NOV 19 1996

Mr. Ronald Tramontano, Director
Center for Environmental Health
New York State Department of Health
II University Place
Albany, New York 12203-3399

Dear Mr. Tramontano:

Thank you for your letter of April 29, 1996, responding to our review of the New York State Department of Health (NYSDOH) radiation control program (RCP). We recognize our delay in responding to your letter; however, some of your responses required additional review. The information provided in your letter directly responded to program review findings and addressed our comments and recommendations.

The NRC evaluation of the RCP responses relative to those items identified in our March 18, 1996 letter and review report is enclosed. Some of the comments and recommendations made during the review were satisfactorily addressed and are closed. The State's response to comments and recommendations regarding the indicator "Status and Compatibility of Regulations" will be reviewed after the Commission's approval of the implementing procedures for the Policy Statement on Adequacy and Compatibility of Agreement State Programs. We will review the status of this item as a part of our next program review.

Thank you for your continued support of the NYSDOH program.

Sincerely, Original Signed By RICHARD L. BANGART

Richard L. Bangart, Director
Office of State Programs

Enclosure:
As stated

cc w/encl: Karim Rimawi, Director
Bureau of Environmental Radiation Protection
Jack P. Spath, NYSERDA

Distribution:

DIR RF (6S-170)	DCD (SP01)	RLBangart
PDR (YES X__ NO___)	PLohaus	SDroggitis
Cmaupin	CGordon, RI	WHehl, RI
NYSDOH File		

DOCUMENT NAME: G:\CHM\95ACKLTR.NYS ** Concurrence by e-mail *See previous concurrence.

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFC	RSAO	DNMS	OSP	OSP:DD		OSP:D
NAME	CGordon	WHehl	CMaupin	PLohaus		RLBangart
DATE	7/8/96**	7/8/96**	06/13/96*	06/13/96*		06/ /96

OSP FILE CODE: SP-AG-20-2

SP-AG-20-2

NRC FILE CENTER COPY

Mr. Ronald Tramontano
Director
Center for Environmental Health
New York State Department of Health
II University Place
Albany, New York 12203-3399

Dear Mr. Tramontano:

Thank you for your letter of April 29, 1996, responding to our review of the New York State Department of Health (NYSDOH) radiation control program (RCP). The information provided in your letter directly responded to program review findings and addressed our comments and recommendations. Enclosed is the NRC evaluation of RCP responses relative to those items identified in our March 18, 1996 letter and review report.

Thank you for your continued support of the NYSDOH program.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosure:
As stated

cc w/encl: Karim Rimawi, Director
Bureau of Environmental Radiation Protection
Jack P. Spath, NYSERDA

Distribution:

DIR RF (6S120)	DCD (SP02)	RLBangart	
PDR (YES_X__ NO___)	PLohaus	SDroggitis	
Cmaupin	CGordon	WHehl	Fcameron
NYSDOH File			

DOCUMENT NAME: G:\CHM\95ACKLTR.NY
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFC	RSAO	DNMS	OSP	OSP:D	OSP:DD	OGC
NAME	CGordon	WHehl	CMaupin	PLoh	RBangart	Fcameron
DATE	06/ /96	06/ /96	06/ /96	06/ /96	06/ /96	06/ /96

OSP FILE CODE: SP-AG-20-2

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

November 19, 1996

Mr. Ronald Tramontano, Director
Center for Environmental Health
New York State Department of Health
II University Place
Albany, New York 12203-3399

Dear Mr. Tramontano:

Thank you for your letter of April 29, 1996, responding to our review of the New York State Department of Health (NYSDOH) radiation control program (RCP). We recognize our delay in responding to your letter; however, some of your responses required additional review. The information provided in your letter directly responded to program review findings and addressed our comments and recommendations.

The NRC evaluation of the RCP responses relative to those items identified in our March 18, 1996 letter and review report is enclosed. Some of the comments and recommendations made during the review were satisfactorily addressed and are closed. The State's response to comments and recommendations regarding the indicator "Status and Compatibility of Regulations" will be reviewed after the Commission's approval of the implementing procedures for the Policy Statement on Adequacy and Compatibility of Agreement State Programs. We will review the status of this item as a part of our next program review.

Thank you for your continued support of the NYSDOH program.

