



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

December 14, 1989

Stephen C. Joseph, M.D., MPH
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 of the NRC staff held with Assistant Commissioner Gerald Flanders on September 29, 1989 following our review and evaluation of the Department's radiation control program.

As a result of our review of the Department's program and the routine exchange of information between the Nuclear Regulatory Commission and the Department, the staff determined the Department's program for the regulation of agreement materials to be adequate to protect public health and safety. We are deferring a finding regarding compatibility at this time due to the status of the Department's radiation control regulations. The Bureau for Radiation Control has established a regulatory agenda, and we are satisfied that reasonable progress has been made toward the necessary regulatory changes. Please keep us informed on the progress you are making on implementing the regulatory changes.

An explanation of our policies and practices for reviewing Agreement State programs is attached as Enclosure 1.

Enclosure 2 contains a summary of the staff's assessments and comments that were developed from the indicators used for review of the program. These comments were discussed with Dr. Solon and his staff during our exit meeting with him and you may wish to have Dr. Solon address the these comments and recommendations. A copy of this letter and the enclosures is provided for placement in the State Public Document Room or otherwise to be made available for public examination.

I appreciate the courtesy and cooperation extended by your staff to our representatives during the review. I am looking forward to your comments regarding the status of the regulations along with the responses to our recommendations from Dr. Solon.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carlton Kammerer".

Carlton Kammerer, Director
State, Local and Indian Tribe Programs
Office of Governmental and Public Affairs

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PDR STPRG ESGNY
PDC

Enclosures:
As stated

cc w/encls: See next page

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Stephen C. Joseph

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cc: J. M. Taylor, Acting Executive Director for Operations
W. T. Russell, Regional Administrator, Region I
M. Knapp, Director, DRSS, Region I
Dr. L. Solon, Director, Bureau for Radiation Control
William Davis, State Liaison Officer
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Commissioner Roberts
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APPLICATION OF "GUIDELINES FOR NRC REVIEW OF
AGREEMENT STATE RADIATION CONTROL PROGRAMS"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs" were published in the Federal Register on June 4, 1987, as an NRC Policy Statement. The Guide provides 29 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories.

Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in one or more Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing or contributing to difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need for improvement in particular program areas is critical. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a special limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period. The Commission will be informed and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Atomic Energy Act of 1954, as amended.

SUMMARY OF REVIEW AND COMMENTS
NEW YORK CITY DEPARTMENT OF HEALTH
RADIATION CONTROL PROGRAM
FOR THE PERIOD
JUNE 24, 1988 TO SEPTEMBER 29, 1989

Scope of Review

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on June 4, 1987, and the internal procedures established by the Office of Governmental and Public Affairs, State Agreements Program. The Department's program was reviewed against the 29 program indicators provided in the Guidelines. The review included discussions with program management and staff, technical evaluation of selected license and compliance files, the evaluation of the Department's responses to an NPC questionnaire that was sent to the State in preparation for the review, and field accompaniments of Department inspectors.

The 26th regulatory program review meeting with the Department of Health was held during the period September 25-29, 1989, in Brooklyn, New York. The Department's Bureau for Radiation Control was represented by Dr. Robert Kulikowski, Assistant Director and Chief, Radioactive Materials Division. A review of selected license, compliance and incident files was conducted by Lloyd Bolling, SLITP, and John McGrath, Region I, during the period September 26-28, 1989. Field accompaniments of seven Department inspectors at Beth Israel Medical Center were conducted on September 25-27, 1989 by John Pelchat, Region I, and John McGrath. A summary meeting with Assistant Commissioner Gerald Flanders was held on September 29, 1989.

Conclusion

The New York City Department of Health program for the control of agreement materials was found to be adequate to protect public health and safety. A finding of compatibility was deferred until such time as the Department's radiation control regulations can be updated.

Status of Program Related to Previous NRC Findings

Comments and recommendations from NRC's previous review were sent to the State in a letter dated September 22, 1988. All of these comments were satisfactorily resolved with the exception of the comment regarding the status of the regulations.

At the time of the last review, two specific regulatory changes, the label obliteration rule and the advanced notification of certain waste shipments requirement, had not been adopted within the three-year limit for Agreement States. These rules had been deemed to be matters of compatibility. The Department has not yet had an opportunity to incorporate these regulations into the City Health Code.

Current Review Comments and Recommendations

All 29 program indicators were reviewed and the Department fully satisfies 22 of these indicators. Specific comments and recommendations for the remaining seven indicators are as follows:

I. LEGISLATION AND REGULATIONS

Status and Compatibility of Regulations is a Category I indicator. The following comment and recommendation is of major significance with regard to compatibility.

