



STATE OF NEW YORK
DEPARTMENT OF HEALTH

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REGION 1

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Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

January 30, 2001

Duncan White
US Nuclear Regulatory Commission
Region 1
State Agreements Program
475 Allendale Road
King of Prussia, PA 19406

Dear Mr. White:

This is to advise you that the NY State Department of Health proposes to charge fees to facilities that hold radioactive materials licenses issued by the Department and to increase the fees that it charges to the radiation equipment facilities it regulates. The fee change in this proposal is the first since 1979. It implements legislation included in the 1999/2000 State Budget. The proposed fees do not apply to facilities located within New York City limits, as these are regulated by the New York City Department of Health. The new fee schedules are included in a proposed amendment to Part 16 of the State Sanitary Code which has been announced in the January 24, 2001 issue of the State Register. The proposal is open for comment for a 45-day period which ends on March 12, 2001. A copy of the State Register notice is enclosed.

The Public Health Law authorizes the Department of Health to charge fees equal to its cost to carry out the radiation protection programs. For many years fees have been charged for the registration and inspection of X-ray equipment. The monies generated by the current fees raise about 10% of the total cost of the regulatory program. Revenues from fees included in this proposal are estimated to recover about two-thirds of the Department's regulatory program cost. Other funds, which include Federal grants and contracts, other fees and special revenue funds, will cover the balance of the program cost.

Some of the radiation equipment facilities registered by the Department are not normally inspected by State staff. They are inspected instead by staff from one of eight county health departments or by independent inspectors certified by the Department to perform such inspections. The proposal does not change any fees currently paid by the regulated facilities to local health departments or to independent inspectors. Since Department staff does not inspect all radiation equipment facilities, the proposal includes two separate fee schedules for radiation equipment facilities:

NMSS/REG-N-002

1. X-ray facilities not routinely inspected by the Department: fees account for the department's effort to implement the non-inspection components of the regulatory program. These include:
 - Evaluation of new technology and its impact on radiation dose to patients and radiation facility workers;
 - Development of regulations and radiation safety and quality control guides;
 - Examination of trends of skin entrance exposure for some of the x-ray exams;
 - Training and evaluation of Local Health Department staff and Certified Radiation Equipment Safety Officers (CRESO) who perform Part 16 inspections;
 - Review of inspection reports submitted by CRESOs;
 - Survey of a sample of newly installed x-ray equipment for compliance with the Federal standard requirements;
 - Investigation of reports of radiation overexposure and therapy misadministrations;
 - Investigation of complaints and allegations involving regulated facilities;
 - Response to inquiries from facilities, patients and the public covering radiation protection and exposure issues.

2. X-ray facilities routinely inspected by the Department: fees account for inspections by state staff as well as all other components of the regulatory program described above.

Department staff carries out all regulatory activities relating to the licensure and inspection of radioactive materials. Therefore, only one fee schedule for radioactive materials licensees is included in the proposal.

Comments on this proposal should be sent to William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Room 2415, Empire State Plaza, Albany, NY 12237.

If you have any questions or need clarification of this proposal, please feel free to contact me at (518) 402-7550 or e-mail at BERP@health.state.ny.us.

Sincerely,



Karim Rimawi, Ph.D.
Director
Bureau of Environmental Radiation Protection

Enclosures

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Department of Health

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

New Fee Schedule for Radiation Protection Programs

I.D. No. HLT-04-01-00003-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed action: Amendment of sections 16.10, 16.21, 16.40, 16.41 and 16.50 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 225(5)(p) and (q)

Subject: New fee schedule for radiation protection programs.

Purpose: To support the Department of Health's regulatory program for x-ray registrants and radioactive materials licensees.

Substance of proposed rule: Part 16 of the State Sanitary Code is amended to revise the schedules for fees to be charged to radiation equipment facilities registered by the department and to institute new fees to be charged to radioactive materials users who are issued licenses by the department. The amendments affect sections 16.10, 16.21 and 16.50 of the existing Part 16 and add two new sections 16.40 and 16.41. The changes to these sections are summarized in the following:

Section 16.10 - Inspections, surveys, checks and tests; vacating installations; securing radiation sources.

Paragraph (1) of subdivision (a) of section 16.10 is amended to delete all requirements dealing with the payment of fees.

Section 16.21 - Radiation installation; fees for inspection and other radiation protection services.

Existing section 16.21 is repealed in its entirety and the number is reserved.

A new Section 16.40 Fees is added with the following requirements:

Fee requirements: Unless exempt, all facilities that are required to register their radiation equipment with the department, or to hold a radioactive materials license issued by the department are required to pay fees.

Exemptions: Agencies of New York State and its political subdivisions, except for hospitals and higher education academic institutions operated by such agencies, are exempt from all fees. Also, radiation equipment facilities that are registered by New York City Department of Health or hold a radioactive materials license by New York City Department of Health are not subject to these fees, unless they also hold a registration or a license issued by the department. In the latter case, fees apply only to the activities registered or licensed by the department.

Payment of fees: Fees are assessed annually, and are to be paid within 30 days from billing.

Prorating fees: Fees for a period other than one year will be prorated to correspond to the period covered by the bill.

No refund policy: Except when a payment is not required, no fees will be refunded.

Failure to pay fees: The department may not issue, or may suspend or revoke an existing registration or a license if fees are not paid.

Fees charged by others: The amendment does not alter the ability of NY City Department of Health or any county health department's ability to charge fees for its regulatory activities, as long as these fees are consistent with its authority to charge fees under the Public Health Law.

Also, Certified Radiation Equipment Safety Officers can continue to charge fees for the inspection of x-ray equipment provided that such fees do not exceed the estimated cost of their services.

Fees paid prior to the effective date of this amendment: When assessing the new fees, credit will be allowed for the portion of the registration fee paid by a facility which covers a period which extends beyond the effective date of the new fee schedule.

Late payment of fees: A late payment charge will be assessed at the rate of 1.5% for each 30 day late period or part thereof.

Section 16.41 Fee schedule.

