REPORT AND STAFF EVALUATION

OF THE

NEW YORK CITY DEPARTMENT OF HEALTH RADIATION CONTROL PROGRAM

FOR THE PERIOD

APRIL 26, 1986 THRU SEPTEMBER 25, 1986

24th Regulatory Program Review

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April 2, 1987

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Stephen C. Joseph, M.D., M.P.H. Commissioner of Health New York City Department of Health 125 Worth Street New York, New York 10013

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Dear Dr. Joseph:

This is to acknowledge your letter of February 10, 1987 responding to our comments and recommendations regarding our recent review of the Department's radiation control program.

We are pleased that the Department has completed action to amend its radiation control regulations. This should no longer be an issue in determining the compatibility of the Department's program with that of the NRC.

We are also pleased that the Bureau for Radiation Control has taken action to address our other concerns. We are planning to do a follow-up review of the Bureau's program during the week of April 27 - May 1, 1987 at which time we will re-examine these areas of the Bureau's program and may be in a position to offer a finding of cdequacy and compatibility.

We appreciate the expeditious action taken to address our concerns.

Sincerely,

Original bisned by Theres I. Markey

Thomas E. Municy Regional Administrator

COMMUSSIONER OF HEALTH Stephen C. Joseph, M.D., M.P.H.



125 WORTH STREET NEW YORK, N.Y. 10013 February 10, 1987

Dr. Thomas E. Murley Regional Administrator United States Regulatory Commission Region I 631 Park Avenue King of Prussia, Pennsylvania 19406

Dear Dr. Murley:

Thank you for your letter of November 26, 1986 outlining in some detail the findings of the program review and evaluation conducted by Mr. McGrath, Region I State Agreements Officer of the Radicactive Materials Program of the Department of Health's Bureau For Radiation Control. I have discussed this report with Deputy Commissioner Jean Cropper and Dr. Leonard Solon, Director of the Bureau and I have received their comments relative to your letter.

Regarding the issue of compatibility, the Board of Health of the City of New York met and approved for publication in the City Record the amended regulations to Article 175 (Radiation Control) of the Health Code. This action occurred on September 11, 1986. At a subsequent meeting of the Board on October 23, 1936, these regulations were adopted and became effective. I feel that a finding of compatibility is now in order since the amendments were worked out with your staff before submission to the Board of Health.

In reference to the specific findings as outlined in inclorance i with your letter, I offer the following comments.

1. Licensing

The Bureau shares the Agreements Officer view that the focumentation for two broad license renewals for in 1111 i.e. for Memorial Sloan-Kettering Cancer Conter at Columbia Iniversity-Presbyterian Hospital) had important omissions and were insubstantial in several areas. The Bureau has corrected these licenses to assure compliance with NRC Regulatory Guides. Full Cycle Directives, and Standard Review Plans and provisions of 1005PR of applicable to our licensees. Although the irregularities is the above two broad licenses occurred under the province of employee tow retired, current licensing and supervisors staff have avail themselves of training opportunities at Region 1 esseuartors

It is our intention to prevent recurrence of inadequacies in the future and to review major licensing actions at the senior supervisory level by way of quality assurance in this area.

2. Compliance Inspection Performance

Agreements Officer John McGrath accompanied two of the Bureau's Assistant Scientists on field inspections. On the basis of the observations reported to us, it is apparent that some radiological health and safety matters may have been overlooked. As a result, the Bureau is availing itself of the opportunity to send Assistant Scientists to the five week health physics training courses at Oak Ridge Associated Universities. Mr. Fred Schnee is currently attending the course that began February 9, 1987 and Esther Perlmutter and Louis Mazzola will attend the course scheduled to begin July 20, 1987.

With respect to employing the enforcement conference to supplement the Department's Administrative Tribunal civil penalty procedure, I view this type of conference as a suitable method of reinforcing with the licensees their responsibilities in the use of radioactive materials.

In an effort to implement your recommendation concerning inspection documentation, the Bureau has revised their internal <u>Inspection</u> <u>Report</u> form in consultation with Mr. McGrath. A copy is appended. In addition, the Bureau is seeking to develop a quality assurance plan to assure the adonue; of compliance inspections.

3. Fersonal Recruitment and Supervision

Reconstitution of Technical Advisory Consister on Fediation

I have instructed Ir. Folor. Director, Bureau Fir Radiation Control to begin the process of reestablishing the Technical Advisory Cormittee on Radiation. I would expect that this committee would be formalized by late firing of this year Page 3

Dr. Thomas E. Murley

February 10, 1987

The continued constructive cooperation of your staff in the training and program surveillance areas of the Department's Radioactive Materials program is very much appreciated. Please let me know if further information or amplification of any of these matters is desired.

Sincerely yours,

Stephen C. Joseph, M.D., M.P.H. Commissioner of Realth

Enclosures: As Stated

cc: J. Cropper

G. Flanders

L. Solon

The City of Of York. New York	ALTH TON CONTROL Dut. Fir.) ION REPORT
ESTABLISHMENT NAME & ADDRESS:	License Number(s):
Primary Liconse Contant	
Inspection Data	Phone #:
SUMMARY OF	Type of Inspection
Program: () NCA or VCW () VRPS () YRPS Sites: () NCA or VCW () VRPS () YRPS () Reinspect by () YRPS () YRPS	VRR VRR
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) DISPOSAL SITE REGULATIONS AVALIABLE			
) WRITTEN DESIGNATION OF PERSONS RESPONSIBLE FOR SAFE DISASAL			
) INSTRUCTIONS TO STAFF			
) TRAINING AND PERIODIC RETRAINING ON CURRENT REGULATORY REQUIREMENTS			
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CITY OF NEW YORK

Lic. No(s).

DEPARTMENT OF HEALTH

RADIOACTIVE MATERIALS INSPECTION REPORT ADDENDUM

Licensee

Inspector

ame	Name
ddress	Agency
*	Signature
	Date of Inspection
hone	
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Total activity used per year:

Radionuclide Activity per year Form

* solid, non-volatile liquid, volatile liquid, so go Does licensee meet the requirements of 0 NYCRE Part 190 -the following:

a. maintain records of radicactive discharges to the environment [380.6 (a)(1)]?

b. make periodic evaluations to determine concentrations of radioactivity in discharges to air and water [380.504)[2][9]

c. keep records of such evaluations [380.6(a)/2)]7

3. If the answer to 2.a. is yes, a. complete this table (as far as possible): Total Activity Average Annual Concentration Radionuclide Released per Year at Discharge Point Air Water Air Water b. Does the total amount of any radionuclide discharged exceed, on an annual basis, 1,000 times the quantities set forth in 6 NYCRR Part 380.10? c. If so, does licensee report those guantities to DEC as required in Part 380.6(b)? 4. If the answer to 2.b. is yes, a. describe the evaluations performed pursuant to Part 380.6(a)(2). b. Are the evaluation methods used adequate for determining the concentrations of radioactivity in discharges to hir and water? 5. Does licensee have a current copy of 6 MYORR Part 300 (April 1985)?

13.

LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Letter dated

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Establishment:

VIOLATION NO.

STATUS · ACTION TAKEN

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John Hald

November 26, 1986

Stephen C. Joseph, M.D., M.P.H. Commissioner of Health New York City Department of Health 125 Worth Street New York, New York 10013

Dear Dr. Joseph:

This is to confirm the discussion Mr. John McGrath, Region I State Agreements Officer, held with you and your staff on September 25, 1986 following our review and evaluation of the Department's radiation control program.

Our review revealed significant deficiencies in two areas of the Department's program. The review of selected licensing actions disclosed that supporting documentation was in many cases inadequate. Two recent broad license renewals in particular were found to be inadequately supported in important areas. It appears that the Department is not strictly following standard criteria and guidance for the issuance of those types of licenses. Technical Quality of Licensing Actions is a Category I indicator.

Our review included the accompaniment of Department inspectors during the inspection of City nuclear medicine licensees. These inspections revealed that inspectors are quite diligent in following Department forms and guides on what aspects of licensee programs are to be reviewed. We are concerned, however, with the depth of the review and the inspectors' ability to discern some violations and safety related problems. We believe that the problem can be attributed to an insufficient background in health physics and radiation protection which can be addressed through further training. NRC sponsors a five-week health physics course specifically designed for Agreement State personnel. Travel and per diem costs for approved attendees are funded by NRC. Inspectors' Performance and Capability is a Category I indicator.

Because of the Category I deficiencies, we cannot at this time offer a finding of adequacy and compatibility for the Department's program. We would appreciate your review of our comments and recommendations and would like to receive your specific, lans to address these issues. Enclosure 1 to this letter contains additional details and comments regarding the technical aspects of the program. After reviewing your responses to our comments and recommendations and specifically any commitments on the part of the Department to effect corrective actions, we may then be in a position to consider a finding of adequacy. The finding of compatibility will be contingent upon the revised regulations being adopted as effective rules.

We note that the Bureau for Radiation Control relocation to Livingston Street, Brooklyn required the dismantling of the Bureau's laboratory and we support the Department's plan to reestablish the laboratory at a new site within the City.

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Enclosure 2 to this letter contains an explanation of our policies and practices for reviewing Agreement State programs. We are also enclosing a second copy of this letter for placement in the City's Public Document Room or otherwise to be made available for public review.

I appreciate the courtesy and cooperation you and your staff extended to Mr. McGrath during the review. Please be assured that the NRC will continue to work with the Department in terms of providing technical assistance and training opportunities to attain our mutual goal of protecting the public health and safety.

Sincerely,

Original signed by Thomas E. Murley

Thomas E. Murley Regional Administrator

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Enclosures: As Stated

cc: L. Solon, NYCH D. Axelrod, NYSH L. Roberts, NYSL H. Williams, NYDEC G. W. Kerr, OSP NRC Public Document Room

Distribution: TMurley JAllan DNussbaumer JMcGrath SPO1

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ENCLOSURE 1

COMMENTS AND RECOMMENDATIONS ON THE NEW YORK CITY DEPARTMENT OF HEALTH RADIATION CONTROL PROGRAM

1. Licensing

Technical Quality of Licensing Actions is a Category I indicator. --- The following comment and recommendation is related to problems which we consider to be of major significance.

Comment

The review of selected licensing actions revealed significant technical inadequacies. Of particular concern were the renewals of two broad licenses. The applications accepted by the Bureau as the basis for renewal were deficient in such basic areas as radiation safety committee duties and responsibilities, use and user approval criteria, and inadequate procedures for such activities as instrument calibration, leak testing, waste disposal, and the survey program. Problems noted with other licensing actions included inadequate documentation of physician qualifications, inadequate receipt procedures, and no emergency procedures.

Recommendation

We recommend that the Bureau reconfirm its commitment to adhere to established policies and practices in the licensing program, specifically the NRC licensing guidance (FC Directives, Standard Review Plans, and Regulatory Guides) which has been provided to the program.

2. Compliance

A. Inspectors' Performance and Capability is a Category I indicator.

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The following comment and recommendation is related to a problem which we consider to be of major significance.

Comment

Our review included the accompaniment of Bureau inspectors during routine inspections of Department licensees. Although the inspectors were diligent in following prescribed forms and guidelines on what to review, we are concerned with the depth of the review and the inspectors' ability to discern safety related problems in the licensee's program. For example, a security/access control problem at one facility went unnoticed. Also, the failure to recognize deficiencies in certain records raised questions about the inspectors' technical judgement. We believe that the problem can be effectively addressed by providing training in operational health physics and radiation safety.

Recommendation

We recommend that the Bureau's newer staff obtain additional training in basit: health physics and recommend their attendance at the NRC sponsored five-week course "Health Physics and Radiation Protection." This course is designed for State regulatory personnel and trave! and per diem costs are funded by NRC. The next two courses are tentz*ively scheduled for February 9-March 13, 1987 and July 20-August 21, 1987. We have reserved two slots for New York City staff in each of these courses. We would appreciate a commitment on the part of the Department to avail itself of this training opportunity. With the recent staff turnover and influx of new staff, we believe the Department has a prime opportunity to strengthen the technical foundation of the Bureau.

B. Enforcement Procedures is a Category I indicator. The following comment and recommendation relates to an issue of minor significance.

Comment

Enforcement procedures should be sufficient to provide a substantial deterrent to licensee noncompliance. The Bureau has a number of enforcement options available to it. We were

pleased to note that the Bureau has not hesitated to escalate enforcement actions to civil penalties and orders when necessary. The inspections which were conducted during the review revealed significant violations which were related to licensee management's lack of understanding of their responsibilities under the license. The NRC has, in such cases, employed the enforcement conference as an intermediate mechanism for apprising licensee management of their responsibilities and what NRC expects in terms of achieving compliance.

Recommendation

We recommend that the Bureau consider using the enforcement conference as another option in its enforcement program.

C. Inspection Reports is a Category II indicator.

Comment

The review of selected inspection reports revealed that inspection documentation practices could be improved in a number of areas. Current inspection forms do not provide for documentation of such aspects of licensees' programs as

organization (including committee activities), inspection history (previous items of noncompliance and their current status), scope of licensee activities, receipt and package opening procedures, and posting the license and regulations.

Recommendation

We recommend that the Bureau consider revising inspection documentation practices to more completely describe the status of the licensee's program.

Personnel

Staff supervision is a Category II indicator.

Comment

Supervisory personnel should be adequate to provide guidance and to review the work of senior and junior personnel. From the standpoint of overall program performance, two positions within the Bureau's radioactive materials program are critical, the Assistant Director for Radioactive Materials and the Field Supervisor (radioactive materials). Since December 1985 these positions have been filled on an acting and part-time basis, respectively. We feel that the situation has contributed to the technical problems noted during our review. Additionally, we noted delays in dispatching enforcement correspondence which appeared to be caused by the current staffing situation.

Recommendation

We recommend that the two positions discussed above be filled on a full-time permanent basis as soon as possible. We believe that Bureau management should institute a quality a surance program to verify that Bureau policies are being carried out by the staff.

4. Organization

Technical Advisory Committees is a Category II indicator.

Comment

NRC guidelines recommend the use of technical advisory committees to extend staff capabilities for unique or technically complex problems. The Department currently has no such functioning committee.

