. The Program has never encountered an instance where a hospital deliberately or mistakenly misidentified the number and locations of equipment.

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Note
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In addition, the Program receives FDA forms from equipment installers detailing every tube installed at hospitals and private facilities.

MANAGEMENT OF THE INSPECTION PROCESS

Mandated Facility Quality Assurance Program

"In 1995, the last year the old inspection cycle was in effect, 3,000 facilities were inspected by DOHMH. In 1996,...under new inspection cycle 1,500 were inspected."

The reduction in inspections cited by the audit team reflects a deliberate process to improve the quality and safety of radiation equipment nationwide. This process included implementation by the operator of a comprehensive Quality Assurance Audit system. Program protocols were also revised to include a thorough on-site review of the operator QA audit documentation, a process that substantially increased the duration of each on-site inspection. In spite of this, Program staffing reflects the reduction in total inspections. Program staffing is currently at 9 field inspectors from 17 inspectors in 1995.

The auditors indicated on page 14 of the subject report that in 1996 the New York State Department of Health (NYSDOH) approved Program guidelines extending the inspection cycle. Please note that NYSDOH itself extended the inspection cycle. The audit team reviewed relevant correspondence from this period.

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**Note
13**

".....we examined case folders for all 88 hospitals, and for a random sample of 25 of the 190 radiologist offices performing mammographies as of June 30, 2001....Only 2 of the 113 folders contained evidence that DOHMH inspectors had reviewed these tests (these two folders contained copies of the facilities' expert quality assurance reports)."

Program review contradicts this finding. Program inspections of facility quality assurance programs are rigorously documented. For larger facilities, this documentation takes the form of a multiple page "Quality Assurance Audit" form RC 37 that is completed by the inspector and retained in the facility file. All of the elements required in §175.07(b) for a quality assurance audit are listed in the standard inspection form RC 42 (for a small facility) or the "Quality Assurance Audit" form. RC 37 documentation includes verification of health physicist equipment QA records and test results. Small facility form documentation includes questions 306, 307, 308, 309, 311, 312, and 313 that verify health physicist equipment QA records and test results.

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**Note
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For mammography inspections, a copy of the physicist annual Q/C (QA) report is retained in each facility file. Program inspectors review every test performed by the physicist and complete a standard FDA mammography inspection report that is transmitted electronically to FDA. Hard copies are not kept on file. In addition, the Program has developed a Mammography Addendum Report which lists additional QA items not regulated by FDA.

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**Note
15**

Apparent unfamiliarity with physics terminology may have caused confusion about this issue on the part of the audit team.

The auditors have recommended that quality assurance report documents be retained by the Program in each facility file. A requirement for submittal of hundreds of thousands of pages of quality assurance reports would not enhance inspection rigor or thoroughness. It would, however, be prohibitively expensive and require significant additional storage space. Program inspectors assure effectiveness by reviewing quality assurance reports at the facility, comparing facility results with testing performed on-site by Program inspectors, and thorough documentation on Program RC forms.

As with any regulatory program, the quality assurance requirements recently promulgated in the Health Code and Part 16 of the State Sanitary Code resulted in a significant frequency of violations in the first years as facilities put various components of the regulations into practice. However, the Program and NYSDOH have noted increasing compliance and concomitant decrease in violation frequency for quality assurance related issues.

RESPONSE TO COMPLAINTS

"DOHMH does not maintain a log to record complaints."

A hard copy record of each complaint is submitted to Program supervision for internal investigation. This document is retained to record each and every complaint. Complaint documentation includes the date the complaint was recorded, the nature of the complaint, the date the internal investigation commenced and the outcome of that investigation. However, as a response to audit recommendations the Program will create and maintain a separate complaint log.

"We reviewed all 39 complaint sheets on file for the two years ended June 30, 2001...responded...an average of 12.8 days after they were received"

Complaints are categorized by nature of seriousness (e.g., immediate response, prompt response, routine response, no cause for action). Those complaints categorized as "immediate" are responded to within 48 hours. "Prompt" complaints are required to be investigated within 30 days. Program review indicated all complaints received by the Program during the audit period were categorized as "prompt response" complaints.

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**Note
16**

"We also found that ORH response to six of the complaints did not effectively address the issues identified in the complaints."

Program complaint investigation includes all issues noted by the complainant. The specific issues detailed by the complainant are often not addressed in the facility inspection. When a Program inspector investigates and verifies the absence of a complaint issue, the letters "NCA" (indicating "no cause for action") are entered on the inspection report form. NCA indicates that at the time of the Program inspection issues identified by complainant were not in evidence or were unfounded. As technical shorthand, NCA may not have been obvious to the

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**Note
17**

non-technical audit team members. For Program purposes it assures that each complaint issue is systematically and effectively addressed.