A new section 16.41 is added with the following requirements:

Fee Schedules for radiation equipment facilities:

Non-exempt radiation equipment facilities registered by the department are assessed two types of fees; a registration fee that is the same for all facilities and an annual fee which varies according to the type of equipment used by the registered facility.

The proposed annual fees are as follows:

(a) **Registration Fees.** The annual registration fee is \$50 for each registration issued to a facility.

(b) **Radiation Equipment Facility Fee Categories.** For the purpose of assessing annual fees, all radiation equipment facilities registered by the department are categorized in one of six categories according to the following:

Category I: Facilities with any five or more of the modalities listed below;

Category II: Facilities with three or four modalities;

Category III: Facilities with two medical modalities;

Category IV: Facilities with one medical modality and annual patient workload of 750 examinations or more;

Category V: Facilities with one medical modality and patient annual workload of less than 750 examinations, and all other facilities with one or two of the non-medical modalities except as listed under Category VI;

Category VI: Dental, podiatric, bone densitometry or veterinary facilities.

The modalities to be used in determining the fee category for registered radiation equipment facilities are:

Medical Modalities: radiography, fluoroscopy, computed tomography, angiography, stereotactic breast biopsy systems, Grenz/orthovoltage therapy utilized on humans.

Non-medical Modalities: radiography, fluoroscopy, analytical equipment (including electron microscopes, fluorescence analysis and x-ray diffraction equipment), computed tomography and particle accelerators, not utilized on humans.

(c) **Facility Fee Schedule for Radiation Equipment Facilities Routinely Inspected by the Department.** All radiation equipment facilities, not exempt from fees, that are routinely inspected by the department shall, in addition to the registration fee, be assessed annual fees according to the following schedule:

Category I facilities:	\$1,370
Category II facilities:	\$1,030
Category III facilities:	\$ 690
Category IV facilities:	\$ 275
Category V facilities:	\$ 140
Category VI facilities:	\$ 75

(d) **Fee Schedule for Radiation Equipment Facilities Routinely Inspected by a Local Health Department or by a Certified Radiation Equipment Safety Officer.** All registered radiation equipment facilities not exempt from fees that are routinely inspected by a local health department certified by the department to perform such inspections or by a certified radiation equipment safety officer as directed by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed an annual fee according to the following schedule:

Category I facilities:	\$ 425
Category II facilities:	\$ 320
Category III facilities:	\$ 210
Category IV facilities:	\$ 85
Category V facilities:	\$ 45
Category VI facilities:	\$ 15

(e) Fee Categories for Radioactive Materials Licensees and Radiation Therapy Facilities. For the purpose of assessing annual fees, all facilities holding licenses issued by the department for the use or possession of radioactive materials, and all facilities operating medical therapy accelerators registered by the department are categorized in one or more of six categories according to the following:

Category I: Facilities issued a broad scope medical license;

Category II: Facilities issued a broad scope academic or broad scope research and development license;

Category III: Facilities issued a specific license which allows the use of radioactive materials for both nuclear medicine and brachytherapy, or a license which authorizes the operation of a nuclear pharmacy in an institution or a pharmaceutical production cyclotron;

Category IV: Facilities operating a medical therapy accelerator and/or facilities issued a specific license which authorizes the use of radioactive materials in nuclear medicine, brachytherapy, mobile nuclear medicine service, teletherapy (including Co-60 teletherapy and gamma knife), research and development, academic uses, veterinary medicine or large irradiators;

Category V: Facilities issued a specific license which authorizes the use of radioactive materials in a clinical laboratory, lead paint analyzers, mobile nuclear medicine sites, leak tests, equipment calibration, self shielded irradiators, diagnostic sealed sources, and any other use not included in categories I through VI as listed in this subdivision;

Category VI: Facilities issued a specific license for use of radioactive materials in gas chromatographs.

(f) Radioactive Materials/Radiation Therapy Fee Schedule. (1) Except for facilities exempt from fees, all facilities that hold a radioactive materials license issued by the department or operate a medical therapy accelerator registered by the department, shall be assessed annual fees according to the following schedule:

Category I facilities:	\$5,265
Category II facilities:	\$3,510
Category III facilities:	\$1,400
Category IV facilities:	\$ 880
Category V facilities:	\$ 350
Category VI facilities:	\$ 50

When more than one fee category, as described above, applies to a radioactive materials licensee or a radiation therapy facility, it will be assessed the fee that corresponds to the highest applicable category. In addition to any other category fee that applies, a separate Category III or IV fee will be assessed for each of the following types of services authorized by a radioactive materials license or a registration of a medical therapy accelerator:

- nuclear pharmacy (Category III)
- pharmaceutical production cyclotron (Category III)
- teletherapy service including Co-60 unit, gamma knife or medical therapy accelerators (Category IV)
- veterinary medicine service (Category IV)
- large irradiators (Category IV)
- research and development, except for Category I and II licenses (Category IV)

Section 16.50 - Registration of installations with radiation equipment; authorized registration fees; notification of transfer of radiation equipment.

All requirements relating to fees are deleted from this section.

Text of proposed rule and any required statements and analyses may be obtained from: William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, FAX: (518) 473-7488, e-mail: regs@health.state.ny.us

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 45 days after publication of this notice.

Regulatory Impact Statement
Statutory Authority

The statutory authority for the regulatory radiation program is Public Health Law sections 201(1)(r) and 225(4) and 225(5)(p) and (q). These give the department the authority to register and inspect installations with

radiation equipment and to license and inspect the transfer, receipt, possession and use of radioactive materials, other than special nuclear materials in quantities sufficient to form a critical mass. They also authorize the department to charge registration fees not to exceed a rate of \$50 per year and, subject to the approval by the commissioner and the director of the budget, charge adequate and reasonable fees for licensing, inspection and other radiation protection services not exceeding the estimated costs of such services. Chapter 54 of the Laws of 1999 established the Radiological Health Special Revenue Fund - Other (SRO). Chapter 412, Part L, section 22 of the laws of 1999 allows the deposit of the fees collected by the department into the account of this SRO.