Recommendation

We recommend that the Department proceed with its plans to reconstitute the Commissioner's Technical Advisory Committee on Radiation.

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RADIATION CONTROL PROGRAM: New York City Department of Health REVIEW MEETING NUMBER: 24th DATES OF REVIEW: September 8-12, 23-25, 1986 PERIOD OF REVIEW: April 26, 1985 - September 25, 1986 NRC REPRESENTATIVE: John R. McGrath RADIATION CONTROL PROGRAM REPRESENTATIVES: Leonard Solon, Director, Bureau for Radiation Control, Richard Borri, Acting Assistant Director for

Radioactive Materials

CONCLUSIONS

The review revealed significant deficiencies in the Bureau's program and a finding of adequacy and compatibility was deferred. Two recent broad license renewals were inadequately supported and accompaniments of Bureau inspectors led to concerns about their technical capabilities.

SUMMARY MEETING WITH MANAGEMENT

A summary meeting to present the results of the regulatory program review was held with Dr. Stephen C. Joseph, Commissioner, Department of Health. Also present were Mr. Jean Cropper, Deputy Commissioner of Environmental Affairs; Mr. Gerald Flanders, Assistant Commissioner for Field Services; Dr. Leonard Solon, Director, Bureau for Radiation Control; and Mr. Thomas Kaiser, Deputy Director for Administration, Bureau for Radiation Control. The following comments were discussed.

- 1. The review of selected licensing actions revealed significant technical inadequacies. Of particular concern were the renewals of two broad licenses. The applications accepted by the Bureau as the basis for renewal were deficient in such basic areas as radiation safety committee duties and responsibilities, use and user approval criteria, and inadequate procedures for such activities as instrument calibration, leak testing, waste disposal, and the survey program. Problems noted with other licensing actions included inadequate documentation of physician qualifications, inadequate receipt procedures, and no emergency procedures. We recommend that the Bureau reconfirm its commitment to adhere to established policies and practices in the licensing program, specifically to NRC licensing guidance (FC Directives, Standard Review Plans, and Regulatory Guides) which has been provided to the States.
- 2. Our review included the accompaniment of Bureau inspectors during routine inspections of Department licensees. Although the inspectors were diligent in following prescribed forms and guidelines on what to review, we are concerned with the depth of the review and the inspectors' ability to discern safety related problems in the licensee's program. For example, a security/access control problem at one facility went unnoticed. Also, the failure to recognize deficiencies in certain records raised misgivings about the inspectors' technical judgement. We believe that the problem is mainly one of insufficient background in operational health physics and radiation safety.

We recommend that the Bureau's newer staff obtain additional training in basic health physics. We believe that the NRC sponsored five-week course "Health Physics and Radiation Protection" would be excellent training for your staff. The course is designed for Agreement State regulatory personnel and is completely funded by NRC. The next two courses are tentatively scheduled for February 9 - March 13, 1987 and July 20 - August 21, 1987. We have reserved two slots for New York City staff in each of these courses. We would appreciate a commitment on the part of the Department to avail itself of this training opportunity. With the recent staff turnover and influx of new staff, we believe the Department has a prime opportunity to strengthen the technical foundation of the Bureau.

3. The Bureau has a number of enforcement options available to it. We were pleased to note that the Bureau has not hesitated to escalate enforcement actions to civil penalties and orders when necessary. The inspections which were conducted during the review revealed significant violations which were related to licensee management's lack of understanding of their responsibilities under the license. The NRC has, in such cases, employed the enforcement conference as an intermediate mechanism for apprising licensee management of the responsibilities and what NRC expects in terms of achieving compliance.

We recommend that the Bureau consider using the enforcement conference as another option in its enforcement arsenal.

- 4. The review of selected inspection reports revealed that inspection documentation practices could be improved in a number of areas. Current inspection forms do not provide for documentation of such aspects of licensees' programs as organization (including committee activities), inspection history (previous items of noncompliance and their current status), scr of licensee activities, receipt and package opening procedures, and posting the license and regulations. We recommend that the Bureau consider revising inspection documentation practices to more completely describe the status of the licensee's program.
- 5. From the standpoint of overall program performance, two positions within the Bureau's radioactive materials program are critical, the Assistant Director for Radioactive Materials and the Field Supervisor (radioactive materials). Since December 1985 these positions have been filled on an acting and part-time basis, respectively. We feel that the situation has exacerbated the problems noted during our review. For example, the delays in dispatching enforcement correspondence is a direct result of the current staffing situation.

We recommend that the two positions discussed above should be filled on a full-time permanent basis as soon as possible. In addition, we believe that Bureau management should institute a quality assurance program to periodically verify that Bureau policies are being carried out by the staff.

6. NRC guidelines recommend the use of technical advisory committees to extend staff capabilities for unique or technically complex problems. The Department currently has not such functioning committee. We recommend that the Department proceed with its plans to reconstitute the Commissioner's Technical Advisory Committee on Radiation.

The reviewer indicated that because of the significance of the deficiencies we could not offer a finding of adequacy and compatibility. However, if the Department provided a response, we would review it and if appropriate commitments were made by the Department regarding corrective actions, we may be in a position to offer a finding of adequacy at that time. The reviewer indicated that a finding of compatibility would also be contingency upon the publication of the reviewed regulations.

Dr. Joseph indicated that the Department would review our comments and provide a response. Department management generally responded positively to the recommendations offered, particularly with regard to training of the staff.

Laboratory support was also discussed. The relocation of the Bureau to Brooklyn required the dismantling of the Bureau's laboratory. The Department has formulated plans to reestablish the laboratory at a new site somewhere in the City and it was stated that we support this plan.

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PROGRAM CHANGES RELATED TO PREVIOUS NRC COMMENTS AND RECOMMENDATIONS

1. Comment

The Bureau staff, although having a technical background, have not all had additional formal training in radiation protection.

Recommendation

We recommend that Mr. Mazzola and the Bureau's new staff person, who we understand does not have formal radiation protection training, attend the NRC sponsored five-week course in Health Physics and Radiation Protection. In addition, we recommend that Mr. Kamble attend the NRC courses in licensing practices and procedures, in view of his new duties in the licensing area.

Reply by the Bureau for Radiation Control

Ms. Esther Perlmutter, a recently appointed Assistant Scientist has attended an NRC course entitled "The Medical Uses of Radionuclides for State Regulatory Personnel." The course was held at the Oak Ridge Training University, Oak Ridge, Tennessee from June 24 - 28, 1985.

In addition, Bapu Kamble, Scientist, has been selected and directed to attend the NRC course, "Introduction to Licensing Practices and Procedures."

As courses become available, it is our intention to see that members of the Bureau staff who can improve the quality and productivity of their assignment take them.

Present Status

Neither Mr. Mazzola nor Ms. Perlmutter have attended the five-week course. Mr. Kamble has repeatedly refused to attend the Licensing Course. The Bureau is taking personnel action against Mr. Kamble on this issue. Ms. Perlmutter has attended the medical course and the inspection procedures course. It was again recommended that Ms. Perlmutter, Mr. Mazzola, Mr. F. Schnee and a new staff member attend the five-week course.

2. Comment

The Bureau has issued licenses authorizing material and procedures not requested in the licensee's application, specifically the authorization for Group III when no isotope generators were requested.

Recommendation

The Bureau should review licenses more carefully to assure that licenses authorize the material and procedures requested and that authorization for Group III is fully supported by information in the file.

Reply by the Bureau for Radiation Control

The license reviewing officers of the Bureau are now examining license applications more carefully to assure that licenses authorize the specific material and precise procedures requested.

In addition, we now require that all Group Licenses are supported by sufficient documentation in the license folder.

Present Status

The licensing program has not improved. More significant deficiencies were noted in the program requiring the deferral of the finding of adequacy. See report details.

3. Comment

The Bureau has issued licenses for Group VI materials and procedures where applicants did not provide information on periodic inventories or procedures for transporting sealed sources within the institution.

Recommendation

Notwithstanding the fact that the City Health Code requires a quarterly inventory, the Bureau should assure that an applicant's procedures address this point. The Bureau should also assure that the applicant has adequate procedures for transporting sources.

Reply by the Bureau for Radiation Control

The licensing specialists now require specific information from applicants on periodic inventories of sealed sources with all applications for new licenses, renewals and amendments.

Procedures for the transportation of sealed sources within institutions are now required for applicants for new licenses, renewals and amendments.

Present Status

Although a repeat of this particular deficiency was not noted, the overall licensing program has not improved.

4. Comments

Licensee violations of the Health Code or license condition are currently being written up on Department Form 148E and left by the inspector at the licensed facility. 148E's are not always prepared in a manner that clearly describes the violation. Bureau inspectors have, at management's direction, specifically refrained from referencing the Code Section or license condition being violated. When a 148E is followed up by an enforcement letter, the violation is clarified and an appropriate Code Section or license condition is cited.

Recommendation

We recommend that all enforcement correspondence be clear and specific as to the violation, referencing the appropriate Code Section or license condition.

During our summary meeting with Deputy Commissioner Cropper, the use of Form 148E was discussed in detail. As a result of that discussion it is our understanding that the Bureau could discontinue the practice of leaving a 148E at each "site" inspected and instead provide the inspection results to the licensee in an enforcement letter summarizing the "site" inspections. We feel that this would be a substantial improvement in the Bureau's procedures.

Reply by the Bureau for Radiation Control

The continued use of Department Form 148E is under study by the Bureau staff. We are now reducing the use of Department Form 148E by the field staff. This form shall be used only to report inspection findings to licensees at small facilities, to which enforcement letters are not mailed.

The Bureau is also eliminating the use of Department Form 148E in inspecting broad licensed facilities and multiple-licensed institutions. However, these larger facilities will continue to receive enforcement letters on the inspection findings, which are mailed from the Bureau office.

Present Status

The Bureau's new procedures are just beginning to be implemented. The lack of a full-time compliance supervisor has hindered the implementation of the new procedures.

5. Comment

The documentation of inspection findings remains a problem area for the Bureau. On the one hand, the Bureau uses a variety of forms and produces an extraordinary amount of paper. On the other hand, however, the documentation does not always provide useful information in a readily retrievable, convenient form. For example, some inspections result in multiple copies of Forms 148E, RC-10, RC-16 and RC-17 (for some licenses as many as 100 copies each). However, in some cases the information provided by the inspectors is not in sufficient detail to draw conclusions about the adequacy of the licensee's program.

Recommendation

We believe that the Bureau should consolidate and simplify the forms that are now being used in the radioactive materials inspection program. The Bureau also needs to assure that inspection documentation provides sufficient detail to assess the adequacy of the licensee's radiation protection program.

Reply by the Bureau for Radiation Control

The Bureau for Radiation Control is consolidating inspection forms in order to reduce the documentation handled by the inspectors. We are evolving forms to facilitate reporting of relevant details of inspection findings and to provide a convenient method for maintaining useful information in accessible form. The objective is to assure that the information resulting from the inspection surveillance is sufficient to assure achieving health and safety in the licensee's program.

Present Status

Some consolidation of inspection forms has occurred, however, documentation practices need to be further improved. See report details. EVALUATION OF AGREEMENT STATE RADIATION CONTROL PROGRAM STATE REVIEW GUIDELINES, QUESTIONS AND ASSESSMENTS Name of State Program: NEW YORK CITY DEPARTMENT OF HEALTH Date of NRC Review: September 1986

I. LEGISLATION AND REGULATIONS

A. Legal Authority (Category I)

NRC Guidelines: Clear statutory authority should exist, designating a state radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement. States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA. Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Questions:

1. Please list all currently effective legislation that impacts the State's radiation control program.

Answer: The statutory authority to regulate agreement materials and other sources of radiation is contained in the 1960 amendment to the State Public Health Law.

2. What changes have been made to the statutory authority of the Radiation Control Program (RCP) to license, inspect, and otherwise regulate agreement materials since the last review?

Answer: The Public Health Law has not been amended since the last review.

 If your State regulates uranium or thorium recovery operations and associated wastes pursuant to an amended agreement and UMTRCA, explain any changes to the statutory authority for these functions.

Answer: N/A

4. Are copies of the current enabling act and other statutes (e.g., Administrative Procedures Act, Sunshine Act., etc.) which govern the conduct of the agreement materials program on file in the RCP office and with the NRC? If revisions have occurred since the last review, the changes should be included.
Answer: Copies of the State enabling legislation and other relevant statues are on file at the City Department of Health offices and with the NRC.

5. If the State's regulatory authorities are divided between agencies, what procedures and memoranda are in effect to provide clear understanding of the divisions of responsibilities and requirements for coordination?

Answer: The enactment of the State Atomic Energy Law on March 9, 1959 placed the coordination of regulatory atomic energy activities within the State of New York on a statutory basis. This law established the Office of Atomic Development headed by a director responsible to the Governor. In order to assist the office to fulfill its coordinating function, the State Atomic Energy Law requires that all agencies of the State and its political subdivisions keep the Office fully and currently informed as to their activities relating to atomic energy and ionizing radiation. In addition, the legislation established a State Atomic Energy Coordinating Council consisting of a director as chairman and such other persons, including representatives of agencies of the State and its political subdivisions. as the Governor may appoint, to advise, assist and make recommendations to the director with respect to the coordination of atomic energy activities of agencies of the State and its subdivisions.

- 6. Does the State have the authority to:
 - a. apply civil penalties? If so, cite legislation.

Answer: Yes. Sections 3.12, 3.13 and Article 7 of the New York City Health Code authorize the application of civil penalties.

b. collect fees? If so, cite legislation.

Answer: Yes. Sections 175.01 and 5.07 authorize the collection of fees.

 require surety or long-term care funds? If so, cite legislation.

Answer: No.

d. require performance bonds or sureties for decommissioning licensed facilities? If so, cite legislation.

Answer: No.

 require performance bonds or sureties for clean-up of licensed facilities after a contamination accident? If so, cite legislation. Answer: No.

f. require long-term care funds for uranium mill or low-level waste facilities? If so cite legislation.

Answer: No.

g. enter into low-level waste compacts? If so, cite legislation.