MANAGEMENT AND PERFORMANCE INFORMATION

"Neither the CAMIS nor any other information system, maintained by DOHMH provides information about all the inspections performed at a facility."

The Program agrees with audit findings that a comprehensive database containing a detailed inspection history for each facility would be a useful tool. Given sufficient resources, future Program inspectors will utilize electronic handheld devices to record inspection results, download records to a centralized database that will produce all required correspondence and reports. FDA currently uses such a system for its MQSA program.

RECOMMENDATIONS

1. "Amend DOHMH guidelines to specify a time frame for initial inspections, and perform initial inspections within this time frame."

The Program concurs and has taken action as noted above.

2. "Perform cyclical inspections and re-inspections within the time frames prescribed by DOHMH guidelines.

As stated above, we believe that our cyclical inspections are fully compliant with our guidelines, which follow the New York State Department of Health in using national standards (NRC) in determining the timeliness of cyclical inspections. The 60-day Health Code requirement is to either reinspect *or* take appropriate actions. We interpret this in some cases to mean that reinspection may be performed beyond the 60-day period, depending upon the action/s taken.

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Note
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3. "Take appropriate action when re-inspections determine that the conditions causing Category 1 violations have not been corrected."

The Program currently takes appropriate action in every instance.

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Note
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4. "During inspections of hospitals, examine the number of radiological machines required by DOHMH policies, and adhere to the policy that requires the sample size to be increased when violations are found."

The Program concurs about determination of initial tube inspection quantity and has taken action as noted above. The Program currently adheres to a policy of increasing tubes inspected when a hospital inspection reveals two or more Category 1 violations.

* See State Comptroller's Notes, Appendix C

5. "Develop a sampling methodology that gives all the radiological equipment in a hospital a reasonable chance of inspectors to use this methodology, and monitor the inspectors to ensure that the methodology is used."

The Program concurs and has taken action as noted above.

6. "Develop processes for identifying radiological machines that have not been inspected.

The Program concurs and has taken action as noted above.

7. "Improve record keeping practices so that facility case folders are complete and can be located.

The Program concurs and plans to address record keeping issues.

8. "Review facility quality assurance programs as required during inspections, and document this review in facility case folders.

The office has been reviewing quality assurance aspects (with documentation) since the program was initiated.

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Note
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9. "Require all facilities with mandated quality assurance programs to submit their expert quality assurance reports to DOHMH."

The Program does not agree that such a requirement would increase the rigor and effectiveness of Program review of facility QA programs.

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Note
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10. " Evaluate the effectiveness of the facility quality assurance programs, and on the basis of this evaluation, determine whether facilities should be inspected more frequently.

The Program and NYSDOH have noted increasing compliance and concomitant decrease in violation frequency for quality assurance related issues. Facilities with quality assurance program problems are currently reinspected.

11. "Maintain a log of the complaints received about radiological equipment or equipment operators, and respond promptly to the issues identified in the complaints.

The Program concurs and will create and maintain a separate complaint log.

12. "Enhance the CAMIS or develop an alternative data base system to provide a comprehensive history of facility inspection results and related inspection information. Track facilities on this system from their day of registration, and use the system to schedule inspections for facilities.

The Program concurs and plans to take action as funding is identified.

APPENDICES

**Office of Radiological Health
2 Lafayette Street - 11th Floor
New York, N.Y. 10007**

Fax: (212) 676-1579
Telephone: (212) 676-1580,1

M E M O R A N D U M

DATE: September 13, 2002

TO: Radiation Equipment Staff

THROUGH: Gene Miskin, Director

FROM: *jm* Joseph M. Aufrichtig, Asst. Dir

SUBJECT: Unregistered Facilities

Beginning immediately, **all** facilities not currently registered will receive an AT-18. This includes new facilities and renewals which are not current. This is actually an extension of a very old policy. The reemphasis is that there are no grace days of any kind, for new facilities. A thirty (30) day grace period **only** is allowed for renewals for the permit division to process. Facilities can avoid an AT-18 if they show the inspector physical proof of an attempt to register such as a check stub or a canceled check. Inspector should attach a copy of the proof to the report. Calling our office to request new or renewal forms, while the inspector is on site is *not considered* new permit or renewal in progress.

