

DATED: MAY 6, 1993

Mr. Christopher G. Atchison, Director
Iowa Department of Public Health
Des Moines, IA 50319

Dear Mr. Atchison:

This letter refers to the discussion Mr. Hubert Miller, Region III Deputy Administrator and Mr. James Lynch, State Agreements Officer held with you, Mr. David Fries, Director, Division of Administration and Planning, Mr. Donald Flater, Chief, Bureau of Radiological Health, and Mr. Daniel McGhee, Environmental Specialist, on February 26, 1993. As a result of our follow-up review of the State's radiation control program, our view is that the Iowa program has made continuing progress to correct serious management and programmatic deficiencies identified during the last review, however, a finding of adequate and compatible cannot be made at this time.

The past three reviews, in July 1990, October 1991 and September 1992, resulted in the withholding of a finding of adequate and compatible due to significant programmatic deficiencies. The current review found the radioactive materials program has shown progress. Eight of the 12 indicators identified during the last review as deficient have been closed out. We commend the Iowa Department of Health on the development of the radioactive materials computerized tracking system. This system is well designed and automates many administrative functions which allow program staff to concentrate on technical issues. The system also provides an excellent management tool for the program.

While these efforts are encouraging, additional effort by the Department is needed to reestablish an adequate radioactive materials program. Our review identified the need for additional attention in the following areas: maintenance of adequate staffing levels; completion of technical training for inspectors/reviewers; and quality assurance reviews of licensees and reports by management. In this regard, the recent restructuring of the Bureau of Environmental Health which is allowing Mr. Flater increased interaction time with the radioactive materials program is important. Active and consistent management of the materials program is essential to

improvement and stability of Iowa's program. Also, as we discussed in our exit meeting, we recommend that you develop a program plan outlining program goals, strategies and priorities. In addition to ongoing efforts to resolve previously identified deficiencies, the program faces numerous other tasks such as development of regulations, regulatory guides and internal procedures. A plan should help you deal most effectively with these competing demands.

The notification that the recently hired health physicist has resigned is of serious concern. Staffing is a key element in the steps that must be addressed for the program to obtain compatibility and adequacy. We understand that you are taking measures to fill this position and we consider the expediting of hiring to be important.

As the State has not yet reestablished an adequate and compatible program, the NRC offers continued short-term assistance to you to achieve our common goal of public health and safety by providing licensing and inspection training and technical assistance. Region III licensee reviewers and Mr. Lynch will provide the training and assistance to your staff.

We plan to conduct a full review of your radioactive materials program December 6-10, 1993. At that time, we will determine whether the program is adequate and compatible with NRC programs. Based on the progress to date, and the nature of the additional improvements that need to be made, we anticipate that you will make every effort to obtain a finding of adequacy and compatibility at that time. In the meantime, we request that monthly status reports continue to be provided to Mr. Lynch so that NRC staff may monitor the progress of the program recovery.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of our assessments and comments which were discussed with you and your staff at the conclusion of the review. As stated earlier, we request specific responses from the State on the current review comments and recommendations in Enclosure 2 and in this letter within 45 days of this letter date.

In accordance with NRC practice, I am also enclosing a copy of this letter for placement in the State's Public Document Room or otherwise to be made available for public review.

Christopher G. Atchison

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I appreciate the courtesy and cooperation extended the NRC staff during the review. I am looking forward to your response.

Sincerely,

Carlton Kammerer, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
John R. Kelly, Director
Division of Health Protection
Donald A. Flater, Chief
Bureau of Radiological Health
A. Bert Davis, Regional Administrator
NRC Region III
Hubert J. Miller, Deputy Regional Administrator
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State Public Document Room
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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 May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 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 several 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 of 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 follow-up or 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 of the results of the reviews of the individual Agreement State programs 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 Act, as amended.