Legislative Objectives

The Legislature amended the Public Health Law in 1955 to empower the department to regulate radiation hazards with the purpose of reducing unnecessary exposure to patients, operators and the public. In the following years, the department instituted a regulatory program in which entities operating radiation equipment or possessing or using radioactive materials in medicine, education or basic research were regulated by the department or by an equivalent program by the New York City Department of Health. The program is progressive, utilizing appropriate changes in technology and radiation protection criteria to ensure that the legislative mandate of protecting the public health and safety is fulfilled.

Section 225(5)(q) of the Public Health Law also authorized the department to recover the cost of the programs by charging adequate and reasonable fees for its regulatory activities. Such fees will enable the program to maintain the staffing level required to conduct a program which meets the legislative mandate. By establishing a Special Revenue Other fund in 1999 and eliminating all support from the general fund, the Legislature intended the program to be funded through fees.

Needs and Benefits

The public and occupationally exposed individuals benefit from a regulatory program which aims at optimizing the exposure needed to maintain the quality objectives of diagnostic or therapeutic administration of radiation to patients while keeping radiation doses as low as reasonably achievable. To that end the department has developed and implemented a radiation protection program which fosters the conduct of effective radiation safety (RS) programs by all regulated entities and quality assurance (QA) programs by medical and chiropractic facilities.

As part of its program, the department registers all installations with radiation equipment outside New York City. The department carries out studies and develops regulations, procedures and guides for acceptable RS/QA programs which reflect the complexity of the programs carried out by the different types of entities it regulates. Installations with radiation equipment are inspected periodically for compliance with the regulations. Inspections are carried out by department staff or by the New York City Department of Health and eight other local health departments certified by the department (CLHU) to conduct all or part of the inspection of installations with radiation equipment within their respective jurisdiction. New York City Department of Health and Dutchess, Niagara, Rockland, Suffolk, Ulster and Westchester County Health Departments inspect all installations with radiation equipment within their respective jurisdictions. Nassau County Health Department inspects medical and chiropractic x-ray facilities. Onondaga County Health Department inspects dental, podiatric and veterinary facilities only. The department also certifies independent Radiation Equipment Safety Officers (RESO) to carry out inspections of dental, podiatric and veterinary facilities outside the areas of jurisdiction of the CLHUs. Department staff conduct all inspections not carried out by CLHU staff or by RESOs. This includes all installations with radiation equipment, other than dental, podiatric or veterinary facilities, in 50 counties of the state.

The department also issues licenses to, and periodically inspects, all entities outside New York City boundaries that possess or use radioactive materials in medicine, education or basic research. In addition to meeting the legislative mandate, the department's program to regulate radioactive materials is also compatible with the program developed by the US Nuclear Regulatory Commission (NRC) for regulating similar entities. The compatibility with the federal program is required under a 1962 agreement between New York State and the US Atomic Energy Commission, the predecessor of the NRC, under which the NRC relinquishes its authority to regulate byproduct materials under the Atomic Energy Act.

In order to conduct a regulatory program which covers both radiation equipment and radioactive materials and which meets the legislative mandate and maintains compatibility with NRC's program, the department estimates that it needs a staff of 26 full-time equivalent positions at a total cost of about \$2.5 million annually. Because of existing funding from other

sources, only a portion, equal to about 75%, of this cost needs to be recovered through fees. The amount of \$1,884,800 was appropriated in FY 2000-2001 budget for the radiation protection program SRO. Fee schedules proposed in this amendment are designed to recover approximately this amount annually.

Costs

Cost to State Government:

This proposal will generate revenue in the amount of \$1,875,000/year for the NYS Department of Health, which will allow it to continue to carry out its radiation protection program, and will result in an equal amount of savings to the state general fund.

Existing regulations exempt all state government facilities from fees. Under this proposal all state government facilities, except for hospitals and higher education institutions operated by government agencies, will continue to be exempt from fees. Non-exempt state facilities will be assessed annual fees, which range from \$880 for a SUNY college to about \$6,145 for a large university with a medical college and a hospital. Other facilities will have annual fees that fall between these two extremes and which depend upon the nature and complexity of their programs in which x-rays or radioactive materials are used. There are 29 currently exempt state operated hospitals and universities/colleges that will pay a total of \$65,085 in fees. Of this total, \$17,660 is for X-ray registrants and \$47,425 for radioactive materials use.

Cost to Local Government:

Existing regulations exempt all local government facilities from fees. Under this proposal all local government facilities, except for 27 community hospitals and higher education institutions (11 have both radiation equipment and radioactive materials license, 14 have radiation equipment and two have radioactive materials licenses only), will continue to be exempt from fees. Non-exempt local facilities will be assessed annual fees which range from \$50 for a community college to about \$3,650 for a large county medical center. Other facilities will have annual fees that fall between these two extremes and which depend upon the nature and complexity of their programs in which x-rays or radioactive materials are used.

Cost to Private Regulated Parties:

There are about 10,400 private installations with radiation equipment and about 500 radioactive material installations that are regulated by the department and will be impacted by this fee proposal. Currently, entities issued radioactive materials licenses by the department pay no fees. Radiation equipment registrants pay a registration fee at the rate of \$20 annually and an inspection fee, if inspected by the department, which ranges from \$86 to \$286 every two to three years. This proposal will increase the fees significantly to all private regulated entities. Fees were developed for the radiation equipment registrants and radioactive material licensees programs separately based on the effort expended by the department on the respective programs. For each program, facilities were divided into six fee categories which are believed to provide an equitable estimate of the department's effort in regulating these entities.