Office of Radiological Health
2 Lafayette Street - 11th Floor
New York, N.Y. 10007

Fax: (212) 676-1579
Telephone: (212) 676-1580,1

M E M O R A N D U M

DATE: September 13, 2002

TO: Radiation Equipment Staff

THROUGH: Gene Miskin, Director

FROM:  Joseph M. Aufrechtig, Asst. Dir

SUBJECT: **RC 54 Instructions**

Beginning with your next hospital inspection, form RC 54 (X-Ray Identification) will be completed and filled out for *every hospital inspection*. This form will identify and locate **every** x-ray tube in the particular hospital and will mark all those that were inspected at that cycle. Please fill out all the boxes in an orderly fashion, building by building, floor by floor, room by room. Do not forget to mark the year of inspection in its designated place.

The field inspector will submit one original and three copies of this form. This is in addition to the original, and one copy of the large audit form, which must be submitted with the rest of the hospital reports.

At the time of the next cycle inspection of this hospital, the inspector will receive a copy of the previous inspection audit form, and a copy of the previous RC 54. The inspector will use this as a guide, so as **not to inspect the same tubes** as previously done. This will continue for up to three cycles (depending on the size of the hospital). In addition it is expected that at least one operating room and/or a special procedures room is inspected each time (this is actually an old rule). Supervisors must check for this. Hospital reports lacking these qualifications are unacceptable.

Please cooperate. To ensure that we protect the public, as best as possible, it is crucial that no x-ray units slip through the cracks.

YEAR OF
INSPECTION

**THE CITY OF NEW YORK – DEPARTMENT OF HEALTH
OFFICE OF RADILOGICAL HEALTH
RADIATION EQUIPMENT DIVISION**

X-RAY IDENTIFICATION

Office of Radiological Health

2 Lafayette Street - 11th Floor
New York, N.Y. 10007

SANTIAGO AIL
PENDER AIL

Fax: (212) 676-1579
Telephone: (212) 676-1580,1

M E M O R A N D U M

DATE: September 10, 2002

TO: Radiation Equipment Staff

THROUGH: Martin Schnee (will chair the meeting)

FROM: *JM* Joseph M. Aufrichtig, Asst. Dir

SUBJECT: Friday Meeting Agenda - Sept. 13, 2002

- ✓ 1. RC-54 form - X-ray Identification of all x-ray units in a hospital facility --- to be used for information purposes and to insure that every tube in the hospital is inspected over a period of time. (handout forms with RC-54 instruction memo) *after hours (ex: 6 AM - 1:30)*
- ✓ 2. No grace period at all for new facilities --- 30 day limit for renewal registrations. Automatic AT-18 in each case if no physical proof shown of attempt to register (make copy of proof and attach to papers). Proof found later should be brought to the hearing, as evidence. (memo handout). Calling our office *after* inspector arrives *is not called in progress.* (handout-memo)
- ✓ 3. Review of key points in completing the AT-18 form (time of service, etc.).
- ✓ 4. *(J)* Review of key points in completing dailies) *hold for instructions from MJS*
- ✓ 5. Complete zip code district changeover, as expected by every auditor, inspector general etc. Give all your undone work to the person who now has that district. If you are in the process of making an appointment, or you need work to fill in the rest of September, you may retain some facilities for this purpose. The next changeover will take place in two to three years. (handout of new district list)
- ✓ 6. New installations will not be permitted to operate until we have conducted our inspection. The registration forms will be changed to notify the facility of this rule which is clearly delineated in the Health Code. You will be notified when enforcement action will begin.
- ✓ 7. Complaint forms -- how to respond. (handout)
- ✓ 8. *Reinspections - 60 days*

On _____ at _____, I interviewed _____ complainant or No Access
at _____

Who stated that _____

or Anonymous

On _____ at _____ O.A.M. I Inspected _____
at _____ O.P.M. Type or Establishment

operated by _____ and found that _____

facility

Must address complaint clearly. Try to
answer in words of complaint. Any additional
findings do not have to be answered on
this form. You can write see inspection
dated 1/10/2 for additional findings.

Give your recommendation.