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE IOWA RADIATION CONTROL PROGRAM
SEPTEMBER 5, 1992 TO FEBRUARY 21, 1993

SCOPE OF REVIEW

This follow-up program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs. The State's program was reviewed against the 30 program indicators provided in the guidelines. The review included inspector accompaniments, discussions with program management and staff and technical evaluation of selected license and compliance files.

The follow-up program review meeting with Iowa representatives was held during the period February 22-26, 1993 in Des Moines. The State was represented by Donald A. Flater, Chief, Bureau of Radiological Protection, Daniel K. McGhee, Environmental Specialist, Thomas H. Wuehr, Environmental Specialist and Reginald F. Glick, Environmental Specialist. The NRC was represented by Hubert J. Miller, Region III Deputy Administrator and James L. Lynch, Region III State Agreements Officer (RSAO).

Mr. Lynch interviewed program staff, reviewed procedures and selected license and compliance files in the Radioactive Materials Program. He also accompanied Mr. McGhee on a February 23, 1993 inspection of an academic licensee and Mr. Wuehr on a February 24, 1993 portable gauge inspection. Mr. Miller participated in several interviews and represented NRC management at the exit meeting.

CONCLUSION

At this time, due to several unresolved issues, the staff is unable to offer a finding that the program is adequate and compatible. Although much progress has been made, further concentrated efforts are needed to upgrade the radioactive materials program to one that is both adequate and compatible. NRC intends to continue to provide training and assistance to Iowa inspection and licensing staff to assist with this goal. As we discussed during the follow-up review exit meeting on February 26, 1993, it is our view that development of a program plan would likely help you significantly as you continue efforts to resolve past deficiencies and otherwise carry out the various aspects of the Radioactive Materials Program. We provided you with an example of such a plan in our March 9, 1993 letter to Mr. Flater. We stand ready to provide assistance to you in the development of this plan.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous follow-up review were reported to the State in a letter to Governor Branstad dated October 22, 1992. Of the thirty program indicators, 12 were determined to be deficient at that time, 5 of those comments were considered to be significant. The NRC was unable to offer a finding that the Iowa program was adequate and compatible. The Iowa Department of

Public Health (IDPH) has taken actions to satisfy 8 of the indicators since the October 1992 follow-up review. The remaining 4 indicators are currently being addressed by the State but are not yet resolved. The unresolved specific comments and recommendations from the 1992 follow-up review along with current findings and recommendations are detailed in the following section.

FOLLOW-UP ASSESSMENTS TO THE OCTOBER 1992 COMMENTS AND RECOMMENDATIONS

1. Inspector's Performance and Capability (Category I Indicator)
Significant Comment

Comment

Inspectors should be qualified to evaluate health and safety issues and be able to determine compliance with State regulations. It was determined through accompaniments and interviews with the two inspectors that they had neither the training nor knowledge to perform many of the categories of inspections required in the Iowa program. The types of licenses which they are not yet qualified to inspect include: nuclear medicine, radiation therapy, teletherapy, nuclear pharmacies, broad scope research and development, well logging and large irradiators.

With the resignation of the Radioactive Materials Program Supervisor, a formal system of approval by supervision prior to the performance of inspections in new license categories has not been established.

Recommendation

We recommended that the State take immediate action to train inspection personnel for all types of license programs and/or hire additional inspectors who are qualified to perform those types of inspections.

We recommended that a consultant be contracted to perform inspector training and to assist Iowa staff in the preparation of inspection and related administrative procedures.

We recommended that State personnel accompany NRC and other Agreement State inspectors for purposes of training when opportunities arise.

We recommended that inspectors demonstrate to supervisors, in a formal manner, an appropriate level of understanding with regard to regulations, guidance and policies prior to independently performing various types of inspections.

Current Status

An inspection training program is ongoing. Inspection procedures and improved field notes with regulatory references have been developed by a consultant and all three inspectors have been instructed in their use. The RSAO and the IDPH consultant have accompanied the inspectors on inspections providing training and auditing performance.