Radioactive Material Licensees/Radiation Therapy Installations:

The proposed annual fees for these entities are as follows:

Fee Schedule for Radioactive Materials Facilities Licensed by NYS DOH

Category	Example	Annual Fee	Total # Paying	Private Installation
I	Large medical center	\$5,265	6	3
II	Large university	\$3,510	13	7
III	Hospitals providing nuclear medicine and brachytherapy	\$1,400	72	70
IV	Hospitals or physicians providing nuclear medicine	\$880	397	370
V	Clinical Laboratories	\$350	36	34
VI	Gas chromatographs	\$50	2	0

Some of the entities will be assessed fees from more than one category. The most likely cases are those of hospitals that provide radiation therapy using accelerators or Co-60 units (Category IV) in addition to nuclear medicine and brachytherapy services (Category III). The highest fee to be assessed will apply to one medical university in the state which will be assessed a radioactive materials/radiation therapy annual fee of \$7,545 (sum of Category I, III and IV fees). Radiation Installations registered with New York State Department of Health:

All private installations with radiation equipment that are registered with the department will pay a registration fee at the rate of \$50 per year and an additional annual fee. Because not all installations with radiation equipment are inspected by the department, two separate fee schedules were developed for the annual fees; one applies to those routinely inspected by the State DOH, and the other for those inspected by a CLHU, or by a CRESO. A registered radiation installation will pay a registration fee plus the applicable annual fee in the schedule below:

Fee Schedule for Radiation Installations Registered with NYS DOH

Category	Example	State Inspected Facilities		Non-State Inspected Facilities	
		Annual Fee	Number Paying	Annual Fee	Number Paying
I	Large Hospital, University or Radiology Practice	\$1,370	22	\$ 425	20
II	Medium Hospital or Radiology Practice	\$1,030	147	\$ 320	112
III	Small Hospital or Radiology Practice	\$ 690	127	\$ 210	116
IV	Physician, Chiropractor - > 750 studies/year	\$ 275	491	\$ 85	852
V	Physician, Chiropractor - < 750 studies/year	\$ 140	238	\$ 45	663
VI	Dentists	\$ 75	- 0 -	\$ 15	7,593

It should be noted that installations not inspected by the department will also pay an inspection fee to the CLHU or CRESO who performs their inspection. Fees assessed by CLHUs and CRESOs vary by county or individual.

Local Government Mandates

Thirty facilities operated by local governments will be required to pay applicable fees as described above.

Paperwork

This amendment requires regulated entities to remit annual payments to the Department. In order to reduce the number of payments, the department will combine the registration fee with the annual fee in one annual bill.

Duplication

This amendment does not duplicate any other state or federal regulations. The US FDA regulates mammography and imposes a fee on facilities providing such services in NY State. In order to avoid duplication, mammography was intentionally left out from the list of modalities which determine x-ray fee categories in this proposed amendment. A facility that only provides mammography services will only pay the \$50 registration fee, but will not be assessed an annual fee by the department.

Alternatives

One alternative is to keep the frequency of inspections and the number of tubes inspected as they currently are. Under this alternative the department collects about \$250,000 annually in registration and inspection fees from installations with radiation equipment. This represents about 10% of the cost of the program. This is not sufficient to support a regulatory program that meets the legislative intent nor compatibility with the NRC program. As indicated in "Needs and Benefits" section above, the department needs to raise about 75% of its program cost from fees in order to maintain a viable regulatory program.

Federal Standards

The proposal does not exceed any federal government standards.

Compliance Schedule

The NY State budget for FY 2000-2001 assumes that the department will support its regulatory program through the SRO established in that budget. Therefore, the proposed fees will become effective upon adoption of this amendment.

Contact Person:

William Johnson, Department of Health, Division of Legal Affairs, Office of Regulatory Reform, Corning Tower, Rm. 2415, Empire State Plaza, Albany, NY 12237, (518) 473-7488, FAX: (518) 473-7488, e-mail: regsqna@health.state.ny.us

Comments submitted to department personnel other than this contact person may not be included in any assessment of public comment issued for this regulation.

Regulatory Flexibility Analysis

Effect on Small Business and Local Governments

The proposed rule will apply to about 9,800 small businesses and 29 local government entities that operate radiation equipment. The small businesses affected include about 6,000 dentists, 740 podiatrists, 740 veterinarians, 1,340 physicians and 940 chiropractors. The local government entities affected include 9 hospitals and 20 colleges and universities.

In addition, about 214 small businesses and 14 local government hospitals and universities, outside New York City, are issued radioactive materials licenses by the department and will be affected by this rule. The small businesses include 22 clinical laboratories, about 164 physicians, 3 Red Cross facilities, 8 veterinarians and 17 research and development facilities.

The only compliance requirement added by this rule is the payment of a fee which will be billed annually. No reporting or recordkeeping is required other than the maintenance of the record of payment.

Professional Services

No new professional services are required to meet the requirements of this amendment.

Compliance Costs

The costs to the affected regulated entities relative to this amendment are limited to the assessed fees. The fees were calculated on the basis of the department's effort to regulate different types of entities. For installations with radiation equipment, the fees vary depending upon the number of radiation equipment modalities registered. For radioactive material licenses, the fees vary depending upon the nature of their use of radioactive materials. Medical facilities performing radiation therapy in addition to using radioactive materials in diagnostic nuclear medicine are assessed a higher fee than those that perform diagnostic procedures only.

Annual fees for radiation installations with radiation equipment that are registered with the department

For installations with radiation equipment that are registered by the department, the assessed fee depends upon whether the entities are inspected by the department staff or other inspecting parties. Eight county health departments perform radiation equipment inspections within their jurisdiction and bill installations for this function. Also, dental, podiatric and veterinary facilities that are not inspected by county health department staff are inspected by independent inspectors, Certified Radiation Equipment Safety Officers (CRESO), certified for that purpose by the department. As a result, two fee levels were developed for the same type of installation, depending upon who routinely inspects them.

Dentists, podiatrists and veterinarians will experience an increase of their annual radiation equipment fees from \$20 to \$65. For 203 chiropractic facilities inspected by department staff the fee will increase from \$50 to \$190 per year. For another 663 chiropractors who are inspected by county health department staff, the increase will be from \$20 to \$95 per year. About 35 physicians who perform less than 750 x-ray examinations will pay \$190 in fees, and another 500 who perform more than 750 examinations per year will pay \$325 per year. The current fee paid by physicians ranges from \$50 to \$65 per year. The 850 physicians not routinely inspected by the department, will see an increase in fees from \$20 to \$95 (<750 exams) or to \$135 (>750 exams).

There are 132 radiologists and radiology clinics inspected by the department. The number of x-ray modalities used by these facilities ranges from one modality with a fee of \$325, to five modalities with a fee of \$1,420 annually. Current fees for radiologists inspected by the department range from about \$50 to \$85. A similar number of radiologists inspected by local health departments will see an increase in fees from \$20 to \$95 (one modality) to \$475 (five modalities).