Sincerely,

Richard L. Bangart

Richard L. Bangart, Director
Office of State Programs

Enclosure:
As stated

cc w/encl: Karim Rimawi, Director
Bureau of Environmental Radiation Protection
Jack P. Spath, NYSERDA

EVALUATION OF NEW YORK RESPONSES TO MARCH 18, 1996 PROGRAM REVIEW

NRC has reviewed the responses contained in the April 29, 1996, letter from Mr. R. Tramontano, Director, Center for Environmental Health, NYSDOH, to Mr. R. Bangart, Director, NRC Office of State Programs. Those items which were closed based upon the State's response are discussed below. Other items, which were addressed in the response, will remain open and will be assessed during the next review of the State's program.

The March 18, 1996 letter from R. Bangart, Director, OSP to B. DeBuono, M.D., Commissioner, New York State Department of Health provided the following recommendations.

1. Status and Compatibility of Regulations (Category I)

Recommendation

(1) We recommend that the NYSDOH adopt the Decommissioning Rule as soon as possible.

(2) We recommend that NYSDOH revise its Quality Management (QM) rule definitions, "written directive," "prescribed dose," and "prescribed dosage," by December 6, 1996 in order to be compatible with those of the NRC.

(3) We recommend that NYSDOH perform a review of its licensees based upon the EP rule requirements; the results of the review should be documented and provided to the NRC to confirm that no licensees meet the requirements of this rule. NYSDOH may defer rule adoption provided action is taken to adopt the applicable portions of the EP rule if an application subject to the provisions of the rule is received. Until the NYSDOH rule becomes effective, the applicable provisions of the EP rule should be incorporated through license condition.

NYSDOH April 29, 1996 Response

(1) The NYSDOH's legal staff advised the Department that they cannot adopt the decommissioning rule as written due to a lack of legal authority to expend funds paid to the State with the Department of Health as a trustee. NYSDOH will achieve compliance instead through the use of a reasonable alternative where they will require medical and educational institutions to submit a statement of intent to demonstrate financial assurance. Given that NRC is in the process of amending its compatibility policy statement, and we expect the states to be granted greater flexibility in achieving compatibility, it would be very difficult for us to justify a costly and time consuming rulemaking effort on this issue. Therefore, we will implement this approach through license conditions and require our licensees to submit statements of intent for financial assurance for decommissioning.

The Department regulates over 540 licenses most of which are medical or academic institutions or governmental agencies. We do not regulate industrial or commercial facilities. Most of our licensees use only

short-lived materials, sealed sources and/or small quantities of radioactive materials. A review of license files indicate that only 11 non-governmental facilities would actually need to provide financial assurance. These facilities are well-established institutions that present a small risk of "going out of business." Further, it is our understanding that the State of Florida's financial assurance rule, which has been in place for several years, exempts hospitals and universities from their bonding requirements. Florida's radiation control program has been found to be both adequate and compatible in it's most recent review (1995).

If we were to follow the Florida example, none of our licensees would be required to do anything on this issue. However, we are not proposing to follow that model, but to require facilities to provide us with sufficient surety within the limitations of the Department's legal authority.

(2) The Department's position on this issue is clearly dated in a letter dated March 16, 1995, from Stephen Gavitt to Paul Lohaus. We believe that despite the absence of the three definitions from our regulations, our quality assurance requirements include all the elements of the NRC's QM rule. Again, since the NRC is revising its final policy on compatibility and the status of its QM rule, coupled with the procedural difficulties in promulgating new regulations in New York State, we feel it would be more prudent for us to await the final NRC compatibility policy and QM rule prior to making changes to our regulations. Once NRC's positions are finalized, we will review our rules for compatibility as it applies at that time.

(3) The Department has performed a review of its licensees based upon the NRC Emergency Planning rule requirements. The results indicate that we do not currently authorize any licensee to possess radioactive materials in quantities sufficient to require an emergency plan. Should the Department receive an application subject to the provisions of this rule, then we would incorporate the applicable Emergency Planning provisions in license conditions pending adoption of the rule.

Evaluation of State's Response

(1) Currently, without State adoption of the decommissioning rule a determination on compatibility cannot be made. The legal limitations and information identified in the State's response to meet the intent of the rule will be reviewed after Commission approval of the implementing procedures for the new adequacy and compatibility policy statement. This item remains open.