Answer: No.

h. establish, license and/or operate a low-level waste site?

Answer: No.

 If any responses to the above question are negative, explain any plans the State may have regarding those issues.

Answer: At the present time the city has no plans regarding the issues discussed in question #6.

I.A <u>Reviewer Assessment</u>: The Department meets these indicator guidelines. Recent reactivation of the State Committee on Licensing on an informal basis has filled the void left by the abolition of the Atomic Energy Coordinating Council.

There are no facilities in the City requiring sureties or long-term care funds, such as uranium mills or low-level waste disposal facilities. Policy regarding low-level waste compacts etc. is being addressed at the State level.

B. Status of Regulations (Category I)

NRC Guidelines: The State should have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards and effluent limits), and those required by UMTRCA, as implemented by Part 40. The State should adopt other regulations to maintain a high degree of uniformity with NRC regulations.

Questions:

1. When did the RCP last amend regulations in order to maintain compatibility and when did the revisions become effective?

Answer: The City of New York Health Code was last amended on November 15, 1977 and became effective on November 25, 1977. Section 175.10 (equivalent to 10 CFR Part 19) was amended.

Referring to the enclosed NRC chronology of amendments (Attachment A) note the effective date of the NRC changes last adopted by the RCP.

Answer: August 16, 1974.

3.a. Were there any compatibility items that were not adopted by the RCP?

Answer: No.

b. If so, please identify and explain why they were not adopted.

Answer: N/A

- I.B. <u>Reviewer Assessment</u>: During the last review, it was recommended that steps be taken to update the Department's regulations. Draft amendments to the City regulations were prepared and provided to NRC for comment. Comments were provided and the Department is proceeding to formally adopt the changes. A Board of Health meeting on September 11, 1986 approved publication of draft rules for public comment. A finding of compatibility is being withheld until the changes become effective.
 - C. Updating of Regulations (Category II)

NRC Guidelines: The RCP should establish procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable but no later than 3 years. Opportunity should be provided for the public to comment on proposed regulation changes. (Required by UMTRCA for uranium mill regulation.) Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

 Does the RCP have a schedule or program for revising and adopting changes to regulations within three years of adoption by the NRC?

Answer: The maintenance of the City's regulations in compatibility with NRC regulations will be accomplished in the future by periodic revision at least once every three years. A file on all proposed and final NRC rules is now maintained as they are published.

 Has the RCP adopted all regulations deemed a matter of compatibility by NRC within three years? (Refer to NRC chronology).

Answer: No. However, the Bureau for Radiation Control has drafted all items deemed a matter of compatibility by the NRC, and has forwarded them to the Office of State Programs for review before presenting them to the Office of the General Council for preparation of legal drafts suitable for presentation to the New York City Board of Health. The Board of Health approved on September 11, 1986 the publication of the proposed revision.

3. What are the RCP's procedures for adopting new regulations? Briefly describe each step in the procedure.

Answer: The adoption procedure used by the New York City Department of Health involves the following steps:

- a. Identify purpose of action.
- b. Develop draft regulations.
- c. Review by Office of the General Counsel.
- d. Lega' draft prepared by Office of General Counsel for presentation to Secretary of Board of Health for placement on calendar of Board of Health.
- A copy of draft is published in The City Record inviting comments.
- f. Review of comments.
- q. Final review by the Board of Health with decision.
- h. Publication in The City Record.
- 4. How is the public involved in the process?

Answer: All draft regulations are published in the City Record inviting public comments. A public hearing may be held if there is sufficient demand for it by interested parties.

a. Does the NRC have the opportunity to comment on draft changes to RCP regulations?

Answer: The NRC is provided with draft proposed amendments and any revisions for comment.

b. If so, does the RCP respond to the comments?

Answer: The Department responds to all comments and questions raised by NRC.

I.C. <u>Reviewer Assessment</u>: In the past the Department has not met its goal of updating the regulations at three-year intervals, however, the Bureau staff indicated that revisions will now be made every three years.

II. ORGANIZATION

A. Location of the Radiation Control Program Within the State Organization (Category II)

NRC Guidelines: The RCP should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management.

 Attach a dated organization chart(s) showing the RCP and its location within the department and State organization.

Answer: A dated organization chart is attached as Appendix A.

 Is the RCP on a comparable level within the State organization with other health and safety programs so as to compete effectively for funds and staff?

Answer: The Bureau for Radiation Control is comparable with other bureaus in Environmental Health Services in terms of competing for staff and funding. The Bureau for Radiation Control is located in Environmental Health Services of the City Department of Health.

3. Does the program director have access to appropriate levels of State management?

Answer: The Director, Bureau of Radiation Control, has access to the Deputy Commissioner, Environmental Health Services, New York City Department of Health and the Commissioner, New York City Department of Health.

- II.A Reviewer Assessment. The Department meets these indicator guidelines.
 - B. Internal Organization of the RCP (Category II)

NRC Guidelines: The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy. Where regional offices are utilized, the lines of communication and administrative control between the regions and the central office (Program Director) should be clearly drawn to provide uniformity in inspection policy, procedures and supervision.

Questions:

1. Attach dated copies of your internal RCP organization charts.

Answer: A dated copy of the organization chart for the Bureau for Radiation Control is attached as Appendix B.

 How is the RCP organized so as to provide specific lines of supervision from program management for executing program policy?

Answer: The organization chart shows specific lines of management used in executing program policy. Weekly formal and informal meetings and daily contact among staff members facilitate adherence to program policy.

- 3. If regional offices are used:
 - a. To whom do regional personnel report administratively?

Answer: N/A

b. To whom do regional personnel report technically?

Answer: N/A

- If the RCP contracts with other agencies to administer the program:
 - Identify the contracting agencies and indicate their responsibilities.

Answer: N/A

b. To whom do contract personnel report administratively?

Answer: N/A

c. To whom do contract personnel report technically?

Answer: N/A

- II.B Reviewer Assessment: The program meets these indicator guidelines.
 - C. Legal Assistance (Category II)

NRC Guidelines: Legal staff should be assigned to assist the RCP, or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP program, statutes, and regulations.

Questions:

1. Are legal staff members assigned to assist the RCP or do procedures exist to obtain legal assistance expeditiously?

Answer: The New York City Department of Health has a full-time legal staff, Office of the General Counsel, which assists all bureaus in legal matters. The Departmental Advocate within the Administrative Tribunal framework also provides legal assistance to the Bureau. Is the legal staff knowledgeable regarding the RCP, statutes, regulations and needs?

Answer: The legal staff is familiar with statutes, regulations and needs of the Bureau for Radiation Control and has provided consultation and assistance primarily in amending the New York City Health Code, providing legal interpretation of Health Code for certain public groups and all Bureaus within the Department of Health.

 If legal assistance was utilized since last review, provide a summary of the circumstances.

Answer: Legal assistance by the Office of the General Counsel was provided in drafting amendments to the New York City Health Code. Legal assistance by the Inspector General's Office was provided in one case before the Administrative Tribunal.

II.C Reviewer Assessment: The Department meets these indicator guidelines.

D. Technical Advisory Committees (Category II)

NRC Guidelines: Technical Committees, Federal Agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems. A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The Committee should represent a wide spectrum of medical disciplines. The Committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans. Procedures should be developed to avoid conflict of interest, even though Committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

Questions:

 Discuss practices followed for obtaining technical assistance when needed (e.g., consultants, technical and medical advisory committees, licensees, the NRC and other State and Federal Agencies).

Answer: the Bureau for Radiation Control utilizes the services of its medical advisory committee, Committee on Human Applications of Radioactive Materials, to review and advise on the use of radiopharmaceuticals which have not received an NDA number from the U.S. Food and Drug Administration. The committee also comments on the uses of certain devices containing radioactive materials. The Technical Committee to the Commissioner of Health has in the past also been available for consultation and advise on a broad range of issues. Certain technical and regulatory questions are referred to the Office of State Programs or Region I of the NRC. 2. What steps arc taken to avoid conflicts of interest?

Answer: The members of the advisory committees are requested to excuse themselves from commenting on matters directly involving institutions where they are employed.

 Are any committees involved in setting policies? If so, explain.

Answer: The committees are strictly advisory and are not involved in setting policy.

 Attach a list showing the membership, specialties and affiliations of the Medical and/or Technical Advisory Committees.

Answer: A list showing committee membership is available in Region I files.

 Indicate whether the advisory committees are established by statute, by appointment of the Governor, by appointment of the Board of Health, by appointment of the Agency, or by other means.

Answer: The Committee on Human Application of Radioactive Materials and the Technical Committee to the Commissioner of Health are appointed by the Commissioner of Health. The terms of appointment are indefinite.

6. What is the formal meeting frequency of each committee, and are minutes of committee meetings prenared?

Answer: Neither the Committee on Human Applications of Radioactive Materials nor the Technical Committee to the Commissioner has a formal meeting frequency. A meeting may be called to resolve a serious problem which may require joint interaction of the members. Most matters are resolved by requesting comments from the members by mail or phone.

7. What was the date of the last formal meeting of each committee?

Answer: Several years ago, the Committee on Human Applications of Radioactive Materials met, exact date unknown.

8. Are individual committee members contacted for consultation?

Answer: Occasionally, an individual committee member who represents a particular specialty may be contacted directly for consultation.

 Discuss how each committee is used, the average workload placed on the committee, and the remuneration, if any.

Answer: The Committee on Human Applications and the Technical Committee to the Commissioner are used primarily to provide technical reviews and recommendations to the Bureau. The average workload of the medical advisory committee is about 30 applications reviewed per year. The average workload of the Technical Committee to the Commissioner is indeterminate. The committee members do not receive any remuneration.

II.D <u>Reviewer Assessment</u>: Currently, the Commissioner's Technical Advisory Committee on Radiation is nonfunctioning. A number of members resigned in 1984 over the Department's policy regarding the incineration of biomedical waste. The Committee, however, was never officially disbanded. The Department is considering reestablishing the committee (with different membership) and it was recommended that they proceed with this plan.

III. MANAGEMENT AND ADMINISTRATION

A. Quality of Emergency Planning (Category I)

NRC Guidelines: The State RCP should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.

The Plan should define the responsibilities and actions to be taken by State agencies. The Plan should be specific as to persons responsible for initiating response actions, conducting operations and cleanup. Emergency communication procedures should be adequately established with appropriate local, county and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the Plan while in draft form.

The plan should be reviewed annually by Program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

Questions:

 Is the RCP responsible for its own emergency plan or are accidents involving radioactive materials incorporated into a comprehensive State plan developed and administered by another State agency? Please provide copies of all applicable plans for review.

Answer: The staff of the Bureau for Radiation Control has prepared a Radiation Accident Plan which is designed to ensure coordinated effort by local, state and federal agencies executing disaster operations in the event of an accident involving radioactive materials. A copy of the plan dated August 1986 is available in Region I files.

2. What written procedures or plans does the RCP use for responding to incidents involving radioactive materials?

Answer: Radiation Accident Plan described above.

3. If the plan covers major accidents at nuclear facilities, how does it cover non-catastrophic incidents such as those involving transportation of materials?

Answer: The plan is designed to cover radioactive materials incidents and accidents at fixed facilities and during transportation within the City of New York. There are no nuclear power facilities within the jurisdiction of the City of New York nor is any part of the city within the evacuation planning zone of a nuclear power facility.

4. How does the plan define responsibilities and actions to be taken by all State Agencies (initiating response actions, operations, cleanup, etc.)?

Answer: Refer to the Radiation Accident Plan.

5. How does the plan provide for notification of and communications with appropriate government agencies?

Answer: Initial notification is usually made to the New York City Police Department, which then notifies the Poison Control Center. The Poison Control Center staff contacts the Director, Bureau for Radiation Control. Further notifications would be made by the Director after evaluation of the situation.

6. How is the response program organized so that qualified individuals are readily available through identifiable channels of communication?

Answer: The Radiation Accident Plan includes a list of staff members of the Bureau for Radiation Control available for response to radiation emergencies. The list provides the names, addresses and telephone numbers of agencies which might provide assistance to the Bureau during an emergency, and the names, addresses and telephone numbers of responsible individuals in the Bureaus and other state and federal agencies.

7. Has the plan been distributed to all participating agencies?

Answer: Yes. The plan was widely distributed to the participating agencies after it was finalized.

8. Has the NRC had opportunity to comment on the plan in draft form?

Answer: The NRC reviewed the plan in draft form and in its final version during its annual program review. 9. Is the plan reviewed annually by the RCP for adequacy and to assure the content is current?

Answer: Yes. The most recent revision was made in August 1986 This revision updated the list of Bureau staff and telephone numbers as well as reflected some recent reorganizations of agencies referenced in the plan.

 Are drills performed periodically to test the plan for radioactive materials emergencies? Explain, for example, how nonroutine office hours communications are checked.

Answer: The plan is tested each time the Bureau responds to an emergency. Since the Bureau responds to an incident on an average of once a month, the staff has ample opportunities to determine the adequacy of the plan.

III.A Reviewer Assessment: The Department meets these indicator guidelines.

B. Budget (Category II)

NRC Guidelines: Operating funds should be sufficient to support program needs such as: staff travel necessary to conduct an effective compliance program, including routine inspections, followup or special inspections (including pre-licensing visits) and responses to incidents and other emergencies; instrumentation and other equipment to support the RCP; administrative costs in operating the program including rental charges, printing costs, laboratory services, computer and/or word processing support, preparation of correspondence, office equipment, hearing costs, etc. as appropriate. Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

Questions:

1. What fiscal year is used by your State?

Answer: July 1 to June 30.

 Indicate the amount for funds obtained from each source (fees, State General funds, HHS, NRC environmental monitoring or transportation surveillance contracts, EPA, FDA and others).

Answer: The Bureau for Radiation Control is funded entirely by the General Fund of the City of New York. Fees collected by the Bureau are not applied directly to the Bureau's budget.

- 3. Show the total amounts assigned to:
 - a. the total radiation control program

Answer: The total Bureau budget for FY '86 is \$1,229,658.

b. the radioactive materials program.

Answer: The total radioactive material budget for FY'86 is \$340,109.