Inspectors routinely communicate with the RSAO regarding inspection issues and training in materials licensing provided by the NRC. This contributes directly to a better understanding of licensee programs by the IDPH staff.

IDPH staff have been scheduled for attendance at NRC-sponsored training courses in various regulatory program areas.

A consultant was hired and has provided several training sessions on inspection issues and has performed inspector accompaniments. He has been retained on contract for ongoing consultation and training. Periodic inspection refresher training is planned.

An Inspection Manual was prepared by the consultant which includes inspection procedures, inspection priorities, narrative report guidance and updated field note reports. He is currently preparing an Enforcement Manual which includes the enforcement policy, procedures, boilerplated letters and citations.

All three inspectors accompanied an NRC inspector during routine inspections of NRC licenses in Iowa. Agreements have been made with other States for accompaniments, however, none have been performed to date. Iowa personnel have been concentrating on completion of Iowa inspections.

A qualification journal is being developed by the consultant for inspectors and reviewers. At present, NRC qualification checklists are used. Comments resulting from inspection accompaniments are used to judge inspectors' level of knowledge.

Follow-up Recommendations

We recommend that IDPH inspectors be provided additional training and experience for all types of licensee programs, including complex programs such as radiation therapy, broad scope research and development and nuclear laundries.

We recommend that qualification journals continue to be developed for assessment of staff progress and employee guidance.

2. Status of Inspection Program (Category I Indicator) Significant CommentComment

The inspection program should be adequate to assess licensee compliance with State regulations and license conditions. The State does not currently have an inspection program capable of assessing license compliance for numerous licensee categories. This situation is due to the loss of inspection personnel and the fact that the program has not obtained technical expertise to assess licensee compliance.

The inspection staff was unable to provide an accurate accounting of licenses that were due (or overdue) for inspection. The inspection tracking system was last audited in October 1991. Updates to the tracking system since then are incomplete and, in some cases, inaccurate. The evaluation of the tracking system was complicated by the fact that numerous inspection reports were missing from the license files.

Recommendation

We recommended that the State immediately obtain qualified technical support to allow the assessment of licensee compliance for all licenses.

We recommended that the inspection tracking system be evaluated and maintained in an accurate, updated fashion.

Current Status

The two inspectors with the program at the time of the last review have received considerable amounts of training to increase their inspection skills and competence. The training has been given by the consultant and by the RSAO. These inspectors have performed inspections on a regular basis, and along with licensing training, have added to their knowledge and experience.

The new inspector, with a Masters degree in Health Physics, was hired to provide health physics expertise to the program. He is currently being trained in the inspection program which includes the accompaniment of other inspectors.

A new tracking system capable of tracking inspections, licensing actions, fees, reciprocity authorizations and expirations was developed. The system is also used to print notices, letters and reports. An arrangement was made with the Bureau of Information Management to have a programmer/analyst devote approximately 80% of her time to develop the system. The result is an excellent product which allows for better management of the program.

Follow-up Recommendation

We recommend that inspectors be provided additional training and be given the opportunity to inspect or accompany qualified inspectors for the various types of programs which are licensed in the State.

3. Staffing Level (Category II Indicator) Significant CommentComment

A continuing staffing problem has existed in the Iowa radioactive materials program for years. At the time of the 1991 follow-up review, the State had a technical staffing level of 0.76 person-year per 100 licenses. That level was significantly less than the 1.0 to 1.5 level recommended by the NRC and was also less than the staffing level noted during the 1990 review.

As a result of the recent resignations of the two senior technical staff, the program is currently staffed by 1.75 working technical staff (junior grade) persons detailed to the program. Considering the State's 227 licenses, the staffing level is 0.77 person-year per 100 licenses. The lack of sufficient staff, and particularly senior staff, leaves the program in a very vulnerable position as the personnel have a heavy workload to maintain the program and are not sufficiently trained to perform basic functions such as the licensing and inspection of medical programs.