(2) As noted in the NRC letter of March 18, 1996, we encourage the State to revise QM rule definitions to make them compatible with those of the NRC by December 6, 1996. Since NYSDOH has not completed this action, we will re-evaluate this issue after Commission approval of the implementing procedures for the new adequacy and compatibility policy statement. This item remains open.

(3) The State's actions are appropriate to address the recommendation and this item is closed.

2. Responses to Incidents and Alleged Incidents (Category I)

We recommend that the NYSDOH consider, in those cases where an allegation appears directly related to significant health and safety matters, that the program perform timely and on-site investigations to independently assess allegations, such as the misadministration allegation. Criteria should be established for use in decision-making about which allegations are referred to licensees for evaluation. For those allegations referred to licensees, NYSDOH should conduct assessments of licensee evaluations. It is also recommended that the program maintain complete files showing actions taken and how allegations are resolved.

NYSDOH April 29, 1996 Response

An inspection has been scheduled for the facility in question to be conducted in May 1996. The inspector has been instructed to review all pertinent records and information relating to the allegation and to collect information on actions the licensee has taken. Such information will be maintained in a computer file clearly indicating actions taken and how the allegation was resolved.

Evaluation of State's Response

The State's actions are appropriate to address the recommendation regarding the facility in question. Internal procedures should also be modified, as necessary, to contain appropriate guidance regarding allegation investigation and circumstances under which allegation referral to licensees is appropriate. This item is closed.

(FYI) RLB2 PHL SLD

EXECUTIVE TASK MANAGEMENT SYSTEM

<<< PRINT SCREEN UPDATE FORM >>>

TASK # - 6S120 DATE- 05/03/96 MAIL CTRL. - 1996

TASK STARTED - 05/03/96 TASK DUE - 05/17/96 TASK COMPLETED - / /

TASK DESCRIPTION - 4/29/96 RESPONSE FROM NY STATE DOH RE NRC REVIEW AND EVALUATION OF NY PROGRAM

REQUESTING OFF. - NYSDOH REQUESTER - R. TRAMONTANO WITS - 0 FYP - N

PROG.- CG/CHM PERSON - STAFF LEAD - CG/CHM PROG. AREA -

PROJECT STATUS -

DRAFT TO MANAGEMENT DUE: 5/17/96

PLANNED ACC. - N FINAL LETTER TO NY STATE DOH: 6/3/96

LEVEL CODE - 1

DCD (SP01)

RLB2
PHL
SCO
CHM
White Flint
(SP-120)

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Office of Public Health II University Place Albany, New York 12203-3399

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

Karen Schimke
Executive Deputy Commissioner

April 29, 1996

96 MAY -3 AM 7:44
OSP

Richard Bangart, Director
Office of State Programs
United States Nuclear Regulatory Commission
Mail Stop 3-D-23
Washington, D.C. 20555

Dear Mr. Bangart:

Commissioner DeBuono asked that I respond to your letter of March 18, 1996, and the report on the results of the Nuclear Regulatory Commission's review and evaluation of New York State's radiation control program. Enclosure #2 of your letter lists items that remain open and require a specific response. Following is the Department's response to the items listed in that enclosure relating to the Department of Health.

Decommissioning Rule, 10 CFR 30, 40 and 70

As indicated in the NRC report, the Department of Health could not adopt the NRC rule as written. The Department's legal staff advised that the Department lacked the legal authority to expend funds paid to the State with DOH as trustee. We will achieve compliance instead through the use of a reasonable alternative where we require medical and educational institutions to submit a statement of intent as a means to demonstrate financial assurance. Given that NRC is in the process of amending its compatibility policy statement, and that we expect the states to be granted greater flexibility in achieving compatibility, it would be very difficult for us to justify a costly and time consuming rulemaking effort on this issue. Therefore we will implement this approach through license conditions and require our licensees to submit statements of intent for financial assurance for decommissioning.

