

Public Advocate for the City of New York

DIAGNOSIS: NEGLECT CITY FAILS TO INSPECT X-RAY EQUIPMENT

A Report by Public Advocate for the City of New York

Public Advocate Betsy Gotbaum MAY 2005

Visit us on the web at <u>www.pubadvocate.nyc.gov</u> or call us at (212) 669-7200.

OFFICE OF THE NEW YORK CITY PUBLIC ADVOCATE

Betsy Gotbaum Public Advocate for the City of New York

PREPARED BY:

Jill E. Sheppard Director of Policy and Research

Melissa Brennan Policy Research Associate

WITH THE ASSISTANCE OF:

Christine Constantinople Intern

> Peter Hitt Intern

Laura Smith Intern

Introduction

Physicians and patients alike rely on X-ray equipment to provide information about known or suspected illnesses or injuries. X-ray equipment that is not inspected as frequently as required by the State Department of Health has the potential to cause several public health risks.

One serious risk is that equipment may malfunction and provide false or unreliable results. If a malignant cyst in a woman's breast goes undetected by a machine that is overdue for inspection, her ability to treat cancer in its early stages could be significantly limited.¹ In addition, X-ray equipment emits radiation, and that radiation is known to cause cell mutations that can lead to cancer, according to the Mayo Clinic.² Most X-ray equipment emits only low doses of radiation, but even low doses can increase one's lifetime risk of developing cancer. The risk of overexposure has a greater impact on technicians who regularly operate equipment than on the general public.

Recognizing the potential for harm posed by the use of malfunctioning X-ray equipment, State law requires that hospitals, clinics, and radiology offices that operate X-ray equipment be registered and periodically inspected.³ In New York City, the Office of Radiological Health, a division of the Department of Health and Mental Hygiene (DOHMH) is charged with dispatching inspectors to these places of business subsequent to their registration,⁴ and periodically from then on.

The State Sanitary Code provides that "[h]ospital clinics, mammography, and radiologist installations shall be inspected at least once every year," and certain other facilities that operate radiation-producing equipment shall be inspected at least once every two or three years.⁵ Similarly, the City Health Code provides for annual inspections for hospitals, clinics, and radiology centers, and biennial and triennial inspections for certain other facilities.⁶ Both codes, however, allow the City and State Departments of Health to establish their own inspection timetables.⁷

In January of 1992, the Office of the NYC Comptroller conducted a study of facilities with X-ray equipment and found that almost 40% had not been inspected annually as required.⁸ Subsequently, DOHMH revised its inspection timetable, providing for X-ray equipment in hospitals and clinics to be inspected only every two years. Despite the relaxed timetable, DOHMH is still failing to inspect all facilities.

¹ New York City Office of the Comptroller, "Radiation Out of Control: The Department of Health's Bureau for Radiation Control Is Not Inspecting All X-Ray Equipment in New York City," Jan. 1992.

² Mayo Clinic, "X-Ray: Risks," Dec. 31, 2003. Available online at <u>http://www.mayoclinic.com/invoke.cfm?id=FL00064</u>

³ NY Public Health Law §225

⁴ 24 RCNY Health Code §175.51

⁵ 10 NYCRR §16.10 (a)(1)(i)

⁶ 24 RCNY Health Code §175.51 (n)(2)(A)-(C)

⁷ 10 NYCRR §16.10 (a)(1)(ii); 24 RCNY Health Code §175.51 (n)(3)

⁸ NYC Comptroller, 1992.

Methodology

The Public Advocate's Office identified non-hospital radiology practices across New York City using the New York Physician Profile web site (<u>http://www.nydoctorprofile.com/welcome.jsp</u>). This database lists 250 radiologists registered to practice in New York City.

Investigators from the Public Advocate's Office visited 47 non-hospital radiology facilities throughout New York City to determine whether DOHMH inspects equipment within the established two-year timeframe. The distribution of the selected sites was roughly proportional to the distribution of radiology practices across the City.

This sample included:

- Two practices in the Bronx;
- Fifteen practices in Brooklyn;
- Twenty-three practices in Manhattan;
- Seven practices in Queens.

Investigators collected the vast majority of information through in-person site visits. Representatives obtained copies of the facilities' latest inspection records and other supporting documents. Investigators confirmed with each facility that the information provided could be reliably used to determine the date of last inspection and collected additional information by phone and fax as necessary.

Findings

Of the $\overline{47}$ private facilities surveyed, the Public Advocate's Office found that nearly 20 percent (nine) had not been inspected within the timeframe required by law. Of these nine facilities:

- Two are in the Bronx;
- One is in Brooklyn;
- Four are in Manhattan;
- Two are in Queens.