Comment

The Department's radiation control regulations were last updated in October 1986, however, two items necessary for compatibility were not included. As noted during our previous review, there have been a number of changes to NRC regulations which the Department need to adopt. We understand that the Bureau for Radiation Control has established a regulatory agenda which calls for the necessary regulatory changes to the Health Code to be in place by June 30, 1990.

Recommendation

We recommend that the Bureau proceed with its plan to update the Health Code and that all appropriate recent changes to NRC regulations, such as the medical misadministration reporting requirements, be incorporated.

II. MANAGEMENT AND ADMINISTRATION

Laboratory Support is a Category II indicator.

Comment

We were pleased to note that the Bureau has succeeded in obtaining laboratory space at the Department's facilities on First Avenue and will soon be fully operational. We noted, however, that the Bureau does not participate in a periodic quality control program.

Recommendation

Once the Bureau's laboratory is fully operational, we recommend that you plan on participating in a periodic quality control program, such as that sponsored by the Environmental Protection Agency.

III. LICENSING

Licensing Procedures is a Category II indicator.

Comment

As was noted during previous reviews, the Bureau's files are still in very poor condition. Documents unable to be located during our review and misfiled documents are still common. We were pleased to note, however, that the Bureau has purchased new file folders and has begun the mammoth task of reconstructing the files. Those licenses that have been reorganized into the new folders were found to be in excellent shape.

Recommendation

Although the job of reorganizing over 800 complex files is a formidable task, we encourage the Bureau to continue to attack it. For those files which have already been reorganized, the Bureau staff has seen the benefits.

IV. COMPLIANCE

- A. Status of Inspection Program is a Category I indicator. The following comment and recommendation concerns an issue which is of minor significance in terms of public health and safety.

Comment

At the time of the review, the Bureau had one Priority 2 licensee significantly overdue for inspection, but the inspection was subsequently completed. The inspection program does not therefore have a significant backlog in its higher priority licenses, but the computer printout indicating the last inspection date for the lower priority licenses is organized in such a way that it is difficult to determine the status of the program.

Recommendation

Although the number of overdue inspections did not appear to be large, the Bureau needs to reorganize the database so that it can more accurately assess the backlog and use this information in the preparation of inspection schedules.

- B. Inspectors' Performance and Capability is a Category I indicator. The following comment and recommendation concerns an issue which is of minor significance in terms of public health and safety.

Comment

During the period September 25-27, 1989, seven Bureau inspectors were accompanied on an inspection of Beth Israel Medical Center. For the most part, the inspection staff performed adequately in the technical aspects of the inspection, but we were concerned about the overall organization and tone of the inspection. Because of the number of inspectors on-site, there was a great deal of overlap and inefficiency. We also noticed that inspection findings were not always placed in proper perspective. Some violations were safety related, but others were more administrative in nature and are not critical in terms of an immediate public health impact.

Recommendation

The Bureau needs to better organize inspections such that each inspector's time is fully utilized in the most efficient manner. For example, entrance and exit management interviews should be handled by one, and no more than two, inspectors. We also recommend that the inspection staff make more of an effort to put violations in their proper perspective. In addition to providing licensee management a more realistic appraisal of their program, such an effort will help improve Department/licensee relations.

- C. Inspection Procedures is a Category II indicator.

Comment

As a result of a Departmental directive, radioactive materials licensees in the City of New York are given 30 days notice of routine inspections. NRC recommends that such inspections be conducted on an unannounced basis. We have found that such inspections provide a more accurate picture of day-to-day licensee operations.

Recommendation

We recommend that the Department rescind the order concerning 30-day notice of inspections and allow the Bureau for Radiation Control to conduct inspections on an unannounced basis.

D. Inspection Reports is a Category II indicator.

Comment

The Bureau has made some progress in inspection documentation practices in recent years; however, documentation of inspection findings were not always supported by information in inspection reports and some violations indicated in reports were not included in enforcement letters. Inspection reports which consisted of multiple copies of Form RC-17 were often difficult to follow.

Recommendation

Inspection reports need to clearly document inspection findings in a manner which facilitates retrieval of information, particularly regarding violation. We recommend that the Bureau reorganize its inspection form RC-17. Copies of NRC inspection forms were provided to the Bureau staff for use as models.

Summary Meeting with Department Management

A summary meeting to present the results of the regulatory program review was held with Assistant Commissioner Gerald Flanders on September 29, 1989. Dr. Leonard Solon, Director, Bureau for Radiation Control, and Dr. Robert Kulikowski, Assistant Director and Chief, Radioactive Materials Division, were also present. The NRC representative, John McGrath, indicated that the Bureau had made significant progress since the last review and appeared to be on the road to establishing a first-class program. Much of the credit for the turnaround belong to Dr. Kulikowski who has provided the necessary leadership for the program.