NCA - VRR - VRPPS - Needs referred

PENALTY FOR FALSIFICATION: FALSIFICATION OF ANY STATEMENT MADE HEREIN IS AN OFFENSE PUNISHABLE BY A FINE OR IMPRISONMENT OR BOTH.
(N.Y.C. ADMINISTRATIVE CODE SECTION 912.9.0)

SIGNATURE OF PUBLIC INSPECTOR AND NUMBER

DAULGE NO. _____ DATE _____

EN-122721

Office of Radiological Health
2 Lafayette Street - 11th Floor
New York, N.Y. 10007

Fax: (212) 676-1579
Telephone: (212) 676-1580,1

M E M O R A N D U M

•DATE: June August 15, 2002 (Revised from June 3, 2002)

TO: R/E Supervisory Staff

THROUGH: Gene Miskin, Director

FROM: Joseph M. Aufrichtig, Asst. Dir

SUBJECT: Hospital Tube Identification/ Inspection

In order to insure that all the x-ray units in each hospital are inspected over a period of time, (we inspect approximately 20% of all the units in a given hospital per cycle inspection), X-ray Identification form RC54 has been formulated. This form will list the location and unit type etc. of every unit located in the hospital and whether it has been inspected, during the current cycle inspection.

When the hospital is assigned at the next cycle, the field inspector will receive a copy of the previous RC54 forms (the number will increase as the program continues). The inspector should inspect those tubes not previously inspected, as noted in the form. In addition, the inspector is required to inspect at least one special procedures, operating room etc. These rooms are often very busy and difficult to gain access to. An appointment should be made with the hospital staff, during or before the entrance interview, to allow for inspection of these rooms. Where necessary, the inspector will be given permission to begin, or end, the inspection day earlier, or later than usual, to accomplish this. If the inspector works more than a seven hour day, compensatory time will be granted. Alternatively, inspectors may choose to arrange their schedules, in such a way as to maintain a seven hour workday.

These changes will go into effect immediately after the mandatory general staff meeting for the radiation equipment division scheduled for Friday, September 13 and chaired by Martin Schnee, Assistant Director, designate.

cc: Field Inspection Staff

Office of Radiological Health
2 Lafayette Street - 11th Floor
New York, N.Y. 10007

Fax: (212) 676-1579
Telephone: (212) 676-1580,1

M E M O R A N D U M

DATE: September 6, 2001 (revised August 21, 2002)

TO: Radiation Equipment Staff

THROUGH: Gene Miskin, Director

FROM: *JMA* Joseph M. Aufrichtig, Asst. Dir

SUBJECT: Complaint Protocol

The Division of Radiation Equipment receives approximately 20 complaints per year. Most of the complaints we process, come to us directly by phone and occasionally via the mail. A small number are referred from other Public Agencies. Form EH-1A is completed (attached), a copy made, and assigned to an inspector.

The majority of the complaints fall under three categories:

1. Neighbors of radiographic facilities worried about radiation coming from the facility into their domain.
2. Claims that proper testing procedures are not being performed by the facility.
3. Claims that the facility is using unlicensed personnel to take x-rays.

The overwhelming majority of complaints addressed by the Radiation Equipment Division are of the non-immediate type, not associated with immediate and imminent health hazard.

In many cases, due to the nature of the complaint, we will not make an appointment with the facility, but rather will inspect without previous announcement. Where concerned neighbors are involved, we will take readings in the relevant apartment, office etc. If violations are found, these will be reinspected using the usual guidelines for re-inspections.

In no case is the name of the complainant ever disclosed to the facility complained about.

A separate file of all complaints is maintained by the Assistant Director.

**Office of Radiological Health
2 Lafayette Street - 11th Floor
New York, N.Y. 10007**

*Fax: (212) 676-1579
Telephone: (212) 676-1580,1*

M E M O R A N D U M

DATE: June 29, 2001

TO: R/E Supervisors

THROUGH:

FROM: *JM* Joseph M. Aufrichtig, Asst. Dir

SUBJECT: Reinspection Policy

This memo repeats a long standing policy relative to reinspections. Reinspections are assigned to be performed after thirty days, but less than 60 days, from the date of the initial inspection. In some special situations extensions may be granted. In cases of potential hazard or repeat re inspections ten to fifteen days only should be granted.

Office of Radiological Health
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M E M O R A N D U M

DATE: October 6, 2000

TO: Radiation Equipment Staff

FROM: Joseph M. Aufrichtig, Asst. Dir

SUBJECT: Operating Room Inspections

From time to time it is important to remind the field staff of the necessity to inspect *all* parts of a hospital's x-ray equipment. This became a factor when we introduced the concept of inspecting a representative portion of the units in a hospital, instead of doing each and every tube. For the most part this has been carried out. The most difficult areas to inspect involve the operating/special procedures rooms. In almost all cases an appointment must be made to inspect at a time when these very busy rooms are available.

An operating/special procedures room **must** be inspected at every hospital that has one or more of these rooms. Speak to the chief technician and/or administrator of x-ray and set an exact appointment before beginning the inspection. This will generally mean calling the responsible party before going to the facility. Upcoming hospital inspections are posted on the bulletin board in my room, well in advance of the date of inspection. The initials of the assigned inspector are noted and the name and phone number of a contact person.