In addition, eleven hospitals and 13 colleges and universities operated by local governments will no longer be exempted from paying radiation equipment fees to the department. These include nine hospitals that are inspected by the department staff and will be assessed fees ranging from \$125 to \$1,420 annually. Two other hospitals are inspected by CLHD staff and will be assessed an annual fee of \$475 each.

Seven colleges/universities operated by local government are inspected by department staff and will be assessed fees of \$125 to \$1,080 annually. Six others are inspected by CLHD staff and will be assessed fees that range from \$65 to \$370 annually.

Twenty-seven local/community hospitals and colleges will pay a total fee of \$26,150 in fees. Of this total, \$12,820 are for X-ray registrants and \$13,330 for radioactive materials users.

Annual fees for entities holding a radioactive material license issued by the department and certain installations using accelerators for medical therapy

No radioactive materials fees are currently paid by any of the regulated entities. The amount of such fees that are proposed to be assessed to the different small business and local government entities depend upon the

nature of their use of the radioactive materials. The annual fees for small businesses will range from about \$50 for a facility that only operates a gas chromatograph to \$880 for physicians licensed to use radioactive materials in nuclear medicine or cardiology procedures. A clinical laboratory will be assessed a fee of \$350. Eight veterinary facilities using radioactive materials in animal care will be assessed a fee of \$880 each. American Red Cross sites that use radioactive materials sources will be assessed a fee of \$350 each. The cost to local government colleges using radioactive materials ranges from \$50 to \$880 for a college with a more involved use of radioactive materials in educational and research programs. Fees to local government hospitals range from \$880 for use in diagnostic nuclear medicine to \$3,160 for a large county medical center active in research, clinical medicine and radiation therapy.

Minimizing Adverse Impact

The estimated fee recovers about 75% of the total cost to the department of its regulatory radiation protection program. Other sources of funds are used to make up for the remaining 25% of the cost which reduces the adverse fiscal impact on the regulated facilities. Also, government operated hospitals, colleges and universities that were previously exempted from the fees will now be assessed fees which helps reduce the amount charged to private facilities.

Feasibility Analysis

The proposed amendment will result in increased fees for regulated entities, as described above. However, the amount of the fees assessed depend upon the nature of the programs and, in some cases, the volume of the services provided by facilities. Those providing a lower volume of x-ray services will pay less than those providing a higher volume of x-ray services or a wider range of services.

Small Business and Local Government Participation

The fee schedules proposed in this amendment were shared with all local health departments and 15 of the small businesses affected by the proposal. It was also shared with the Radiological Society of New York State, the New York State Chiropractic Association, the New York State Medical Society, all local chapters of the Dental Society of New York State, the Healthcare Association of New York State, the Campus Radiation Safety Officers and the Certified Radiation Equipment Safety Officers.

Reporting, Record Keeping and Other Compliance Requirements

The only compliance requirement added by this rule is the payment of a fee which will be billed annually. No additional reporting, record keeping or other compliance requirements are imposed by this amendment.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas

Approximately 2430 rural facilities statewide will be assessed higher fees to support the regulatory program. These include about 85 hospitals and clinics, 307 physicians, 144 chiropractors, 1250 dentists, 266 podiatrists, 327 veterinarians, 5 clinical laboratories and 46 educational facilities.

Professional Services

No additional professional services will be needed in rural areas in order to comply with the proposed amendment.

Costs

There are two separate fee schedules, one for radiation installations registered with the department that use or possess radiation equipment and another for persons holding a radioactive material license issued by the department or a radiation installation registered with the department and that uses an accelerator for medical therapy. Facilities that have both radiation equipment and radioactive materials are subject to fees from both schedules. All the facilities in rural areas are inspected by the department, or CRESOs, with the exception of Ulster County, which conducts an x-ray equipment inspection program under the auspices of the department. The increase in annual fees for all rural facilities are given in the following table:

See Appendix printed in the back of this issue.

Minimizing Adverse Impact

The estimated fee recovers about 75% of the total cost to the department of the regulatory program. Other sources of funds are used to make up for the remaining 25% of the cost which reduces the adverse fiscal impact on the regulated facilities. Also, government operated hospital, colleges and universities, which were previously exempted from fees under Part 16, will now be assessed fees which helps reduce the amount charged to private entities.

Rural Area Participation

This amendment was shared with the Radiological Society of New York State, the New York State Chiropractic Association, the New York

State Medical Society, the Dental Society of New York State, the Healthcare Association of New York State, the Campus Radiation Safety Officers and the Certified Radiation Equipment Safety Officers. These organizations have membership from and interest in rural areas. Letters were sent to about 20 individual practitioners, colleges and universities in rural areas.

Comments submitted to department personnel other than this contact person may not be included in any assessment of public comment issued for this regulation.

Job Impact Statement

Nature of Impact

Some of the physicians who perform a small number of x-ray examinations may discontinue their x-ray service or stop employing a radiologic technologist in their offices because of the increase in fees.

Categories and Numbers Affected

As most physicians with low x-ray workload have already discontinued providing such services from their offices, the number of radiological technologists' jobs which may be eliminated as a result is expected to be quite small (less than 5).

Regions of Adverse Impact

No specific region of the state is expected to be impacted by this amendment more than others, except that New York City facilities are not affected by this proposal.

Minimizing Adverse Impact

Facilities most likely to feel the fiscal impact are the ones with a smaller volume of x-ray studies. These facilities are assessed a smaller fee than similar facilities with a larger number of patient exams. Thus, facilities with larger incomes from x-ray services carry a larger portion of the fee burden.

Self-employment Opportunities

The department uses CRESOs to perform x-ray inspections of dental, podiatric and veterinary facilities outside counties with CLHUs. The fees assessed from these facilities are kept low (\$65 per year) and should not result in the closing of any of these facilities. Therefore, no adverse impact is expected which will reduce the self-employment opportunities of the CRESOs.