The Department regulates over 540 licensees most of which are medical or academic institutions or government agencies. We do not regulate industrial or commercial facilities. Most of our licensees use only short-lived materials, sealed sources and/or small quantities of radioactive materials. A review of our license files indicates that only 11 nongovernment facilities would actually need to provide financial assurance (Enclosure #1). These facilities are well established institutions that present a small risk of "going out of business." Further, it is our understanding that the State of Florida's financial assurance rule, which has been in place for several years, exempts hospitals and universities from their bonding requirements. Florida's radiation control program has been found to be both adequate and compatible in it's

~~9605130132~~ 7 pp.

SP-AE-20-2

most recent review (1995).

If we were to follow the Florida example, none of our licensees would be required to do anything on this issue. However, we are not proposing to follow that model, but to require facilities to provide us with sufficient surety within the limitations of the Department's legal authority.

Emergency Planning Rule

The Department has performed a review of its licensees based upon the NRC Emergency Planning rule requirements. The results indicate that we do not currently authorize any licensee to possess radioactive materials in quantities sufficient to require an emergency plan. Enclosure #2 is a table of our broad scope and other large licensees indicating their possession limits and the corresponding R values for the Emergency Planning rule. Should the Department receive an application subject to the provisions of this rule then we would incorporate the applicable Emergency Planning provisions in the license conditions pending adoption of the rule.

QM Rule Definitions

The Department's position on this issue is clearly stated in a March 16, 1995 letter from Stephen Gavitt to Paul Lohaus (Enclosure #3). We believe that despite the absence of the three definitions from our regulations, our quality assurance requirements include all the elements of the NRC's QM rule. Again, since the NRC is revising its final policy on compatibility and the status of its QM rule, coupled with the procedural difficulties in promulgating new regulations in New York State, we feel it would be more prudent for us to await the final NRC compatibility policy and QM rule prior to making changes to our regulations. Once NRC's positions are finalized, we will review our rules for compatibility as it applies at that time.

Response to Allegations

An inspection has been scheduled for the facility in question to be conducted in May 1996. The inspector has been instructed to review all pertinent records and information relating to the allegation and to collect information on actions the licensee has taken. Such information will be maintained in a complete file clearly indicating actions taken and how the allegation was resolved.

We appreciate the thorough review made by the NRC staff. Please feel free to contact Dr. Karim Rimawi or Mr. Stephen Gavitt should you have any questions or need additional information.

Sincerely,

Ronald Tramontano

Ronald Tramontano, P.E.
Director
Center for Environmental Health

Enclosures

cc: Dr. Rimawi
Mr. Gavitt
Mr. Gordon, NRC Region I
Mr. Spath, NYSERDA

ENCLOSURE # 1

Department Licensees that meet the NRC Decommissioning Financial Assurance Requirements

Non-Government Licensees

Rochester Institute of Technology
Columbia University
Cornell University
NYU Medical Center
Rensselaer Polytechnic Institute
Syracuse University
New York Medical College
Winthrop-University Hospital
Albany Medical Center
North Shore University Hospital
University of Rochester

Government Licensees

SUNY @ Albany
SUNY @ Buffalo
SUNY @ Binghamton
SUNY Environmental Science and Forestry
Roswell Park Cancer Center
SUNY Health Science Center
SUNY @ Stony Brook
NYSDOH - WCL&R
Broome Community College
Buffalo State College
SUNY @ Brockport
Helen Hayes Hospital

Determination of the Sum of the Ratios for New York State Department of Health Radioactive Material Licensees for Evaluation of the Need for Emergency Planning

Note: The R Value was determined by assuming that each licensee possessed the most limiting isotopes as indicated in Schedule C.

I) Academic Broad Scope Licensees:

License No.	Licensee	R Value	Possession Limit Notes
537-2	Columbia University	0.0125	Atomic No. 3 - 83: NTE 100 mCi.
537-3	Columbia University	0.0525	50 Ci. H-3; 500 mCi. I-125
5-3A	Cornell University	0.375	Atomic No. 3 - 83: 500 mCi. per isotope, NTE 5 Ci.
1030	New York University Medical Center	$<<0.01$	Very small possession limits.
1035	Rensselaer Polytechnic Institute	0.104	Atomic No. 3 - 83: 100 mCi. per isotope, NTE 10 Ci.; Atomic No. >84: 1 mCi. per isotope.
459-1	SUNY @ Albany	0.0179	Atomic No. 3 - 83: 50 mCi. per isotope, NTE 1 Ci.
1049	SUNY @ Buffalo	0.392	Atomic No. 3 - 83: 1 Ci. per isotope, NTE 10 Ci.
1051*	SUNY @ Buffalo (BMR)		Atomic No. 3 - 83: NTE 35 Ci.; 10000 Ci Ni-63. Currently in process of decommissioning.
588	SUNY @ Binghamton	0.0863	Atomic No. 3 - 83: 150 mCi. per isotope, NTE 750 mCi.
469	SUNY Environmental Science and Forestry	0.0156	Atomic No. 3 - 83: 50 mCi. per isotope, NTE 1 Ci.
40	Syracuse University	0.0544	Atomic No. 3 - 83: 100 mCi. per isotope, NTE 800 mCi.