4. What is the change in budget from the previous year and what is the reason for the change (new programs, change in emphasis, statewide reduction, etc.)?

Answer: There has been no significant increase in the Bureau's budget over FY '85.

5. Describe your fee system, if you have one, and give the percentage of cost recovery. Enclose a copy of the fee schedule.

Answer:

License Category|License|Renewal|Amendment|Basic Inspection|Per Site

	Fee	Fee	Fee	Fee	Inspection Fee
Teletherapy	\$ 304	\$109	\$74.10	\$121.60	\$152.00
Sealed Source	228	1 152	1 74.10	85.50	114.00
Unsealed Source	152	114	74.10	95.00	95.00
Unsealed Source Broad License	228	190	74.10	159.60	190.00
76 or more sites 26 - 27 sites 1 - 25 sites	532 380 266	532 380 266	74.10 74.10 74.10 74.10	1260.00 912.00 494.00	95.00 95.00 95.00

The fees collected in FY '85 amounted to \$443,186.40 for the total radiation control program and \$160,081.40 for the radioactive materials program. For the materials program the percentage cost recovery is about 40%.

6. Does the RCP administer the fee system?

Answer: Yes. The Bureau administers the fee system with the aid of the Fiscal Administration of the New York City Department of Health. In addition, the Bureau program and its fiscal component are audited by the Office of the Comptroller, Fiscal Administration, and the State Department of Health.

7. What recourse does the RCP have in the event of non-payment?

Answer: Before a new license, renewal or amendment is issued to the applicant, he is required to pay a fee for the licensing action. If the fee is not paid after 35 days of the first mailing of the bill, a second bill is mailed. If the bill is not paid after 35 days of the second bill, a third bill is mailed with a notice to appear before the Administrative Tribunal. A suggested fine of \$250.00 is added to the amount of the third bill. No payment may result in a State Supreme Court decision and the submission of the entire matter to a collection agency. Non-payment may also result in termination of the radioactive materials license. After the completion of an inspection of a radioactive materials license, a bill is submitted to the licensee for payment. If no payment is received, the steps outlined above can be taken.

 Overall, is the funding sufficient to support all of the program needs? If not, specify the problem areas.

Answer: Due to inflation, the costs of salaries, equipment, services, rent, etc. tend to exceed the amount of revenue collected from the fee system, although any shortfall is covered by the General Fund. a proposed new fee schedule for inspections would increase these fees by 53%.

III.B Reviewer Assessment: The Department meets these indicator guidelines.

C. Laboratory Support (Category II)

NRC Guidelines: The RCP should have the laboratory support capability in-house, or readily available through established procedures, to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, etc., on a priority established by the RCP.

Questions:

1. Are laboratory services readily available in-house or through other departments within the State organization?

Answer: Yes, to the extent that services are available from the City Bureau of Laboratories.

 If services are provided by other departments, discuss the arrangements, supervision, charges and interdepartmental communications.

Answer: Yes. Temporary informal arrangement with the Bureau of Laboratories.

- 3. If laboratory services must be provided by a non-State agency:
 - a. Discuss the contractual arrangements.

Answer: N/A

Answer: N/A

c. If a State licensee provides the service or equipment, what are the costs?

Answer: N/A

- Describe the capability of the laboratory as follows:
 - a. Can it qualitatively and quantitatively analyze low-energy beta emitters?

Answer: Yes. The Bureau has a Packard Model 300C Tri-Carb Liquid Scintillation System for qualitatively and quantitatively analyzing low energy beta emitters.

b. Can it qualitatively and quantitatively analyze alpha emitters?

Answer: Yes. Nucleus Model 5300 Alpha and Gamma Spectrometer and Multi channel analyzer.

c. Can it selectively determine the presence and quantity of gamma emitters?

Answer: Yes. See above.

d. Can it handle samples in any physical form - wipes, liquids, solids, gaseous?

Answer: Yes.

e. Does the lab participate in a periodic quality control program?

Answer: The laboratory does not participate in a periodic quality control program.

5. How much time does it take to obtain the results from sample analyses on both a routine basis and on an emergency basis?

Answer: It takes the laboratory from 2 to 20 days to obtain the results from routine analyses and 1 day to obtain the results from emergency analyses.

List the number and types of laboratory instrumentation and services available.

Answer: Gross alpha and beta counting, low energy beta counting, and alpha and gamma spectroscopy are performed in the laboratory. The following instrumentation is on hand: Packard Model 300c Tri-Carb Liquid Scintillation System, and a Nucleus Model 5300 Alpha and Gamma Spectrometer.

- III.C Reviewer Assessment: Although the above capabilities appear to meet the guidelines, there are advantages to having "inhouse" lab capability and the Bureau should proceed with plans to establish their own lab facility.
 - D. Administrative Procedures (Category II)

NRC Guidelines: The RCP should establish written internal procedures to assure that the staff performs its duties as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies and procedures, decommissioning, and other functions required of the program.

Questions:

 What procedures are established to assure adequate and uniform regulatory practices (e.g., administrative procedures, policy memos, licensing and inspection guides, escalated enforcement procedures, decommissioning procedures, etc.)?

Answer: The Bureau has established procedures for all routine licensing and inspection activities. In licensing, the Bureau provides applicants and licensees with expiration reminder letters, application forms, regulatory guides and other guidelines. The license reviewers use checklists, regulatory guides and other technical references in assessing applications. Standard inspection forms and enforcement correspondence are used. Regular and escalated enforcement actions are conducted according to Department policies.

2. To what extent are the procedures documented?

Answer: Source documents for the above procedures are available and are usually obtained from the NRC. They include current regulatory guides, licensing checklists, standard license conditions, sample enforcement correspondence, inspection report forms, information notices, etc.

3. If the RCP has separate licensing and inspection staffs, what are the procedures used to communicate between the two staffs?

Answer: Frequent meetings and daily contact among staff members is sufficient to ensure uniformity of practices, adherence to policy and awareness of pertinent events. 4. How are personnel kept informed of current regulatory policies and practices?

Answer: Frequent meetings and daily contacts.

5. If the RCP collects fees, are fee collection duties assigned to non-technical staff?

Answer: Routine fee collection duties are handled by the non-technical staff of the Billing and Analysis Unit of the Bureau for Radiation Control.

6. How are contacts with communication media handled?

Answer: Contacts with news media may be handled through the Public Information Office of the Department or with the knowledge and approval of upper management, by the Director, Bureau for Radiation Control.

7. What procedures exist to ensure timely release of factual information on matters of interest to the public, the NRC and Agreement States?

Answer: Upper management would be kept informed of any matters of public interest. They would determine what information should be released and the means of publicizing it. The NRC is notified of any matter which may have generic significance, any information released to the public, or any abnormal occurrence.

- 8. If your RCP has regional offices:
 - a. what procedures are in effect to assure the regions have complete copies of the procedures and files?

Answer: N/A

b. how often are periodic staff meetings held with headquarters staff?

Answer: N/A

c. how often are periodic visits/audits made by headquarters staff to regional offices?

Answer: N/A

d. how is uniformity controlled?

Answer: N/A

e. how is supervision handled?

Answer: N/A

III.D Reviewer Assessment: The Department meets these indicator guidelines.

E. Management (Category II)

NRC Guidelines: Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquiries, regulation revisions). RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services and fundings.

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, la.ge scope - Type A Broad, or potential for significant releases to environment) should receive second party review (supervisory, committee, or consultant). Supervisory review of inspections, repress and enforcement actions should also be performed.

Questions:

 How does the staff keep program management abreast of the status of regulatory actions (such as backlog, problem cases, inquiries, and revision of regulations)?

Answer: Management is informed of work status and problems through frequent staff meetings and conferences. Reports are prepared for management periodically on request.

 a. Is a periodic statistical tabulation of licenses, licensees, inspections and backlogs prepared by category?

> Answer: Various indicators of program status are stored on an IBM Model 3275 HSA 102 computer station, with the main terminal located at 111 Eighth Avenue, New York. This computer stores the names and addresses of licensee, license numbers, license expiration dates, dates of last inspection, numbers of sites found at facilities c licensees, and the telephone numbers of the licensees.

b. If so, specify how frequently the tabulation is prepared.

Answer: Weekly, monthly and quarterly reports are prepared manually on activities of the Bureau. Quarterly reports are received as printouts form the IBM computer.

3. How does RCP management assess workload trends and resources in order to determine future needs or the need for program changes?

Answer: Workload trends are assessed by reviewing the computer printouts and manual reports which are prepared weekly, monthly and quarterly. How does the RCP management keep abreast of changes in legislative and regulatory responsibility?

Answer: The Commissioner is kept informed of changes in legislative responsibility by the New York City office of the State Department of Health.

 Discuss the procedures followed by licensing supervision or RCP management to monitor licensing quality.

Answer: All license review correspondence and final licensing actions are reviewed by the Chief, Radioactive Materials Division after they are prepared. The Chief, Radioactive Materials Division also either assigns the correspondence to a license reviewer for handling or he will reply to the correspondence directly.

Discuss the procedures used for supervisory review of inspection reports.

Answer: All inspection reports are reviewed and approved by the Field Supervisor upon their completion. The Field Supervisor reviews, edits and drafts enforcement correspondence which is forwarded to the Chief, Radioactive Materials Division for final approval. The Field Supervisor reviews licensee responses to enforcement correspondence and determines whether additional correspondence or escalated action is appropriate. He may request advice from the Division Chief at any stage.

7. What license review practices are followed for unusual or complex license applications?

Answer: The staff members consult with each other and, if necessary, with management concerning complex proposals or other evaluation difficulties. Occasionally, the Bureau will use the services of the Committee on Human Applications or the Technical Committee to the Commissioner. The Bureau will also consult with the NRC staff in Region I or the Office of State Programs.

 If applicable, discuss the procedures used for supervisory review of work performed by contract agencies or regional offices.

Answer: N/A

III.E <u>Reviewer Assessment</u>: During the review, a number of significant deficiencies were noted. These deficiencies have gone undetected by Bureau management. It is the reviewer's opinion that Bureau management (Director and Deputy Director) needs to be more directly involved in the technical aspects of the radioactive materials program. It was recommended that the Bureau institute a quality assurance program to keep management apprised of the status of the program and to assure that Bureau policies are being effectively carried out by the staff.

F. Office Equipment and Support Services (Category II)

NRC Guidelines: The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to larger (300-400 licenses) programs. Similar services should be available to regional offices, if utilized.

1 a. In terms of the person-year/100 licenses figure, what level of secretarial/clerical support is provided?

Answer: 1.35 person-years or 0.17 person-years per 100 licenses.

b. If your program has regional office, provide the figures for the support for those offices.

Answer: N/A

Describe the ADP and word processing capabilities available to the RCP.

Answer: The Bureau has an IBM Display Writer System word processor. This system stores certain radioactive materials data, letters, and standard license conditions. The Bureau also has a Wang Model QC09 computer.

- III.F <u>Reviewer Assessment</u>: The Bureau is more effectively utilizing its automatic data processing capabilities. The Department meets these indicator guidelines.
 - G. Public Information (Category II)

NRC Guidelines: Inspection and licensing files should be available to the public consistent with State administrative procedures. Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws.

Questions:

 Are licensing and inspection files available for inspection by the public?

Answer: All licensing and inspection files are available for inspection by the public. However, the public is required to contact the Secretary, Board of Health, to request access. The Secretary determines whether to grant the request.

2. Are medical and proprietary data withheld?

Answer: Yes. Certain medical and proprietary data are withheld.

Answer: None.

 What written procedures and laws govern this? Please provide reference citations.

Answer: Release of information is governed by Article 3, General Provisions of the New York City Health Code.

5. For mill States, are opportunities provided for public hearings in accordance with UMTRCA and applicable State administrative procedures and statutes?

Answer: N/A

III.G Reviewer Assessment: The Department meets these indicator guidelines.

IV. PERSONNEL

A. Qualifications of Technical Staff (Category II)

NRC Guidelines: Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel should be commensurate with the type of licenses issued and inspected by the State.

Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Questions:

 Do all professional personnel hold a bachelor's degree or have equivalent training in the physical or life sciences?

Answer: Yes. All professional personnel in the Radioactive Materials Division hold at least a bachelor's degree in the physical or life sciences.

2. What additional training and experience do the senior personnel need to have in radiation protection?

Answer: Additional training and experience are described in job descriptions for all professional levels.

3. What written position descriptions describe the duties, responsibilities and function of each professional position?

Answer: Job description exist for Assistance Scientist (Radiation Control), Scientist (Radiation Control), and Senior Scientist (Radiation Control). These are available in Region I files.

- IV.A <u>Reviewer Assessment</u>: The Department meets these indicator guidelines, however, based on reviews of casework and accompaniments of inspectors, the newer staff is somewhat weak in training and experience in operational health physics.
 - B. Staffing Level (Category II)

NRC Guidelines: Staffing level should be approximately 1-1.5 personyear per 100 licenses in effect. RCP must not have less than two professionals available with training and experience to operate RCP in a way which provides continuous coverage and continuity.

For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years' of effort, including consultants, are needed to process a new mill license (including insitu mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978. This effort must include expertise in radiological matters, hydrology, geology, and structural engineering.

Questions:

 Complete a table as below, listing the person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, fraction of time spent and the duty (licensing, inspection, administration, etc.).

Answer:

Name	Position	FTE%	Area of Effort
Leonard Solon	Bureau Chief	50	Admin.
Richard Borri	Acting Ass't Director, RAM	100	Supervisor
Martin Schnee	Field Supervisor	60	Supervisor
Bapu Kamble	Scientist	100	Licensing & Inspection
Louis Mazzola Manual Plotsker	Ass't Scientist Scientist	100 100	Inspection Licensing (in training)
John Snyder Vincent Parisi Esther Perlmutter Fred Schnee	Ass't Scientist Physicist Ass't Scientist Ass't Scientist	100 20 100 100	Inspection Laboratory Inspection Inspection (in training)

Total

8.3 Person-Years

 Compute the person-year effort of person-years per 100 licenses (excluding mills and burial sites). Show calculation.

Answer: 8.3 person-years/808 licenses = 1.0 person-years per 100 licenses.