**Fees for Installations with Radiation Equipment that are in Rural Counties
 and Inspected by NYS DOH Staff**

Type of Facilities	Category	Est. Current Fee ¹	Proposed Fee ²	Number Registered	Total Proposed Fee
Facility with 5 or more modalities (e.g. large hospital or university)	I	\$133	\$1420	0	0
Facility with 3-4 modalities (e.g. medium hospital, large radiology practice)	II	\$103	\$1080	75	\$ 81,000
Facility with 2 modalities (e.g. small hospital, small radiology practice)	III	\$83	\$740	5	\$ 3,700
Physician, chiropractor >750 studies/year	IV	\$63	\$325	271	\$88,075
Physician, chiropractor <750 studies/year, colleges	V	\$47	\$190	179	\$34,010
Bone densitometer	VI	\$37	\$125	21	\$2,625
Dentist, veterinarians, podiatrists ³	VI	\$20	\$65	1,733	\$112,645
Total – Under proposed fee					\$322,055
Under current fee					\$69,063
Increase					\$252,992

**Fees for Installations with Radiation Equipment that are Located in Ulster County
 and Inspected by Ulster County Health Dept. Staff⁴**

Type of Facilities	Category	Est. Current Fee ¹	Proposed Fee ²	Number Registered	Total Proposed Fee
Facility with 5 or more modalities (e.g. large hospital or university)	I	\$20	\$ 475	0	0
Facility with 3-4 modalities (e.g. medium hospital, large radiology practice)	II	\$20	\$ 370	4	\$ 1,480
Facility with 2 modalities (e.g. small hospital, small radiology practice)	III	\$20	\$ 260	1	\$ 260
Physician, chiropractor >750 studies/year	IV	\$20	\$ 135	13	\$ 1,755
Physician, chiropractor <750 studies/year, colleges	V	\$20	\$ 95	13	\$ 1,235
Bone densitometer, dentist, veterinarians, podiatrists	VI	\$20	\$ 65	110	\$ 7,150
Total – Under proposed fee					\$ 11,880
Under current fee					\$ 2,820
Increase					\$ 9,060
Increase including all rural counties					\$ 262,052

¹ Includes \$20 annual registration fee

² Includes \$50 annual registration fee

³ Normally inspected by and pay an additional inspection fee to CRESOs.

⁴ Facilities pay an additional fee to Ulster County for inspection services

**Fees for Radioactive Materials Licensees and Radiation Installations that Use Accelerators
for Medical Therapy that are in Rural Counties**

Type of Facilities	Category	Proposed Fee	Number Licensed	Total Fees
Broad scope medical license	I	\$5,265	0	0
Broad scope academic or broad scope and research development license	II	\$3,510	1	\$3,510
Specific license which allows the use of radioactive materials for both nuclear medicine and brachytherapy, or a license which authorizes the operation of a nuclear pharmacy at an institution pharmaceutical production cyclotron	III	\$1,400	0	
Facilities operating a medical therapy accelerator and/or facilities issued a specific license which authorizes the use of radioactive materials in nuclear medicine, brachytherapy, mobile nuclear medicine service, teletherapy (including Co-60 teletherapy and gamma knife), research and development, academic uses, veterinary medicine or large irradiators	IV	\$ 880	37	\$ 32,560
Specific license which authorizes the use of radioactive materials in a clinical laboratory, lead paint analyzers, mobile nuclear medicine sites, leak tests, equipment calibration, self shielded irradiators, diagnostic sealed sources, and any other use not included in categories I through VI as listed in this subdivision.	V	\$ 350	5	\$1,750
Specific license for use of radioactive materials in gas chromatographs.	VI	\$ 50	1	\$ 50
Total				\$ 37,870
Total New Radioactive Materials and X-Ray Fees from rural areas.				\$ 299,922

NEW YORK STATE DEPARTMENT OF HEALTH -RADIATION PROTECTION FEE PROPOSAL
New language is underlined; brackets indicate deleted language.

Pursuant to the authority vested in the Public Health Council by Section 225 of the Public Health Law, Part 16 of the State Sanitary Code, as contained in Chapter 1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is hereby amended as follows:

Paragraph (1) of subdivision (a) of section 16.10 is amended to read as follows:

(1) Any radiation installation subject to the registration requirements of section 16.50(a) of this Part shall be [surveyed] inspected periodically to assure compliance with this Part and the maintenance of radiation exposures as far below the limits set forth in this Part as is reasonably achievable. [The person who establishes, maintains or operates such radiation installation shall, when the installation is inspected by the State Department of Health or a health officer having jurisdiction, as provided in this paragraph, pay the inspection fee or fees charged for the inspection pursuant to section 16.21 of this Part. Payment shall be made, within 30 days after the billing date, to, and in the manner prescribed by, the department or the health officer having jurisdiction, whichever made the inspection.] Except as otherwise provided in subparagraph (ii) of this paragraph, [such] inspections shall be made at a frequency as specified in subparagraph (i) of this paragraph, with the first inspection of an installation to be made at the time of the beginning of operation and subsequent inspections not to exceed the maximum interval specified for such installation in subparagraph (i) of this paragraph. The inspection shall be performed in a manner, and reported in writing on a form, prescribed by the department. The person who makes the inspection shall include in such report all recommendations necessary to accomplish compliance with this Part, and to reduce radiation exposure as far below the limits set forth in this Part as reasonably achievable. The inspection shall be made by the department, the New York City Department of Health or, as the department shall direct, by the appropriate county or part-county health officer having jurisdiction or by a certified radiation equipment safety officer. Such county or part county [,] health officer or the New York City health commissioner shall make the inspection only under an inspection program that is [conducted by him/her and] certified by the department in writing [to him/her] as approved and in effect. He/she may make the inspection [him/herself] or have it made by [his/her] a duly authorized representative approved for such purpose by both such health officer and the department. The operator of an installation required to be inspected by a certified radiation equipment safety officer, shall be solely responsible for having all such required inspections made. [The requirement of the payment of inspection fees shall not apply to the State of New York or any political subdivision thereof or any agency or instrumentality of either.]

Existing subparagraph (iv) of paragraph (1) of subdivision (a) of section 16.10 is hereby REPEALED.

Existing section 16.21 is REPEALED and reserved.