Also of note:

• The first inspection of X-ray equipment is supposed to occur when the machine is first put into use,⁹ yet one facility visited by investigators from the Public Advocate's Office reported that it has been operating an X-ray machine since August of 2004 without ever having been inspected by DOHMH. The facility had previously registered with the City when it obtained the new equipment, but the City failed to dispatch an inspector.

⁹ 24 RCNY Health Code §175.51

Malfunctioning X-Ray Equipment Threatens Public Health

Things can and do go wrong with X-ray equipment. Machines require regular maintenance and can "drift out of whack," when not regularly inspected, according to Thomas Piccoli, a medical imaging physicist at Monmouth Medical Center.¹⁰ Over time, equipment can break or malfunction. Without proper inspection serious problems can go undetected.

• An X-ray machine that does not emit sufficient radiation poses a significant risk to patient health. Such a machine may fail to properly detect a health problem, leading to a misdiagnosis, sometimes with serious consequences.

For example, if an elderly woman who complains of severe hip pain after a fall receives an X-ray to investigate the source of her discomfort, and that machine has not been inspected as frequently as required, inaccurate results could lead to a dangerous misdiagnosis. A machine that does not emit sufficient radiation would fail to detect a fracture¹¹. The undetected injury could become aggravated as the woman continues to walk without treatment, possibly leading to further injury or a permanent disability.

Likewise, a chest X-ray that fails to pinpoint the location of a stab wound could result in a patient not being treated for internal bleeding, leading the individual to die in an emergency room.¹²

• A malfunctioning exposure control device, which regulates the amount of radiation emitted during operation, could cause an over- or underexposure of radiation.¹³

A single overexposure is unlikely to cause health problems in and of itself, but such an exposure adds to one's lifetime cancer risk.¹⁴ Staff who work closely with X-ray equipment on a regular basis are at heightened risk of serious health problems due to repeated exposure, particularly if such equipment is emitting excessive amounts of radiation.

• Timing devices are used to ensure that X-ray equipment shuts off after a set period of time.¹⁵ If a timer is not working properly, a patient may be exposed to radiation longer than necessary. Likewise, if a timer shuts off too quickly, a machine may produce an imprecise or unclear X-ray image. This may result in a

¹⁰ Alexander Lane, "X-ray machines await inspection by the thousand, Staff shortage concerns medical inspectors," *Star-Ledger*, May 20, 2005.

¹¹ Health Protection Agency, "What are the Radiation Risks Associated with medical X-ray examinations?" Available online at

http://www.hpa.org.uk/radiation/understand/radiation_topics/medical/faq/medical1.htm ¹² NYC Comptroller, 1992.

¹³Id.

¹⁴ Health Protection Agency.

¹⁵ NYC Comptroller, 1992.

misdiagnosis or in the patient having to undergo a second X-ray, exposing him/her to added radiation.

- Because different parts of the body vary in sensitivity to radiation, radiologists use varying doses of radiation depending on the area that is to be X-rayed.¹⁶ Malfunction involving components of an X-ray machine that direct the radiation to specific areas and those that adjust the size of the X-ray beam can result in a patient receiving radiation over the wrong part of the body or a larger part of the body than necessary, increasing health risks.¹⁷
- X-ray machines are outfitted with safety lights, which are intended to signal when the machine is taking a picture.¹⁸ Bulbs can burn out, however, and equipment must be monitored to ensure that the safety light is a reliable indicator of radiation emission.

Conclusion and Recommendations

The Public Advocate's Office recommends that the City Department of Health and Mental Hygiene take the following measures:

- Review registration records and immediately inspect all X-ray equipment that has not been inspected over the past two years.
- Ensure that X-ray equipment is inspected when a machine is first put into use and once every two years from then on. Given that all facilities operating X-ray equipment are required to register with the City and that DOHMH is responsible for oversight, it should not be difficult to ensure that all registered places of business are inspected on time.
- Make information available to the public, so that a consumer can verify the last date of inspection for equipment used at a given facility.

Additionally, the New York State Department of Health (NYSDOH) should:

Conduct a biennial audit of DOHMH's radiation protection activities. In the past, such reviews were conducted each year; however, the most recent assessment of DOHMH's inspection activities was conducted in 2001 and, prior to that, in 1999.¹⁹

¹⁶ Radiology Society of North America, "Radiation Exposure in X-Ray Examinations." Available online at <u>http://www.radiologyinfo.org/content/safety/xray_safety.htm</u>

¹⁷ NYC Comptroller, 1992.

¹⁸ Id.

¹⁹ New York State Department of Health Bureau of Environmental Radiation Protection, "2001 Program Review, New York City Department of Health Bureau of Radiological Health X-Ray Equipment Inspection Program," Dec. 31, 2001. New York State Department of Health Bureau of Environmental Radiation Protection, "1998 Radiological Health Program Review," March 3, 1999.