3. Is the staffing level adequate to meet normal and special needs and backup?

Answer: The staffing level is not at the desired point at this time. The Bureau plans to increase the field staff by one person.

- IV.B Reviewer Assessment: The Bureau meets these indicator guidelines.
 - C. Staff Supervision (Category II)

NRC Guidelines: Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel. Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy. Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Questions:

1. Identify the junior and senior personnel.

Answer: Junior personnel include Mazzola, Purlmutter, F. Schnee, and Snyder. Other staff are considered senior personnel.

a. What duties are assigned to junior personnel?

Answer: Junior personnel, at the present time, are limited to inspecting licenses under the supervision of the Field Supervisor. Junior personnel can also review license applications although none are now doing so.

b. Do they review applications and perform inspections independently?

Answer: Yes.

3. a. What duties are assigned to senior personnel?

Answer: Senior personnel review applications and inspect licenses independently and participate in the establishment of policy and standards.

b. Do they independently review and monitor the work of junior personnel?

Answer: Yes.

4. Is there adequate supervisory or senior guidance and direction for junior personnel?

Answer: Yes.

 Discuss procedures established to ensure supervisory review of the licensing, inspection and enforcement functions.

Answer: Supervisory practices are outlined in III.E, above.

6 a. Are RCP staff members allowed to consult or work part time for State licensees?

Answer: No.

b. If so, how are conflicts of interest avoided?

Answer: N/A

- IV.C <u>Reviewer Assessment</u>: Since December 1985, the Assistant Director for Radioactive Materials position has been filled by Richard Borri on an acting basis. The position of Field Supervisor (radioactive materials) has been filled on a part-time basis by Martin Schnee. It is the reviewer's opinion that this situation has contributed to the technical problems noted during the review. It was recommended that the two positions discussed above be filled on a full-time permanent basis as soon as possible.
 - D. Training (Category II)

NRC Guidelines: Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices. (For mill States, mill training should also be included.) The RCP should have a program to utilize specific short courses and workshops to maintain appropriate level of staff technical competence in areas of changing technology.

Questions:

 List all RCP personnel and the NRC training courses they have attended.

Answer: Staff training data is provided in Appendix C.

How does the RCP utilize short courses and workshops to maintain staff proficiency?

Answer: All staff periodically attend short courses and workshops usually sponsored by other agencies as they are made available. The staff members have attended meetings of the Radiological and Medical Physics Society of Greater New York and the Health Physics Society. They have also attended annual meetings of the Conference of Radiation Control Program Directors and the annual All Agreement States Meeting.

- IV.D Reviewer Assessment: The Bureau for the most part meets these indicator guidelines. The Bureau staff, although having technical backgrounds, have not all had additional formal training in radiation protection nor attended the applicable NRC sponsored "core" courses. This is reflected in the casework and inspection efforts. Louis Mazzola, Fred Schnee and Esther Perlmutter should attend the 5-week Health Physics course.
 - E. Staff Continuity (Category II)

NRC Guidelines:

Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area. The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

Questions:

 Identify the RCP employees who have left the program since the last review and give the reasons for the turnovers. Also state whether the positions are presently vacant, filled (name replacement), abolished or other status.

Answer: Perry Letsinger, Julius Kriendler, retired as of December 1985.

2. List the RCP salary schedule:

Answer:

Position Title	Annual Salary Range
Director	\$38,135 - \$63,666
Senior Scientist	\$36,646 - \$46,705
Scientist	\$33,261 - \$41,889
Assistant Scientist	\$28,020 - \$36,561

3. Compare your salary schedule with similar employment alternatives in the same geographical area, such as industrial, medical, academic or other departments within your State.

Answer: Bureau salaries are similar to State programs and medical/academic employers, but less than similar industrial concerns.

4. What opportunities are there for promotion within the RCP organizational structure without a staff vacancy occurring?

Answer: The Department occasionally gives promotional examinations for upgrading to higher grades. Promotion lists of eligible candidates usually last approximately 4 years. As vacancies occur, appointments are made from eligible lists.

IV.E Reviewer Assessment: The Bureau meets these indicator guidelines.

- V. LICENSING
 - A. Technical Quality of Licensing Actions (Category I)

NRC Guidelines: The RCP should assure that essential elements of applications have been submitted to the agency, and which meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Prelicensing visits should be made for complex and major licensing actions. Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions. The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

Questions:

1. How many specific licenses are currently in effect?

Answer: 808

 a. How many new licenses (not amendments in entirety) have been issued since the last review?

Answer: 70

b. How many were major licenses?

Answer: None

Answer: 42

4. How many amendments were issued during the review period?

Answer: 389

 Identify unusual or complex licenses issued since the last review, including name and license number.

Answer: None

Note any variance in licensing policies and procedures granted since the last review.

Answer: None

7. Do you require license applicants to submit details on their radwaste packaging and shipping procedures?

Answer: Licensees who routinely ship significant waste volumes, such as broad licensees, are required to describe their waste packaging and management systems in license renewal applications. New applicants who plan to routinely ship significant waste volumes would be required to describe their waste packaging and management system.

8 a. When do you require licensees to submit contingency plans?

Answer: Licensees who meet the Federal emergency planning criteria would be required to submit contingency plans.

List the licensees who have been required to submit contingency plans.

Answer: None.

9. How many prelicensing visits were made during this review period?

Answer: 21

10. What criterion does the RCP use to determine the need for a prelicensing visit?

Answer: The Bureau uses the following criteria to determine the need for a prelicensing visit: a) unusual or complex activity requested; b) question regarding an application statement or submission which cannot be resolved through correspondence, or about which the license reviewer has reservations; c) verification of measurements offered by the applicant as part of the application; d) expressed or anticipated public interest.

11. How do you ensure up-to-date information has been submitted prior to a license renewal?

Answer: The renewal application is compared to the previous application. The reviewer uses standard guidelines and requests additional information by written memo if the application is incomplete or the submission is inappropriate.

12. Do license files contain all necessary data required to evaluate an application prior to issuing a license?

Answer: Yes. The Bureau does not grant licenses to applicants whose applications are incomplete or unsatisfactory. When problems are unresolved after two written requests for additional information plus verbal discussion, we would dispose of the problem by withdrawing the application.

13. Has the RCP taken any unusual licensing action with respect to licensees operating under multiple jurisdiction?

Answer: No.

 Prepare a table as below showing the RCP's major licensees with name, number and type.

INCLUDE:

- Broad (Type A) Licenses
- LLW Disposal Licenses
- LLW Brokers
- Major Manufacturers and Distributors
- Uranium Mills
- Large Irradiators (Pool Type or Other)
- Other Licenses With a Potential Significant Environmental Impact
- Other Licensees You Consider to be "Major" Licensees

Answer:

Name	License Number		Type	
Albert Einstein College of Medicine	188-2	Broad	Non-Human	Use
Columbia University Columbia-Presbyterian Medical Center	162-1 62-3	Broad Broad	Non-Human Non-Human	Use Use
Downstate Medical Center Memorial Hospital New York University Medical Center	82-110 65-1 86-90	Broad Broad Broad	Non-Human Non-Human Non-Human	Use Use Use
Rockefeller University Sloan-Kettering Institute	183-2 84-1	Broad Broad	Non-Human Non-Human	Use Use

New York University Medical Center	86-96	Broad Human Use (720 Curies of Cesium 137)
Memorial Hospital		Broad Human Use
Columbia-Presbyterian Medical Center	630-1	Broad Human Use
Memorial Hospital for Cancer and Allied Diseases	65-1	Broad Non-Human Use (800 Curies of Cesium 137)
College of Staten Island	1557-2	Specific license (10,000 Curies of Cesium 137)
Albert Einstein College of Medicine	188-7	Broad Human Use (4000 Curies of Cesium 137)

V.A. Reviewer Assessment: The review of selected licensing actions revealed significant technical inadequacies. Of particular concern were the renewals of two broad licenses. The applications accepted by the Bureau as the basis for renewal were deficient in such basic areas as radiation safety committee duties and responsibilities, use and user approval criteria, and inadequate procedures for such activities as instrument calibration, leak testing, waste disposal, and the survey program. Problems noted with other licensing actions included inadequate documentation of physician qualifications, inadequate receipt procedures, and no emergency procedures.

The Bureau should reconfirm its commitment to adhere to established policies and practices in the licensing program, specifically the NRC licensing guidance (FC Directives, Standard Review Plans, and Regulatory Guides) which has been provided to the program. A report on the review of selected license files is attached as Appendix D.

B. Adequacy of Product Evaluations (Category I)

NRC Guidelines: RCP evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC, State, or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users.

The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy. Approval documents for sealed source or device designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Questions:

1. How many new and revised evaluations were made of sealed sources and devices during the review period?

Answer: The Bureau does not evaluate sealed sources and devices. This is the responsibility of the New York State Department of Labor. 2. How many SS&D evaluations have been made for which approval documents have not yet been prepared?

Answer: N/A

3. How does the RCP evaluate manufacturer's data on SS&D's to ensure integrity and safety for users?

Answer: N/A

4. Do you determine whether the manufacturer's information on labels and brochures relating to health, safety, assay, and calibration procedures is adequate on all products?

Answer: N/A

- V.B. Reviewer Assessment: N/A
 - C. Licensing Procedures (Category II)

NRC Guidelines: The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice. License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions. The present compliance status of licensees should be considered in licensing actions. Under the NRC Exchange-of-Information program, evaluation sheets, service licenses, and licenses authorizing distribution to general licensees and persons exempt from licensing should be submitted to NRC on a timely basis. Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process. Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

Questions:

 Has the RCP developed its own licensing procedures or does it use NRC guides? Please provide for review.

Answer: The Bureau primarily uses guides received from the NRC. Frequently, guides have been edited and retyped to clarify references to the Bureau and the New York City Health Code.

What licensing guides, checklists and policy memoranda are made available to the staff?

Answer: The Bureau uses Division 8 and 10 Regulatory Guides and Fuel Cycle Directives of the NRC and Bureau prepared checklists.

3. What guides and/or regulatory position statements are furnished to license and renewal applicants?

Answer: The same guides used by the Bureau staff are sent to applicants for new licenses and renewals.

 Describe the system for advising classes of licensees of new licensing procedures and regulations.

Answer: The Bureau mails copies of new regulations to all licensees at each revision. Licensing procedures are described in the regulatory guides and are mailed to applicants for new licenses and renewals.

5. a. How are licensing actions coordinated with the compliance staff?

Answer: Certain renewals or amendments involve review of relevant compliance history and actions. When necessary, the licensing staff will consult with the inspection staff on the proposed licensing action.

b. Are licensing actions taken while enforcement action is pending?

Answer: If a licensing action is taken which is concurrent with an enforcement action, either the two actions are coordinated, or the licensing action is delayed until the enforcement matter is resolved, depending in the circumstances.

6. For what length of time are various categories of licenses issued?

Answer: All broad licenses--2 years, all other specific licenses--5 years.

7. a. Does the RCP use standard licensing conditions?

Answer: Yes.

b. If so, how does the RCP assure they are comparable with those used by NRC?

Answer: The Bureau uses standard license conditions modeled after those of the NRC. These conditions are updated whenever the Bureau receives a revised set from the NRC.

8. Are the licensing conditions on file in the RCP office and with NRC?

Answer: Yes. The list of standard license conditions dated March 11, 1985 are available in Region I files.

9. What SS&D sheets, service, distribution and "E" licenses are available for RCP staff use?

Answer: The Bureau has a complete SS&D catalog, medical distribution licenses and service licenses distributed by NRC.

10. Describe your practices for distributing SS&D sheets, as well as GL distribution and service licenses, to the NRC.

Answer: N/A

 Describe your procedures for maintaining the license files (How are files and folders arranged? Are telephone contacts and visits documented? Who is responsible for filing materials in folders?).

Answer: License files are arranged alphabetically by licensee name. Each folder contains a copy of the license, amendments, applications, licensing correspondence, inspection reports, inspection correspondence and telephone contacts. The folder also contains the enforcement history of the licensee. This indicates the dates of previous inspection and whether the licensee was in compliance or not. License reviewers are responsible for filing materials in folders.

12. Are there opportunities for license reviewers to accompany inspectors?

Answer: License reviewers occasionally accompany inspectors to resolve certain problems encountered during the licensing process.

V.C. <u>Reviewer Assessment</u>: During the previous review, it became evident that the Bureau's files are something less than immaculate. Numerous documents were misfiled or missing altogether from files. The Bureau was unable, in two days, to locate one entire file. In addition, and notwithstanding the Bureau staff's opinion to the contrary, there did not appear to be a coherent filing system. For example, inspection reports for broad licensees (some of which amounted to more than 100 pages of documents) were scattered among the various files for the licensee. During this review, little improvement was noted compared to filing practices noted in previous reviews. The Bureau does have plans, however, to completely revamp the filing system.

VI. COMPLIANCE

A. Status of Inspection Program (Category I)

NRC Guidelines: The State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions.

The RCP should maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available.

There should be at least semiannual inspection planning for the number of inspections to be performed, assignments to senior vs. junior staff, assignments to regions, identification of special needs and periodic status reports.

Questions:

 How is statistical information maintained about the inspection program to permit periodic assessment of its status by RCP management?

Answer: Dates of the last inspection are stored in the IBM computer. A quarterly printout is provided to the Bureau.

2. Prepare a table as below, indicating the number of inspections made in the review period, by category and priority.

Answer:

License Category	Schedu Freque	lec	1		Inspection Priority		Number of Inspection:
College University	Initia Phase	1 -	ļ	5 years 5 years	Priority	5	19
	Initial Phase	1 1	1 3	year years	Priority	4	7
Broad	Initial		6	months			
Academic	Phase	-	5	years	Priority	2	1
	Initial		5	vears			
Institutional Medical	Phase	-	5	years	Priority	5	45
	Initial	-	1	year	Priority	4	And the second se
	Phase	**	3	years			275
Broad Medical	Initial		6	months	Priority	2	14
	Phase	-	2	years			
Teletherapy	Initial		1	Vear	Priority	4	16
	Phase	÷.	3	years			10
Private	Initial	-	5	vears	Priority	5	20
Medical Practice	Phase	-	5	years			LV
	Initial	-	1	year	Priority	4	20
	Phase	1	3	years			
Total number (of Licens	ses	1	Inspecto	ed -		414

3. Prepare a table (or tables) as below which identifies the Priority 1, 2, and 3 licensees with overdue inspections. Include the license category, the due date, and the number of months the inspection is overdue. (If list is extensive, a comparable computer printout is acceptable.)