New section 16.40 is added to read as follows:

16.40 Fees

(a) General requirement. Unless exempt under subdivision (b) of this section, no person shall establish, maintain or operate a radiation installation with radiation equipment, that is subject to the registration requirements of section 16.50 of this Part, or hold a radioactive materials license as required pursuant to the licensing requirements of section 16.100 of this Part, except upon payment of the applicable fees prescribed in this section and section 16.41 of this Part.

(b) Exemptions. (1) Agencies of the State of New York and its political subdivisions, except for hospitals and higher education academic institutions operated by such agencies, are exempt from the payment of any of the fees prescribed in this section and section 16.41 of this Part.

(2) Any operator of a radiation installation that is registered with the New York City Department of Health or any person that holds a radioactive material license issued by the New York City Department of Health, pursuant to section 16.50(j) and section 16.1(b)(3), respectively, of this Part is exempt from paying the fees prescribed in this section and section 16.41 of this Part, unless they also hold a registration certificate or a radioactive material license issued by the department for which fees are applicable. In the latter case, the applicable fees for the activities registered or licensed by the department shall be assessed.

(c) Payment of fees. (1) Each application for a radiation installation registration or for a new radioactive material license, shall be accompanied by a remittance of the full amount of the applicable annual fees prescribed in section 16.41 of this Part. Annual fees for each subsequent year shall become due on each anniversary date thereafter, determined by the date of original registration or license issued.

(2) Any operator of a radiation installation who holds a current radiation installation registration certificate issued pursuant to this Part or any person who holds a current radioactive material license issued pursuant to this Part, shall pay the prescribed annual fee as billed by the department. Payment of fees shall be made within the 30 day period immediately following the billing date. A late payment charge will be assessed at the rate of one and one half percent for each 30 day late period or part thereof.

(3) The payment of all fees prescribed by this Part shall be by check or money order made payable to the New York State Department of Health.

(d) Prorating fees. For administrative purposes, the department may alter the fee due date and charge a fee for a period greater or less than one year. In such case the amount of the fee due will be prorated to correspond to the length of the period covered by the bill.

(e) No refund policy. Except in those cases where the department has determined that a payment of fees is not required, no fees, or portions thereof, paid to the department pursuant to this Part shall be refundable.

(f) Failure to pay prescribed fee. If an applicant for a license or registration fails to remit with such application the full amount of the fees as prescribed by this Part, the department will not process the application and will notify the applicant that the application will not be processed unless fees are first paid. The department may revoke, suspend or amend a registration or radioactive material license in whole or in part for failure to pay all prescribed annual fees due.

(g) Registration fees charged by New York City Department of Health. Provided that a written schedule of the registration fees to be charged by the New York City Department of Health, not to exceed \$50 per year per installation, has been submitted, in the manner prescribed, to, and approved by, the State Commissioner of Health, the New York City Department of Health is authorized to charge within its jurisdiction registration fees as so approved. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(h) Fees charged by local health departments. Provided that a written schedule of the fees to be charged,

together with a written analysis of the estimated costs of its radiation protection regulatory program, has been submitted to and approved by the State Commissioner of Health, the New York City Department of Health or, as the department shall direct, the appropriate county or part-county health officer having jurisdiction that inspects installations with radiation equipment under a program of inspection certified by the State Department of Health, or any county, part-county or city health district that licenses and inspects radioactive materials in accordance with Section 16.1(b)(3) of this Part, is authorized to charge adequate and reasonable fees for inspection, licensing and/or other radiation protection services rendered, as applicable, not exceeding the estimated costs of such services, except that, with the approval of the State Commissioner of Health, one or more of such services may be rendered without charge. The State of New York or any political subdivision thereof or any agency or instrumentality of either are exempt from the payment of such fees.

(i) Fees charged by certified radiation equipment safety officers. A certified radiation equipment safety officer shall not charge, or propose to charge, a fee for an inspection in excess of a fair and reasonable amount as determined by the department. Such officer shall furnish to the department, upon request, information as to fees charged or proposed to be charged by the officer. Such fees shall not exceed the estimated cost of services.

(j) Fees paid prior to the effective date of this section. Facilities that had paid fees which cover a period that extends beyond the effective date of this section, shall be responsible for the difference between the prorated amount of any fee previously paid for such period and that due under this section for such period.

New section 16.41 is added to read as follows:

16.41 Fee schedule.

Effective upon adoption, the annual fees assessable shall be as prescribed in this section.

(a) Registration fees. Except for entities exempt from fees under section 16.40(b)(1) of this Part, the annual registration fee for radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part is \$50.

(b) Fee categories for radiation installations required to be registered with the department. For the purpose of assessing annual fees, all radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are categorized in one of the following six categories:

Category I: Radiation installations with any five or more of the modalities listed below.

Category II: Radiation installations with three or four of the modalities listed below.

Category III: Radiation installations with two of the medical modalities listed below.

Category IV: Radiation installations with one of the medical modalities listed below and annual patient workload of 750 examinations or more.

Category V: Radiation installations with one of the medical modalities listed below and annual patient workload of less than 750 examinations, and all other radiation installations with one or two of the non-medical modalities listed below except as listed under Category VI.

Category VI: Dental, podiatric, bone densitometry or veterinary installations.

The modalities to be used in determining the fee category for radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part are:

Medical Modalities: radiography, fluoroscopy, computed tomography, angiography, stereotactic breast biopsy systems, and Grenz/orthovoltage therapy, utilized in humans.

Non-medical Modalities: radiography, fluoroscopy, analytical equipment (including electron microscopes, fluorescence analysis and x-ray diffraction equipment), computed tomography and particle accelerators, not utilized on humans.