* This license is in the process of being terminated. Bureau staff have inspected this facility and confirmed that this licensee possesses only small quantities of radioactive materials. These materials will be incorporated into NYSDOH Radioactive Materials License No. 1049.

II) Broad Scope Medical Licensees:

License No.	Licensee	R Value	Possession Limit Notes
590	Albany Medical Center	0.135	Atomic No. 3 - 83: 100 mCi. per isotope, NTE 5 Ci.; 800 mCi of radioiodines.
1026	North Shore University Hospital	0.093	Atomic No. 3 - 83: 100 mCi. per isotope, NTE 10 Ci.
2923	Roswell Park Cancer Center	0.36	Atomic No. 3 - 83: 500 mCi. per isotope, NTE 5 Ci.
47	SUNY Health Science Center	0.8	Atomic No. 3 - 83: 1 Ci. per isotope, NTE 10 Ci.
455	SUNY @ Stony Brook	0.52	Atomic No. 3 - 83: 500 mCi. per isotope, NTE 5 Ci.
436	University of Rochester	0.92	Atomic No. 3 - 83: 1 Ci. per isotope, NTE 25 Ci.; Atomic No. 84 - 104: 10 microcuries per isotope NTE 100 microcuries.
436	University of Rochester	0.5	10000 Ci of H-3 used at the Tritium Fill Station at the Laboratory for Laser Energetics. This laboratory is a free standing, separate building from the rest of the campus. No other radioactive materials are used within this building.

III) Research & Development Broad Scope Licensees:

License No.	Licensee	R Value	Possession Limit Notes
1727	New York Medical College	0.25	Atomic No. 3 - 83: 500 mCi. per isotope, NTE 6 Ci.
448	New York State Dept. of Health Wadsworth Center for Labs. and Research	0.11	Atomic No. 3 - 83: 200 mCi. per isotope, NTE 10 Ci.; Atomic No. 84 - 104: 130 microcuries per isotope NTE 2 mCi.

IV) Academic Specific Licensees:

License No.	Licensee	R Value	Possession Limit Notes
402	Alfred University	0.005	Atomic No. 3 - 83: 10 mCi. per isotope, NTE 200 mCi.
512	Broome Community College	0.008	Atomic No. 3 - 83: 15 mCi. per isotope, NTE 500 mCi.
1052	Buffalo State College	0.008	Atomic No. 3 - 83: 15 mCi. per isotope, NTE 500 mCi.
1193	SUNY @ Brockport	0.003	Atomic No. 3 - 83: 2 mCi. per isotope, NTE 30 mCi.

ENCLOSURE #3

March 16, 1995

Paul H. Lohaus
U.S. Nuclear Regulatory Commission
Office of State Programs
Washington, D.C. 20555-0001

Dear Mr. Lohaus:

This is in response to your letter dated January 28, 1995 concerning the NRC's Quality Management Rule in 10 CFR Part 35.

The Department of Health (DOH) has implemented quality assurance regulations that are at least equivalent to those of the NRC. As early as 1986, the Department identified a need to increase quality assurance requirements for medical uses of ionizing radiation. Since then, the Department has spent a great deal of time and effort developing quality assurance requirements for medical uses of all sources of ionizing radiation for licensees and registrants. Throughout this process the Department sought the input and advice from professional organizations, our Radiological Health Advisory Committee and other individuals within the medical community, Agreement States, and the NRC to assist us in this effort. The regulations were eventually published as a final rule in December 1992. It should be noted that although draft versions were sent to NRC for comment, we received little input from the NRC during the development of our quality assurance regulations.