Answer: None.

 Prepare a table as below indicating the number of overdue license inspections for Priorities 4 through 7.

Answer:

			Due	Months
Licensee	Category	Priority	Date	Overdue
Lincoln Hosp.	Inst. Medical	4	6/20/86	3
Mt. Sinai Med. Ctr.	0	4	5/27/86	3
Mt. Sinai Med. Ctr.	0	4	6/1/86	3
Mt. Sinai Med. Ctr.	41	4	5/3/86	Ă
N.Y.C. Bd. of Ed.	Other	4	2/22/85	19
Mt. Sinai Med. Ctr.	Inst. Medical	4	6/1/86	17
Nuc. Med. Jack Hts.	Pvt. Med.	4	1/20/86	8
Parkway Hosp. (Tele.)	Inst. Medical	4	7/26/86	1
SUNY Ft. Schuvler	College	4	6/23/86	2
St. Lukes -	Inst. Medical	5	2/4/85	10
Roosevelt		~	L/ 4/ 00	10
St. Barnabas Hosp.	Inst. Medical	4	8/25/85	12
York College	College	4	12/7/85	12
Gollub & Schaefer	College	4	0/22/85	12
Wagner College	College	4	2/10/85	10
Westchester So.	Inst. Med	4	7/10/85	10
Nucl Med.	and a news		1110100	14
Booth Mem. Hosp.	Inst. Med.	4	5/13/86	4
Singer & Scheinbrot	Pvt. Med.	4	7/13/85	14
No. Cent. Bx	Inst. Med.	4	8/10/85	12
Comm. Radiology			0/20/00	15
Assoc. (Tele.)	Pvt. Med.	4	5/26/86	٨
Union Hosp, Bx.	Inst. Med.	4	9/19/85	12
N. Bartha	Pvt. Med.	4	5/31/86	3
Lincoln Hosp. (Tele.)	Inst Med	4	9/30/85	11
SUNNY A. Schuvler	College	4	6/22/86	2
Hillcrest Gen. Hosp.	Inst. Med	4	1/13/86	0
J. Disease No. Gen	Inst Med	4	3/8/86	6
(Tele.)	21120. 1100.		5/6/60	0
Lincoln Hosp.	Inst Med	4	6/16/86	2
Nuc. Med.	arrays from.	-	0/10/00	3
Nuclear Medicine	Pvt Med	4	6/30/85	14
Assoc.			0/ 30/ 03	14
Messina & Liebeskind	Pyt Mod	4	6/21/86	2
Bx. Comm. College	College	4	6/30/95	14
Hosp for J	Inst Med	4	1/11/26	14
Diseases	analas nega	7	1/11/00	0

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5. How are inspection schedules planned and how are the dates and personnel assignments made?

Answer: Routine inspection frequency is set by the priority system. Licensees may be inspected more frequently than the priority system requires, depending on their compliance history. Most of the broad licensees and licensees with multiple specific licenses are inspected annually since they have more complex programs and encounter more difficulty in maintaining compliance with the Health Code. Inspections are planned and assigned to field personnel by the Field Supervisor. The Field Supervisor peruses the computer printout and selects the licensees which are due for inspection and makes the assignments.

- VI.A Reviewer Assessment: The Bureau's inspection backlog has increased somewhat since the last review, 30 versus 5. All are Priority IV or lower and with few exceptions, none are overdue for a significant amount of time. The increase has been due primarily to the staff situation, one inspector moved to licensing and newer inspectors being in training.
 - B. Inspection Frequency (Category I)

NRC Guidelines: The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations, e.g., major processors, broad licensees, and industrial radiographers should be inspected approximately annually -- smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency should be consistent with the NRC system.

Questions:

1. Enclose a copy of the RCP's inspection priority system.

Answer: The Bureau's inspection priority system is attached as Appendix E.

2. Who assigns licenses to the priority categories?

Answer: The priority categories are assigned by the Chief, Radioactive Materials Division with the concurrence of higher management.

 Discuss any significant variances in the RCP's priorities from the NRC priority system.

Answer: The Bureau inspects broad licenses annually, whereas the NRC inspects these licensees every 2 years. The Bureau require Priority 4 licenses to be inspected every 3 years versus 4 years for NRC.

4. Is the inspection priority system designed to assure that the more hazardous and/or complex operations are inspected at an appropriate frequency? Answer: The priority system requires that a licensed program having a specific potential hazard be inspected at a definite frequence. The Bureau imposes a higher frequency when conditions warrant.

 Describe the RCP's policy for unannounced inspections and exceptions to the policy.

Answer: As a result of a Departmental directive, licensees are now given 30 days notice of an inspection.

6. Describe the RCP's policy for conducting follow-up inspections.

Answer: Follow-up inspections are required when serious or potentially serious violations are discovered or when the Bureau has reservations concerning the licensee's ability or willingness to correct outstanding violations.

 a. Does the RCP inspect out-of-state firms working in the State under reciprocity or under State licensure?

> Answer: Yes. The Bureau occasionally inspects out-ofstate firms working in the City of New York if it is suspected that a potential hazard exists.

b. How many reciprocity notices were received?

Answer: None during the review period.

c. How many were inspected?

Answer: N/A

- VI.B Reviewer Assessment: The Bureau actually performs inspections more frequently than indicated by their priority system. Most City licensees are inspected at either 1 or 2 year intervals. The Department meets these indicator guidelines.
 - C. Inspector's Performance and Capability (Lategory I)

NRC Guidelines: Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections.

The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Questions:

 a. Does the senior inspector or supervisor periodically accompany the inspectors? Answer: Yes. The Field Supervisor accompanies the field inspectors several times a month. He is required to accompany field inspectors during 5% of all inspections.

b. Are these accompaniments documented?

Answer: Yes. The Field Supervisor documents his accompaniments and evaluates the performance of the field inspectors once a month.

 Give the number of supervisory accompaniments of inspectors since the last review meeting and identify the persons accompanied and the supervisors.

Answer: The following accompaniments were performed by Richard Borri and Martin Schnee.

Date Inspector		Institution
8/13 5/21 3/6, 2/19 2/13, 1/2	Louis Mazzola 9	NYU Medical Center Memorial Sloan Kettering Inst. NY Cornell Medical Center
6/24 5/15 4/23 4/1 3/5, 2/4,	Manuel Plotsker 1/23	Memorial Sloan Kettering Inst. Memorial Sloan Kettering Inst. Nuclear Medi Scan, IMA Med. Assoc. J. Matio, MD. NY Hospital, Cornell Medical Center
5/8, 4/16 4/15, 3/2 3/20 3/14, 2/2 1/30	John Snyder 8, 7	Kings County Hospital Downstate Medical Center Brookdale Medical Center Downstate Medical Center
9/17, 9/11, 9/4, 8/7, 8/29, 8/2	Fred Schnee (for training) 8/1, 0	NYS Institute for Basic Research
8/13 7/17 7/2 6/4, 5/28 2/6	Esther Perlmutter	NYU Medical Center Coney Island Hospital (training) Maimonides Medical Center Maimonides Medical Center NY Cornell (training)

VI.C Reviewer Assessment: During the review meeting two Bureau inspectors were accompanied during the inspection of materials licensees. Esther Perlmutter was accompanied on the inspection of an institutional medical licensee. Fred Schnee participated in the inspection for training purposes. John Snyder was accompanied on the inspection of a group practice medical program. Although the inspectors were diligent in following
prescribed forms and guidelines on what to review, the depth of the review and the inspector's ability to discern safety related problems in the licensee's program was in question. For example, a security/access control problem at one facility went unnoticed. Also the failure to recognize deficiencies in certain records raised misgivings about the inspectors' technical judgement. It was recommended that the Bureau's newer staff obtain additional training in operational health physics.

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

NRC Guidelines: Inquiries should be promptly made to evaluate the need for onsite investigations. Onsite investigations should be promptly made of incidents requiring reporting to the Agency in less than 30 days (10 CFR 20.403 types). For those incidents not requiring reporting to the Agency in less than 30 days, investigations should be made during the next scheduled inspection. Onsite investigations should be promptly made of non-reportable incidents which may be of significant public interest and concern, e.g., transportation accidents. Investigations should include indepth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). Investigation (or inspection) results should be documented and enforcement action taken when appropriate. State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures). Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency. The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Questions:

1. How does the RCP respond to incidents and alleged incidents?

Answer: Whenever an incident or alleged incident is reported, the Bureau makes necessary inquires to establish the nature and severity of the incident. A site visit is made to investigate all incidents requiring reporting to the Bureau. On site investigations are also made of incidents which may be of significant public interest and concern, e.g., transportation accidents.

 Are major incidents (10 CFR 20.403 types requiring reporting in less than 30 days) investigated on a priority basis?

Answer: Major incidents are investigated as soon as someone can be dispatched to the site (At the start of the next workday at the latest). Subsection 175.112(b) of the City Health Code requires that if a theft or loss of radioactive material occurs, the owner, person in charge or radiation safety officer shall immediately notify the Department of Health by telephone. The loss of small quantities of radioactive material which do not threaten the public health safety would not ordinarily receive priority.

3. Are other incidents followed up in the next scheduled inspection?

Answer: In the case of minor incidents, the investigation may be assigned for completion at the inspectors convenience.

4. Are non-reportable incidents that may be of significant public interest and concern promptly investigated?

Answer: Yes. The Bureau promptly investigates non-reportable incidents that may be of significant public interest.

5. How many incident investigations were conducted during the review period?

Answer: 5

6. Attach as an appendix a summary of each incident investigated. Include documentation of investigation results, enforcement action when appropriate, any reenactment and time motion studies, as well as notification of the NRC and state licensees of incident information that may have been relevant to other licensed operations.

Answer: A summary of incidents is attached as Appendix F.

7. Were any incidents attributed to generic-type equipment failure?

Answer: No.

8. What action was or would be taken by the RCP pertaining to incidents attributable to generic equipment failures in regard to notification of the NRC, other licensees and the regulatory agency which approved the device?

Answer: The Bureau would notify the NRC and the licensees affected in a timely manner.

- If a failure should occur in equipment manufactured by a RCP licensee, what action would be taken to:
 - a. stop the manufacture or force changes in design?

Answer: If failure should occur in equipment manufactured by a State licensee, the Bureau would refer the matter to the State Department of Labor, which has jurisdiction.

b. assure retrofit of existing devices?

Answer: N/A

10. When are other RCP licensees and the NRC notified of pertinent information about an incident?

Answer: The NRC is notified of all significant incidents. Other licensees are notified if affected.

11. a. Are medical consultants available and used when necessary?

Answer: Medical consultants are known and available when when necessary. When needed, the Bureau would consult with the Committee on Human Applications.

b. Is the State aware of the availability of medical consultants from NRC?

Answer: The staff of the Bureau is aware of the availability of medical consultants from the NRC, but have not had occasion to use them recently.

 Explain any use of other technical consultants for special problems encountered in incident investigations.

Answer: No other technical consultants were used by the Bureau for special problems encountered in incident investigations.

13. Were there any incidents since the last review meeting that met Abnormal Occurrence Report (AOR) criteria?

Answer: No.

- VI.D Reviewer Assessment: The Bureau meets these indicator guidelines. The Bureau is diligent in responding to all incidents.
 - E. Enforcement Procedures (Category I)

NRC Guidelines: Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended. Enforcement letters should be issued within 30 days following inspections and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated. Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent re-occurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses. Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items. Written procedures should exist for handling escalated enforcement cases of varying degrees. Impounding of material should be in accordance with State administrative procedures. Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

Questions:

1. Describe the State's enforcement procedures.

Answer: The Buraau enforces its regulations in accordance with the provisions of Article 175 of the City Health Code. Enforcement sanctions include (a) civil penalties, provided by subsections 3.12, 3.13, and Article 7 of the Health Code; (b) modification or revocation of licenses, provided by subsection 175.103 of the Code; (c) seizure of radioactive materials, provided by subsection 3.03 of the Code; (d) criminal penalties, provided by Sections 1740 and 1741 New York State Penal Law; (e) an order by the Commissioner, provided by subsection 175.12 of the Code, and (f) hearings before the Administrative Tribunal of the City Health Department, provided by Article 7 of the Code. Enforcement sanctions also include notices of violation, orders of abatement and consent agreements.

 If the RCP can apply civil penalties, explain the procedures for keying monetary penalties to violations.

Answer: Subsection 3.12 provides that any person who is determined to have violated the City Health Code shall be subject to a fine, penalty and forfeiture of not less than twenty-five and not more than five hundred dollars for each violation of a provision of the Code.

3. Describe the RCP's provisions for criminal penalties.

Answer: Sections 1740 and 1741 of the New York State Penal Law provides for criminal penalties for certain violations.

 Describe the policies in effect for issuing field forms equivalent to NRC form 591 or letters for enforcement action.

Answer: The Bureau uses a field form 148E, Inspection Report, Notice of Violation, which is a summary of inspection findings. This form is left with each licensee who is inspected. Enforcement letters are mailed to each licensee with multiple licenses or a single licensee with a program which is large in scope. Enforcement letters are usually mailed to all broad licensed facilities and large specifically licensed facilities.

5. Are there written procedures for handling escalated enforcement cases? Please provide for review.

Answer: Yes. A copy of escalated enforcement procedures is available in Region I files.

6. Can the State issue Orders, including Emergency Orders?

Answer: Yes. The Department may issue orders, including emergency orders, according to subsection 3.01 of the Health Code. 7. Can the RCP impound radioactive material?

Answer: Subsection 3.01 of the Health Code provides that the Department may seize, embargo or condemn any material whenever that material constitutes a danger or is prejudicial to the public health.