(c) Fee schedule for radiation installations routinely inspected by the department. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed annual fees according to the following schedule:

<u>Category I radiation installations:</u>	<u>\$1,370</u>
<u>Category II radiation installations:</u>	<u>\$1,030</u>
<u>Category III radiation installations:</u>	<u>\$ 690</u>
<u>Category IV radiation installations:</u>	<u>\$ 275</u>
<u>Category V radiation installations:</u>	<u>\$ 140</u>
<u>Category VI radiation installations:</u>	<u>\$ 75</u>

(d) Fee schedule for radiation installations routinely inspected by a county or part-county health officer or by a certified radiation equipment safety officer. All radiation installations required to be registered with the department pursuant to section 16.50(a) of this Part that are not exempt from fees under section 16.40(b) of this Part and that are routinely inspected by a county or part-county health officer having jurisdiction, as the department shall direct, under a program certified by the department, or by a certified radiation equipment safety officer as directed by the department shall, in addition to the registration fee prescribed in subdivision (a) of this section, be assessed an annual fee according to the following schedule:

<u>Category I radiation installations:</u>	<u>\$ 425</u>
<u>Category II radiation installations:</u>	<u>\$ 320</u>
<u>Category III radiation installations:</u>	<u>\$ 210</u>
<u>Category IV radiation installations:</u>	<u>\$ 85</u>
<u>Category V radiation installations:</u>	<u>\$ 45</u>
<u>Category VI radiation installations:</u>	<u>\$ 15</u>

(e) Fee categories for radioactive material licensees and radiation installations that use accelerators in medical therapy. For the purpose of assessing annual fees, all persons holding radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department, pursuant to section 16.50(a) of this Part and that use accelerators in medical therapy are categorized in one or more of the following six categories:

- Category I: Persons issued a broad scope medical license.
- Category II: Persons issued a broad scope academic or broad scope research and development license.
- Category III: Persons issued a specific license which allows the use of radioactive materials for both nuclear medicine and brachytherapy, or a license which authorizes the operation of a nuclear pharmacy at an institution or a pharmaceutical production cyclotron.
- Category IV: Radiation installations operating a medical therapy accelerator and/or persons issued a specific license which authorizes the use of radioactive materials in nuclear medicine, brachytherapy, mobile nuclear medicine service, teletherapy (including Co-60 teletherapy and gamma knife), research and development, academic uses, veterinary medicine or large irradiators.
- Category V: Persons issued a specific license which authorizes the use of radioactive materials in a clinical laboratory, lead paint analyzers, mobile nuclear medicine sites, leak tests, equipment calibration, self-shielded irradiators, diagnostic sealed sources, and any other use not included in categories I through VI as listed in this subdivision.
- Category VI: Persons issued a specific license for use of radioactive materials in gas chromatographs.

(f) Radioactive materials/medical therapy accelerator fee schedule. (1) Except for entities exempt from fees under section 16.40(b) of this Part, all persons that hold radioactive material licenses issued by the department and all radiation installations that are required to be registered with the department and that use accelerators in medical therapy shall be assessed annual fees according to the following schedule:

<u>Category I:</u>	<u>\$5,265</u>
<u>Category II:</u>	<u>\$3,510</u>
<u>Category III:</u>	<u>\$1,400</u>
<u>Category IV:</u>	<u>\$ 880</u>
<u>Category V:</u>	<u>\$ 350</u>
<u>Category VI:</u>	<u>\$ 50</u>

(2) When more than one fee category as described in section 16.41 (e) of this Part applies the fee which corresponds to the highest applicable category will be assessed, provided, however, that separate Category III fees will be assessed to any person that holds a license to operate a nuclear pharmacy or a pharmaceutical production cyclotron for each type of these uses that applies, in addition to any other categories of fees that apply; and radiation installations or licensees that provide teletherapy (Co-60, gamma knife or a medical therapy accelerator) services or veterinary medicine services, or use radioactive materials in large irradiators or, except for Category I or II licensees, use radioactive materials in research and development, will be assessed Category IV fees for each type of these uses that applies, in addition to any other categories of fees that apply. If a person that holds a radioactive material license is also the operator of a radiation installation that uses an accelerator in medical therapy and the licensed activities are conducted at such installation, the licensed radiation installation shall be considered as one and the same entity for purposes of assessing fees described under section 16.41(e) of this Part.

Paragraph (a) of section 16.50 is amended to read as follows:

16.50 Registration of installations with radiation equipment; [authorized registration fees;] notification of transfer of radiation equipment. (a) No person shall establish, maintain or operate any radiation installation at which is located or used any radiation equipment in operable condition or intended to be used, unless such installation has been registered as evidenced by a current certificate of registration issued to the operator thereof by the department or has been registered in an alternate manner accepted by the department in accordance with

subdivision (j) of this section.¹⁰ [The operator of each radiation installation required to be registered with the department shall, at the time when application for registration is required to be made as provided in subdivision (b) of this section, pay to, and in the manner prescribed by, the department a registration fee of \$40 per installation for each biennial period of registration. For administrative purposes, the department may charge a registration fee for a period of registration greater or less than two years prorated at five dollars per installation for each three months and any remainder exceeding one and one-half months. Payment of a fee of five dollars shall be required for the issuance of each duplicate registration certificate and each registration certificate issued to replace one voided by a change in location of a radiation installation without a change of operator. In the latter case, the five-dollar fee shall not be required if the change of location necessitates extension of the registration of the installation for a period requiring payment of at least one year's registration fee. The total amount of the registration fee plus the additional fees for lateness of application and the issuance of duplicate and replacement registration certificates shall not exceed a limit of \$100 for a biennial period of registration of an installation. For a period of registration other than biennial, such limit shall be computed at \$12.50 per installation for each three months and any remainder exceeding one and one-half months. No fees, or portions thereof, paid for registration or for the issuance of registration certificates, shall be refunded by reason of the discontinuance, relocation, change of operator, or revocation of the registration certificate of an installation during the period for which the fees were paid. Provided that a written schedule of the registration fees to be charged has been submitted to, in the manner prescribed, and approved by the State Commissioner of Health, any officer or agency, registration with whom is accepted by the department in lieu of registration with the department in accordance with subdivision (j) of this section, is authorized to charge registration fees not to exceed a rate of \$50 per installation per annum. The requirement of the payment of registration fees and fees for registration certificates shall not apply to the State of New York or any political subdivision thereof or any agency or instrumentality of either.]

¹⁰ Radiation equipment exempted from the requirements of this Part under section 16.4 is exempt from the registration requirement.