The NRC was notified by Governor Branstad's office on September 21, 1992 that two staff positions had been approved for the program. A technical staff of 2.3 to 3.4 is required to meet the recommended staffing levels. At least one of the technical staff hired should be an individual with considerable experience in health physics.

Recommendation

We recommended that, considering the current state of the program, that the State maintain the staffing level at the upper end of the suggested range so as to enable the program to develop beyond a borderline adequate and compatible program.

Current Status

The technical staffing level is currently at 3.4 FTE which is at the upper end of the suggested range as recommended by the NRC. IDPH plans to reduce the technical staffing level to about 2.5 FTE when the licensing and inspection backlogs are completely eliminated. The current projection for the reduction is June 1, 1993. After that time, the workload will be closely monitored by the Environmental Specialist III who, as the need arises, can request from the Bureau Chief, the detailing of the other 0.9 FTE to assist the radioactive materials program. IDPH also projects that the

tracking system, as it becomes more sophisticated, will further reduce the technical staff workload. The State has informed us that since this follow-up review was conducted, the recently hired junior health physicist has submitted his resignation. However, the State also informed us that they are taking active measures to fill this position and are currently considering several applicants.

Follow-up Recommendation

We recommend that the State maintain the radioactive materials staffing level at the upper end of the suggested range (i.e., 1.5 FTE per 100 licenses). The NRC stressed in this, and in previous reviews, that a small program such as Iowa's is vulnerable to problems resulting from the loss of staff. Pending the staff gaining considerable experience, a higher staffing ratio should be maintained.

4. Management (Category II Indicator).

Comment

Supervisory review of inspection reports should be performed so that program management may ensure appropriate and consistent inspection and enforcement actions. Eight of 26 inspection reports reviewed during the casework audit did not have approval signatures. A similar supervisory review of complex licensing actions should be performed. In June 1992, the University of Iowa license (Type A broad scope) was renewed and there is no evidence of a supervisory review.

Recommendation

We recommended that program management perform reviews of all inspection reports and of significant licensing actions.

Current Status

The Bureau Chief is currently reviewing and concurring on all inspection reports and license actions. His reviews are performed after another independent review by one of the technical staff. The NRC file audits during the last review identified numerous errors and omissions in documents which are sent to licensees. This review by the NRC detected fewer errors but found some minor problems, such as omissions of names of persons accompanying inspectors, misspelled words, and the omission of sufficient detail on violations discussed in inspection reports.

Follow-up Recommendation

We recommend that additional efforts be made by program management to assure that inspection and licensing documentation is sound. The recent reorganization should allow additional time to be devoted to this area.

SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

Mr. Miller and Mr. Lynch presented the results of this follow-up program review to Messrs. Atchison, Fries, Flater and McGhee during a summary meeting held on February 26, 1993.

The State was informed that the radioactive materials program was improving but had not reached a point where the NRC could consider the program adequate and compatible.

The staffing situation was discussed in detail, with concerns noted by the NRC that with a proposed 2.5 FTE technical staff, the program is vulnerable and in danger of failing if one or more key personnel should leave the program.

Mr. Atchison discussed the recent reorganization which would allow the Bureau Chief more time to manage the Radioactive Materials program. This move was applauded by the NRC as the lack of management supervision has been consistently identified as a program weakness in past reviews.

Mr. Atchison and Mr. Fries committed to the continuation of contractual support for the radioactive materials program in training and administrative areas.

The NRC committed to continue providing short-term support to the Iowa program. These licensing and inspection training efforts will be coordinated by Mr. Lynch.

Mr. Miller suggested that a program (operating) plan might be beneficial to the Radioactive Materials program. The plan would discuss the program's goals, strategies and priorities. Special attention should be given to the staffing needed to accomplish each goal. He promised to send Mr. Flater a copy of a plan in use by the NRC for guidance.

Mr. Atchison was informed that the results of the review would be reported in a letter to him from Mr. Carlton Kammerer, Director, Office of State Programs and that a written response would be requested.