8. Do RCP administrative procedures permit the opportunity for hearings in major enforcement cases?

Answer: Yes. Article 7 of the Health Code provides for the establishment of the Administrative Tribunal. The Department may administratively call violations before the Tribunal. The hearing officer is an attorney who has passed the Bar examination of the State of New York.

9. If during the review period the RCP has issued orders, applied civil penalties, sought criminal penalties, impounded sources, or held a formal enforcement hearing, identify these cases and enclose copies of the pertinent State enforcement correspondence or orders.

Name	License No.	Type of Enforcement Action	Date
St. Lukes - Roosevelt Hosp.	78-2	AT.18- Case dismissed after hearing	5/9/85
Shunkers Int'l Forwarders Corp. Jamaica, NY	N/A	AT-18- \$250.00 fine	6/19/85
Rockefeller Univ.	183-2	AT-18- Case withdrawn	7/9/85
Rockefeller Univ.	183-2	AT-18- \$100 fine	12/24/85
Columbia-Pres. Medical Center	630-1	AT-18- \$500 fine	12/24/45
Staten Island Hosp.	131-2	AT-18 found guilty expectd fine \$950	8/5/86
NY Univ. Med. Ctr.	86-90	AT-18 found guilty expected fine \$1.000	9/8/86

The above do not include any AT-18's issued for non-payment of fees - for inspection, amendments, etc.

AT-18's = summons for civil penalties

10. Are enforcement letters issued within 30 days of the inspection?

Answer: The Bureau attempts to prepare and issue enforcement letters within 30 days of the inspection. However, due to the large workload, it is not always possible to meet this deadline.

11. Are enforcement letters written in regulatory language and reference regulations and license conditions?

Answer: Enforcement letters use standard language from the list of Standard Violations prepared by the Bureau staff. The list references sections of the Code.

12. Do the enforcement letters clearly differentiate between noncompliance items and health and safety recommendations?

Answer: Yes. Health and safety recommendations are noted as such either in a cover letter, or in a notice of violation.

13. If applicable, do the letters separate actions subject to the State radiation control act and State OSHA regulations?

Answer: The Bureau does not enforce OSHA regulations.

14. a. Are enforcement letters issued by inspectors or supervisors?

Answer: Enforcement letters, when issued, are drafted by the Field Supervisor.

b. If issued by inspectors do they undergo supervisory review prior to dispatch?

Answer: Enforcement letters are reviewed and edited by the Division Chief (Mr. Borri) prior to dispatch. They are signed by the Field Supervisor.

15. Do enforcement letters require the licensee to respond within a stated time period? Note the period.

Answer: The Bureau requests a response within 30 days in most instances.

16. a. Are licensee's responses to enforcement letters reviewed by the inspector and the supervisor?

Answer: The response of the licensee is usually reviewed by the Field Supervisor initially and, depending on the seriousness of the issues, may be discussed with the inspector.

b. Are they acknowledged properly?

Answer: The responses the enforcement letters are acknowledged by the Field Supervisor and a copy of the correspondence is filed in the license folders.

17. Has the RCP taken escalated enforcement action against licensees who operate in multiple jurisdictions?

Answer: No enforcement action has been taken against licensees who operate in multiple jurisdictions.

VI.E Reviewer Assessment: The Bureau does not currently use the enforcement conference as an option in its enforcement process. The inspections which were conducted during the review revealed significant violations which were related to licensees lack of understanding of their repsonsibilities under the license. In such cases, it would be appropriate for the regulatory agency to bring the licensee in for a management conference. It was recommended that the Bureau consider using the enforcement conference as an intermediate step in escalating enforcement action.

During the last review it was suggested that for large facilities with many sites, instead of leaving numerous 148E forms with the licensee, one enforcement letter be issued summarizing the violations at the facility. (For broad licensees, enforcement letters are issued which summarize any significant or generic deficiencies). During the previous summary meeting with Deputy Commissioner Cropper, the use of Form 148E was discussed in detail. Mr. Cropper appeared to recognize the shortcomings of the current practice and indicated to the Bureau staff that there was nothing sacred about the 148E and that he saw nothing wrong with discontinuing the practice of leaving the 148E's and instead providing the inspection results in a single enforcement letter summarizing the "site" inspections. This procedure has begun to be implemented.

F. Inspection Procedures (Category II)

NRC Guidelines: Inspection guides, consistent with current NRC guidance, should be used by inspectors to assure uniform and complete inspection practices and provide technical guidance in the inspection of licensed programs. The NRC Agreement States Guides may be used if properly supplemented by policy memoranda, agency interpretations, etc. Written inspection policies should be issued to establish a policy for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, assuring exit interviews with management, and issuing appropriate notification of violations of health and safety problems. Procedures should be established for maintaining licensees' compliance histories. Oral briefing of supervision or the senior inspector should be performed upon return from nonroutine inspections. For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Questions:

 Has the RCP developed its own inspection guides or does it use NRC guides?

Answer: The Bureau primarily uses guides which were obtained from NRC. Some forms have also been developed by the Bureau.

 Are current copies of the internal inspection forms and guides on file in the RCP office and with NRC? Attach any changes or guides developed since the last review.

Answer: Inspection forms and the NRC guides are on file in the Bureau. Bureau inspection forms are also available in Region I files.

3. Are inspectors furnished copies of inspection guides?

Answer: Field inspectors and the Field Supervisor are furnished copies of inspection guides.

 Discuss the use or non-use of inspection policy memoranda, interpretations, etc., to supplement inspection guides.

Answer: The Bureau does not extensively use policy memoranda or interpretations generated from within. However, for the sake of uniformity, the Field Supervisor or the Division Chief may issue an interpretation of the Health Code or an order from higher management. The Bureau follows NRC policies on most inspection and enforcement procedures.

- 5. Are there written procedures establishing policy for:
 - a. unannounced inspections?

Answer: Yes.

b. obtaining corrective action?

Answer: Yes.

c. following-up and closing out previous citations of violations?

Answer: Yes. d. exit interviews with management?

Answer: Yes.

- e. issuing notices of violations and findings of health and safety problems?
- Answer: Yes. f. categorizing the seriousness of violations?

Answer: Yes.

Please provide copies of these procedures for review.

6. What procedures have been established for maintaining licensee's compliance histories?

Answer: All inspection reports, enforcement letters, correspondence and acknowledgement letters are kept on file. A one line entry on an alphabetical index card summarizes the results of each inspection. The inspection results are also entered on the inside cover of the file folder.

Does the senior inspector or supervisor orally debrief the inspector upon return from inspections?

Answer: The field inspector is orally debriefed by the Field Supervisor on the results of each inspection. In the case of large licensees, the enforcement letter is usually prepared by the Field Supervisor after extracting information from the inspection reports.

8. What procedures are there for providing feedback from inspectors to licensing?

Answer: The field inspectors may write a memorandum to the license reviewers concerning a licensing matter encountered during the inspection.

VI.F Reviewer Assessment: The Bureau meets these indicator guidelines.

G. Inspection Reports (Category II)

NRC Guidelines: Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of licensees' programs, and indicating the substance of discussions with licensee management and licensee's response. Reports should uniformly and adequately document the results of inspections and identify areas of the licensee's program which should receive special attention at the next inspection. Reports should show the status of previous noncompliance and the independent physical measurements made by the inspector.

Questions:

 How do inspection reports document the inspection that was conducted and the inspection findings? Explain how the reports substantiate noncompliance and health and safety matters and describe the scope of the licensee's program.

Answer: For most inspections, standard forms are used by the Bureau. Several forms are available for major license categories. The forms cover all inspection areas addressed by the inspection guides and are designed to permit easy notation of the inspector's findings. Items of noncompliance are checked in the form proper and are detailed sufficiently to substantiate citations. Enforcement letters are written to multiple-license and broad license facilities.

- 2. Do the reports
 - a. relate the discussions held with license management and interviews with workers?

Answer: Yes. The reports relate discussions held with license management and interviews with workers.

b. include independent measurements conducted by the inspector?

Answer: Yes. The inspection reports include independent measurements conducted by the inspector.

c. document follow-up of previous citations of violations made by the inspector?

Answer: Yes. The reports document follow-up of previous citations of violations made by the inspector.

d. identify areas of the licensee's program needing special attention at the next inspection?

Answer: Yes. The reports identify areas of the licensee's program needing special attention at the next inspection.

3. Are inspectors routinely inspecting radwaste package preparation and shipping practices and do the reports document the results?

Answer: This area is routinely inspected if the licensee ships waste. The results of the inspection is documented. Packages are inspected if they are available during the inspection.

VI.G Reviewer Assessment: A review of selected compliance files is attached as Appendix H. Contrary to the response to question number 1, inspection reports do not always provide adequate substantiation of items of noncompliance. The review of selected inspection reports also revealed that inspection documentation practices could be improved in a number of areas. Current inspection forms do not provide for documentation of such aspects of licensee's programs as organization (including committee activities), inspection history (previous items of noncompliance and their current status), scope of licensee activities, receipt and package opening procedures, and posting the license and regulations.

H. Independent Measurements (Category II)

NRC Guidelines:

Independent measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements. RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samplers, lab counting equipment for smears, identification of isotopes, etc.).

GM Survey Meter: 0-20 mr/hr Ion Chamber Survey Meter: several r/hr Neutron Survey Meter: Fast & Thermal Alpha Survey Meter: 0-100,000 c/m Air Samplers: Hi and Low Volume Lab Counters: Detect 0.001 uc/wipe Velometers Smoke tubes Lapel Air Samplers

Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities should not be used unless under a service contract. Exceptions for other State Agencies, e.g. a State University, may be made. Agency instruments should be calibrated at intervals not greater than that required to licensees being inspected.

Questions:

 Discuss the RCP's policy for conducting independent measurements as a part of each inspection (e.g., air samples, wipe samples, air flows, dose rates). Are these measurements documented in the inspection report?

Answer: Independent measurements are made whenever indicated during each inspection to verify licensee's measurements and to verify compliance with acceptable area exposure rates, contamination levels, and ventilation/hood exhaust rates. Results of these measurements are noted in the inspection report.

 List the instrumentation that is readily available to the RCP for surveying licensed operations and conducting appropriate independent measurements.

Manufacturer	Type	Mode1	Radiation
Nuclear Chicago	Geiger-Mueller	2650	alpha, beta gamma
Keithley	Ionization	36150	beta, gamma
Victoreen	Scintillation NaI:T1	489-55 Thyac-III	gamma
Berthold	Proportional Xe-filled	LB1210B	beta, gamma
Victoreen	Air Sampler	Persair	
Staplex	Air Sampler Lo-Vol	Staplex LV-1	
Staplex	Air Sampler Hi-Vol	TFIA	
Victoreen	Portable Neutron Monitor	478	neutrons

Velometers

3. Describe the method used for calibrating survey instruments and the frequency of calibration.

Answer: Survey instruments are currently being calibrated by the New York State Department of Health.

VI.H Reviewer Assessment: The Bureau meets these indicator guidelines.

VII. OTHER ASPECTS OF THE STATE'S RADIATION CONTROL PROGRAM

A. Non-Agreement Sources of Radiation

Questions:

 Are the licensing and inspection procedures for NARM the same as for agreement materials?

Answer: Yes. The licensing and inspection procedures for NARM are the same as for agreement materials.

 Give the number of X-ray machine (or tube) and accelerator registrants by category, e.g., dental, medical, industrial, etc.

Permit Category	Number of Tube:
Physicians	1820
Podiatrists	7527
Osteopaths	33
Veterinarians	108
Industrial Establishments	64
Chiropractors	2513
Clinics	1336
Total Number of Tubes	

Number of X-Ray Machine Registrants by Category (Effective 9/4/84)

Number of Active Radiation Certificates by Category

Permit Category	Number of	
	Radiation Certificates	
Physicians	1435	
Dentists	3856	
Podiatrists	647	
Osteopaths	32	
Veterinarians	106	
Industrial Establishments	45	
Hospitals	98	
Chiropractors	284	
Clinics	677	

Total Number of Active Radiation Certificates.....7969

3. How many machine and accelerator inspections were made in the last year (or other appropriate interval)?

Physicians	609
Dentists	1696
Podiatrists	176
Osteopaths	14
Veterinarians	13

Industrial Establishments	23
Hospitals	2651
Chiropractors	81
Clinics	588

Total Number of Inspections... 5,851

4. Does the RCP license X-ray or nuclear medicine technologists?

Answer: The City Department of Health does not license x-ray or nuclear medicine technologists. The State Department of Health program for licensing x-ray technologists covers the City of New York.

VII.A Reviewer Comment: None

B. Environmental Monitoring Program

Questions:

- To indicate the scope of the environmental monitoring program, describe:
 - a. types of media sampled
 - b. the number and location of stations sampled
 - c. the frequency of sample collection
 - d. the analyses run on each type of sample

Answer: The City Department of Health does not have an environment monitoring program. A State-wide program is conducted by the New York State Department of Environmental Conservation.

 Is a copy of the latest environmental surveillance report available for review?

Answer: N/A

VII.B Reviewer Comment: Vone

C. Other Areas

This section of the review is for the use of either the reviewer or the RCP to address issues pertaining only to the individual State, to new areas of concern, ir to generic or State-specific issues raised by NRC staff.

1. Other Generic Issues

Questions:

a. For radiography inspections, to what extent do you make inspections at temporary job sites?

Answer: N/A

b. Are you finding Ir-192 contamination on radiographic equipment?

Answer: N/A

c. What are the State's plans to adopt the low-level waste (LLW) manifest rule (if not already adopted)?

Answer: the manifest rule has been drafted by the staff of the Bureau and is targeted for adoption shortly.

d. For States with LLW disposal sites, what are the State's plans to implement 10 CFR 61?

Answer: N/A

e. Will your State have access to a LLW disposal site after January, 1986. If not, what contingency plans are there for after January, 1986?

Answer: The City has no contingency plan of its own.

f. Have copies of 10 CFR 61 and NRC technical positions on waste form and classification been distributed to State licensees? If there has been feedback please provide documentation.