It is very important that we do not omit these rooms from our inspection protocols. Please do not return hospital papers to this office without such inspections. Mark the top of the machine sheets with the words "operating room" whenever applicable. If there are no such rooms in the institution (very small hospitals may not have one), please make a notation to this effect on the RC37. Supervisors are asked to please check hospital reports for these inspections.

Thank you for your cooperation.

cc: Gene Miskin, Director

State Comptroller's Notes

1. We maintain that the findings in our report support the conclusion that deficiencies in the Department's processes for inspecting radiological equipment present a health risk to the public. To illustrate, we found that initial inspections of equipment were not performed at all or were not performed until months after facilities had begun operations. Once inspections were performed, inspectors identified violations that could have created health risks if they were not corrected. After one inspection, the inspector sealed the facility's x-ray unit because it was deemed defective and dangerous. In this regard, see State Comptroller's Note 4.
2. We modified our report to redefine Category 1 violations. See State Comptroller's Note 6.
3. As stated throughout the following State Comptroller's Notes, DOHMH officials were generally unable to provide us with documentation to support the assertions made in their response to this report. Hence, in most cases, we did not modify the report.
4. In our judgment, DOHMH inspectors can not know whether the risk from radiological equipment in new dental offices is low in advance of an inspection of the equipment. Additionally, we took the words "defective and dangerous" directly from the inspection report.
5. To determine the timeliness of cyclical inspections, we applied the requirements of City and State Health Codes, which include aspects of the NRC guidelines. However, the specific NRC guidelines cited by DOHMH officials relate to nuclear reactors and nuclear matter, not radiological equipment. Additionally, a 1998 NRC report recommended that DOHMH conduct more timely inspections of radiological equipment.
6. We modified our report to redefine Category 1 violations consistent with the definition offered by DOHMH officials. Further, our report identified Category 1 violations at 181 facilities. The total number of Category 1 violations at these facilities was 234. The statistics provided by DOHMH officials account for 181 Category 1 violations. Consequently, we question the relevance and validity of these statistics.
7. DOHMH officials were unable to provide us with documentation supporting the assertion that 10 of the cited facilities were reinspected and all violations corrected. Hence, we have not modified the report.
8. DOHMH officials were able to provide documentation for only 18 facilities in support of the assertion that 21 of the cited reinspection reports revealed that the initial violations had either been corrected or equipment was sealed. For five of these facilities, DOHMH took corrective action, by sealing the equipment. We

have modified our report accordingly. Additionally, DOHMH officials did not provide us with the names of the two offices that were purportedly reinspected on 3/29/00 and 9/22/00, respectively.

9. DOHMH officials were unable to provide us with documentation supporting the assertion that some of these facilities went out of business and ceased operations, while others were cited for lack of a permit. Hence, we have not modified our report. Further, we did not misinterpret the violation status of these facilities. All outstanding violations were the original violations and not new citations for failure to respond to the original violation.
10. DOHMH officials were unable to provide us with documentation supporting the assertion that the case folders contained the most recent inspection report. Hence, we have not modified the report.
11. We modified the report to reflect DOHMH policy requiring additional inspections of equipment if two or more Category 1 violations are found. However, our findings already reflected the existence of multiple Category 1 violations and the failure of DOHMH to perform additional inspections.
12. DOHMH inspectors do not independently verify the quantity and location of radiological equipment in hospitals. Consequently, DOHMH inspectors are relying on the accuracy of the information provided by hospital administrators. Additionally, the information provided by the FDA relates to new equipment and not used equipment. Hence, DOHMH may not be aware of all radiological equipment in use at hospitals.
13. We modified the report accordingly.
14. During the course of our audit, we reviewed the forms (RC 37 and RC 42) identified by DOHMH officials. However, these forms are checklists. To provide reasonable assurance that DOHMH inspectors verified the validity of tests performed at the facility, DOHMH should have a copy of the most recent physicist quality assurance report.
15. DOHMH's response to this issue is contradictory. In this paragraph, officials state that a copy of the physicist annual quality assurance report is retained in each facility file. In the following paragraph of the response, officials state that maintenance of the physicist annual quality assurance reports would not enhance inspection rigor or thoroughness. Additionally, based on our review of these reports, we maintain that they are not voluminous and should be kept on file.
16. The Complaint Protocol document provided by DOHMH officials does not support the assertion that complaints are categorized according to seriousness.
17. These comments are not directly responsive to the issues raised in the report.