The Department's quality assurance regulations not only meet the objectives of the NRC QM rule but provide additional requirements for external professional audits of the clinical and medical physics aspects of radiation therapy programs. The traditional 'peer review' approach has long been used by professional societies and accrediting bodies as a means of assessing programs and determining competency. This requirement of course, does not take the place of our routine inspections which include a review of licensees' and registrants' QA programs. We feel that our regulations are more than adequate to meet our needs and do not anticipate further modifications at this time.

Our response to the specific questions provided in your letter, and a copy of our regulations are attached. We would appreciate any comments the NRC may have on our regulations. If you have any questions or need additional information, please contact me.

Sincerely,

Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation
Protection

xc: Dr. Rimawi, DOH

New York State Department of Health
Bureau of Environmental Radiation Protection

Response to NRC questions on 10CFR Part 35 Quality Management Program.

1. *Has your State adopted a 10CFR Part 35 compatible Quality Management (QM) rule?*

The Department promulgated quality assurance requirements for medical uses of ionizing radiation effective December 30, 1992 (10NYCRR Part 16). These requirements not only meet the objectives of the NRC Part 35 QM rule but include additional requirements for external professional audits of both the medical physics and clinical aspects of therapeutic uses of ionizing radiation. In addition, these requirements apply to medical uses of all sources of ionizing radiation. This rule and draft versions were submitted to the NRC with no substantial comments received.

2. *Identify all variances from the enclosed list of QM-rule requirements that are in your draft or final rule.*

Definitions

a. *Diagnostic Clinical Procedures Manual* : this term does not appear in definition section of our regulations. Sections 16.19 Limitations on Application of Radiation to Humans, 16.23 Quality Assurance Programs for Diagnostic Facilities and the definition "use" in Section 16.2 address the same issues in a manner acceptable to the Department.

b. *Misadministration* : since our regulations cover all types of ionizing radiation, we find it impractical to adopt NRC's definition since it is too prescriptive. Section 16.25 Misadministrations, provides a less prescriptive definition that encompasses the same criteria but organized in a different manner. A fractional error is included (>50% of prescribed fractional dose) rather than weekly as per Part 35; DOH radiopharmaceutical therapy activity >10% error as opposed to NRC >20%/>30uCi error; DOH does not mention gamma stereotactic radiosurgery explicitly however the same error would be caught by DOH definitions; leaking brachytherapy source is not included, however error would be caught in other reporting requirements (leaking source) and misadministration description (dose to wrong part of body, source of radiation other than that prescribed).

c. *Prescribed Dosage and Written Directive* : while these terms do not appear in our definitions, the same objective is accomplished in section 16.24 Quality Assurance Programs for the use of radiation for therapy in humans; diagnostic is provided for via section 16.2 "use" definition, and 16.19 direction of uses by authorized user. DOH requires involvement of authorized user in diagnostic setting for review of all requests for diagnostic procedures for appropriateness and type of procedure performed.

d. *Prescribed Dose* : this appears in Section 16.24 and has the same meaning

e. *Recordable Event*: similar to response for b. Misadministrations, the DOH requirements are essentially the same only presented differently.

f. *Written Directive*: >30uCi of Iodine 131 or 125 covered in license condition; radiopharmaceutical therapy covered in 16.24(b), requirement for written order; other therapies in Written Directive definition addressed in 16.24(a) requirement for therapy QA manual which must describe procedures for written orders for therapy.

2. General Administrative Requirements

a. 35.32 equivalent found in 10NYCRR Part 16, Section 16.24.

b. 35.33 equivalent found in 10NYCRR Part 16, Section 16.25.

3. Other Items to Consider

a-c. RSO, RSC and Supervision - these items are covered in various sections of Part 16 and through licensing.

Need for Flexibility

Like other state health agencies, DOH has vast experience and regulatory authority over medical facilities. The NYS Public Health Law provides DOH with authority to regulate virtually every aspect of medical care at institutions within our state. The Department has promulgated regulations on quality assurance, quality assurance committees, incident reporting, appropriateness of facilities, patients rights, prescriptions, provision of services in accordance with current standards of practice, and others. Our broader experience in the medical field as well as our greater responsibility to regulate all sources of ionizing radiation necessitate greater flexibility in establishing regulations.