Answer: The Bureau distributed copies of 10 CFR 61 and NRC technical positions on waste form and classification to all licensees. However, there was very little feedback.

g. Have there been any applications or approvals for incineration, compacting or disposal?

Answer: Several licensees have applied to the Commissioner of Health for authorization to incinerate, however, the approval has not been granted because of health and safety considerations. h. What use is being made of IE information notices?

Answer: All IE Information Notices received by the Bureau are reviewed for applicability for use by the agency or its licensees. If deemed appropriate, the notices are distributed to the licensees.

 Identify any group of materials licenses for which the RCP has increased frequency of inspection due to problems with that general category. Please discuss the nature of those problems.

Answer: The Bureau has not increased the frequency of any inspections due to problems with a general category.

j. With spect to medical licensees, is the RCP making any efforturing inspections of nuclear pharmacies to determine whether the licensee is actually conducting the required molybdenum breakthrough tests, i.e., what is the RCP doing in addition to record reviews to establish compliance or noncompliance with the requirement?

Answer: The Bureau does not license or inspect nuclear pharmacies. These fall under the jurisdiction of the Department of Labor.

k. Is the RCP mounting any special effort to look at the possibility of reconcentration of radionuclides in sanitary sewers and sewage treatment plants as part of the regular inspection program? If so, please describe.

Answer: The Bureau has looked at the possibility of reconcentration of radionuclides in sanitary sewers and sewage treatment plant, however, the Bureau is not mounting any special effort in this regard.

VII.C. Reviewer Comment: None

List of Appendixes

Appendix	А	-	New York City Department of Health Organization Chart (May 1986)
Appendix	В	-	Bureau for Radiation Control Organization Chart (August 18, 1986)
Appendix	С*	-	Staff Training
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Appendix	E*	-	Inspection Priority System (January 29, 1976)
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Appendix	G	-	Review of Selected Compliance Files

* Retained in Region I files.



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8-18-26



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APPENDIX D

REVIEW OF SELECTED LICENSE FILES

The review of selected licensing actions revealed significant technical inadequacies. Of particular concern were the renewals of two broad licenses. The applications accepted by the Bureau as the basis for renewal were deficient in such basic areas as radiation safety committee duties and responsibilities, use and user approval criteria, and inadequate procedures for such activities as instrument calibration, leak testing, waste disposal, and the survey program. Problems noted with other licensing actions included inadequate documentation of physician qualifications, inadequate receipt procedures, and no emergency procedures.

 Sloan Kettering Institute for Cancer Research License No.: 84-1 Renewal: November 20, 1985 Expires: July 31, 1987

This license authorizes a broad research and development non-human use program: Renewal application dated September 15, 1985, included procurement procedures, instructions for animal caretakers, committee information, instrumentation, internal permit forms, waste management procedures, leak test and instrument calibration procedures, laboratory survey form, emergency procedures, contamination check form, inventory form, committee procedures, instructions for opening packages, training program for laboratory personnel.

The instrument calibration procedures are incomplete, not specifying two points on each scale or indicating ± 10% acceptability. Leak test procedures are incomplete, indicating only that they will be performed every six months. Although survey forms are included, the applicant does not indicate who will perform surveys, i.e., user-weekly, RSO-monthly, nor does the applicant indicate acceptable contamination levels or action levels. Bioassay procedures do not address the possible use of iodine. The application does not discuss the duties and responsibilities of the RSO. There are no limitations or conditions relative to handling liquid or gaseous material, e.g., use of hoods for iodine.

2. Alan I. Shulman

License No.	: 2745-1	
Issued:	November 1,	1985
Expires:	October 31,	1990

This license authorizes a 500 mCi I-125 source in a Lixiscope. The application contained all appropriate commitments and indicated that the user attended the S.A. Huber approved training course.

3. Manoutcher Bashiri, M.D. License No.: 2747-1 Issued: December 26, 1985 Expires: December 31, 1990

> This is a private practice medical license authorizing Groups I and II. The physician did not provide documentation of adequate training for Groups I and II. There were no procedures regarding receipt and opening of packages. The applicant did not indicate who would calibrate the survey meter.

 Columbia University License No.: 162-1 Renewed: September 26, 1985 Expires: June 30, 1987

This license authorizes a broad research and development non-human use program. The renewal application included information on the RSO, instrumentation, committee, survey forms, receipt and opening packages, inventory forms.

The license renewal application is not adequate to support what is authorized by the license. The renewal does not adequately address (1) committee procedures including criteria for approval of uses users, facilities, etc., (2) duties and responsibilities of the RSO, (3) instrument calibration procedures, (4) waste disposal procedures, (5) acceptable contamination levels. The tie-down condition does not reference all of the material on which the renewal is apparently based.

 New York Health Care License No.: 2768-1 About to be Issued Expires: August 31, 1991

> This license will authorize medical Groups I-IV. The license includes an ALARA statement, instrumentation, calibration procedures, facility drawing, personnel training, personnel monitoring, receipt procedures, survey procedures, leak test procedures, moly check procedures, lab rules, emergency procedures, waste disposal procedures.

Applicant indicated use of wrist rather than finger badges. No information on qualifications, duties or availability of RSO. Off-hours receipt of material was not covered. Need procedures for opening packages. Brooklyn Cardiac Diagnostics License No.: 2748-1 Issues: February 19, 1986 Expires: February 28, 1991

> This license authorizes medical Groups I, II and other diagnostic procedures. The application included information on the user and RSO procedures for receiving and opening packages, safety rules, ALARA program, labeling and posting, leak testing, storage, disposal, record keeping, emergency procedures and personnel training.

 409 Laboratory License No.: 2750-1 Issued: March 3

Issued: March 3, 1986 Expires: March 31, 1991

This license authorizes medical Groups I and II. The application included information on user qualifications, instrumentation, calibration, personnel monitoring, facility descriptions, survey procedures, lab rules. No information was provided regarding waste disposal. No emergency procedures were provided. Procedures for receipt and opening packages were not adequate.

Brownstein & Princer, M.D., P.C.
License No.: 2619-1
Renewed: April 7, 1986
Expires: December 31, 1990

This license authorizes in vitro studies. When renewed in its entirety, the license did not include Items 6, 7, or 8. This was corrected by a subsequent amendment.

The licensing folder did not contain all of the documentation contained in the field folder. The two files should be reorganized as per Bureau policy.

9. New York Hospital Cornell Medical Center License No.: 53-80 Renewed: October 15, 1985 Expires: June 30, 1990

The license authorizes 1 Ci of H-3 and S-35 and 100 mCi of C-14 for in vitro studies. This license was selected by OSP for review. No problems were noted.

10. City College of the City University of New York License No.: 55-15 Renewed: August 8, 1985 Expires: July 31, 1987

This license authorizes a broad scope non-human use research and development program. The renewal application dated May 29, 1985 contained information on users, and RSO qualifications, instrumentation, calibration procedures, personnel monitoring including bicassay, facility descriptions, responsibilities of the committee and RSO, training of personnel, waste disposal, receipt procedures and the licensees radiation safety manual.

The following deficiencies were noted: (1) the calibration procedures indicated that survey meters would be calibrated at only one point; (2) the application did not indicate the membership of the Radiation Safety Committee; (3) there were no procedures or criteria for approval of users and uses of radioactive material.

APPENDIX G

REVIEW OF SELECTED COMPLIANCE FILES

The review of selected inspection reports revealed that inspection documentation practices could be improved in a number of areas. Current inspection forms do not provide for documentation of such aspects of licensees' programs as organization (including committee activities), inspection history (previous items of noncompliance and their current status), scope of licensee activities receipt and package opening procedures, and posting the license and regulations.

 Sloan Kettering Institute for Cancer Research License No.: 84-1 Renewed: November 20, 1985 Expires: July 31, 1987 Inspection Date: April-June, 1986 Inspector(s): Schnee, Perlmutter, Mazzola, Plotsker, Snyder Enforcement Letter: Dated August 7, 1986 but not sent

A number of laboratories were found where records of contamination checks procurement, utilization and disposal were not maintained. The overall radiation safety program was found to be adequate.

Findings: No discussion of previous items of noncompliance. No information on organization. The main body of the report consisted of 77 RC-17 forms corresponding to 77 rooms or "sites" visited during the inspection. Some of the items of noncompliance were not adequately documented, simply being the check of the appropriate box on the RC-17. Excessive delay in dispatching enforcement correspondence.

2. Columbia University License No.: 162-1 Renewed: September 26, 1985 Expires: June 30, 1987 Inspection Date: December 1985 - February 1986 Inspector(s): Mazzola Enforcement Letter: September 8, 1986

One lab was found to have no procurement, utilization or disposal records. No deficiencies were noted with regard to the "General Radiation Safety Program." Excessive delays in issuing enforcement correspondence.

Findings: The enforcement letter was addressed to the RSO. This report had a good discussion of RSO audits and receipt procedures. There was apparently no review of any committee actions, such as user approvals, taken in the last year. Items of noncompliance were supported only by checks in boxes of RC-17 form. 3. City College of New York License No.: 55-15 Renewed: August 8, 1985 Expires: July 31, 1987 Inspection Date: February-March 1985 Inspector(s): Plotsker Enforcement Letter: April 16, 1985

No items of noncompliance were noted during the inspection.

The inspection report did not discuss: (1) committee membership or activities such as effectiveness of approval process, (2) there was no discussion of training in the main inspection report and the RC-17 form block re instruction was usually left blank or checked "N/A", (3) there is nothing in the report discussing the overall materials receipt and inventory program, (4) with regard to surveys, the RC-17's indicated that individual lab survey records were adequate, but there was no discussion of the RSO audit surveys.

 Rockefeller University License No.: 183-2

This is a broad scope non-human use license. An inspection by the entire staff was done during the period May 20 - October 8, 1985. The enforcement letter was dated March 31, 1986. Two items of noncompliance were applicable to the general radiation safety program. (1) Monthly contamination surveys were not being performed, and (2) records of procurement, utilization, and disposal were not being maintained. Three other minor violations at individual facilities were also discussed. The licensee responded on April 17, 1986. The City acknowledged the reply on May 7, 1986.

Findings: The licensee response indicated that they "received no notification of the alledged (sic) violations." The report indicated that a "concluding discussion" had been held at which the inspection findings were discussed, however, no further details were provided. 148E's noted violations not discussed in enforcement correspondence. These included material unaccounted for and material found where "not listed on computer printout." Mr. Borri indicted that these were considered under the records violation. The problem as Mr. Borri discussed it was not what would be concluded from the inspection report alone. Violations need to be more clearly supported and explained.

5. Mt. Sinai Medical Center License No.: 80-1 thru 80-224

> Mt. Sinai is a multi-license facility with a centralized radiation safety program which makes it the equivalent of a major institutional broad license. During the period July - October 1985 the City inspection staff conducted an inspection of each of the licenses at Mt. Sinai. An enforcement letter dated December 9, 1985 reported on the entire inspection effort. No violations were noted regarding the overall safety program, but various violations were noted regarding individual licenses. The most significant finding was that numerous licensees were not performing contamination checks at the required frequency (or not at all). In one case excessive removable contamination was found on trays in one room. The licensee's response to the enforcement letter dated December 23, 1985 simply indicated that the violations had been corrected. In an acknowledgement dated January 28, 1986, the City apparently accepted this response. The inspection report covered the overall program including receipt of shipments, training, licensee audits, personnel monitoring, and transportation. The violation concerning the excessive contamination concerning a lab tray where the City survey discovered removable contamination of 1,000 cpm gross beta/gamma. The City regulations establish a limit of 1,000 cpm.

 Columbia-Presbyterian Medical Center License Number: 62-3

This is a broad scope non-human use license. An inspection by the entire staff was conducted during the period June-September 1985. An enforcement letter dated February 21, 1986 indicated that no violations were noted with regard to the overall radiation safety program, but 15 violations were mainly posting and record keeping violations, but one facility was cited for excessive contamination in a refrigerator, 9,600 cpm. The main inspection report covered audits, training, receipt, personnel, monitoring, an excellent discussion of the activities of the committee and RSO, and waste disposal. The remainder of the report consisted of 148E's, RC-16's, and RC-17's for each facility visited. There were many blanks on the forms failing to indicate such information as personnel monitoring employed, adequacy of instruction, material on hand.

 Wyckoff Heights Hospital License No. 94-1, -2, -3

These three licenses authorize nuclear medicine, in vitro studies, and teletherapy, respectively. During May-June 1986 an inspection was performed of the three licenses. An enforcement letter issued July 22, 1986 listed the following violations: (1) no radiation safety committee,

(2) inventory of sealed sources not performed, (3) radioactive waste disposed of as ordinary trash, (4) records of disposal not complete, (5) "Notice to Employees" not posted, (6) leak test of teletherapy unit not performed, (7) tests of interlocks not performed, (8) instruments not calibrated, (9) 5-year inspection and maintenance not performed on teletherapy unit. The licensee responded on August 27, 1986 indicating that the surveyor (inspector) did not request information re the committee or source inventory. The other citations were responded to adequately. The 148E's left at the facility after the inspection detailed different violations, such as failure to perform annual teletherapy calibration.

 City Hospital at Elmhurst License No. 149-2

> This is a group medical license (I-IV). A routine inspection was conducted by Plotsker on November 26-27, 1985. Two violations were noted in the enforcement letter dated March 13, 1986: (1) contamination survey records were not maintained, and (2) one door was not properly posted. The licensee responded on April 16, 1986 and the City acknowledged the response on April 22, 1986. On Forms RC-17 the "Instruction" section was blank or checked N/A.

 Methodist Hospital at Brooklyn License Nos.: 54-2, -3, -7, -9

These licenses authorize Group VI, Groups I-V and in vitro studies (2 locations), respectively. An inspection was performed October 25, 29-30, 1985. An enforcement letter dated January 3, 1986 indicated no violations. The RC-16's and 17's which constituted the report did not provide adequate information on personnel monitoring and instruction to workers.

 Victory Memorial Hospital License Nos.: 1518-2, -3, -4

These licenses authorize Group I-V, in vitro studies, and Group VI respectively. A routine inspection was conducted on August 9, 12, 1985. An enforcement letter dated August 22, 1985 indicated no items of noncompliance.