

# UNITED STATES

WASHINGTON DL 20555-0001

April 11, 1994

Mr. Christopher G. Atchisol, Director Iowa Department of Public Health Lucas State Office Building Des Moines, IA 50319

# Dear Mr. Atchison:

This is to transmit the results of the NRC review and evaluation of the Iowa radiation control program conducted by Mr. James Lynch, NRC Regional State Agreements Officer, which was concluded on December 14, 1993. The results of this review were discussed with you, Mr. David Fries, Director, Division of Administration and Planning, Mr. John Kelly, Director, Division of Health Protection, Mr. Donald Flater, Chief, Bureau of Radiological Health, and Mr. Daniel McGhee, Program Coordinator, Radioactive Materials Program.

As a result of our review of Iowa's program and the routine exchange of information between the NRC and the State, we believe that the State's program for regulating agreement materials is adequate to protect the public health and safety and is compatible with the regulatory program of the NRC. We applaud your efforts in this achievement and encourage continued support of the agreement materials program.

Please note that there has been a change made in the format of this letter from our previous review letters. This letter summarizes the findings regarding all 30 program indicators as opposed to only discussing those indicators where deficiencies were noted. Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the review findings where recommendations are made for improvements in the radiation control program. Minor deficiencies and recommendations were noted for eight indicators. None of the recommendations are considered significant enough to affect the finding of adequacy and compatibility. We request specific responses from the State on the findings and recommendations in Enclosure 2 within 30 days of this letter.

Enclosure 3 presents a summary of the review findings where the State has adequately satisfied the indicator. A response to the items in Enclosure 3 is not required.

We commend the State for the filling of the the Environmental Specialist vacancy. With the new hire, the current technical staffing level for the radiation control program is 3.4 FTE for 216 licenses. The present person-year per 100 licenses is a ratic of 1.57 FTE per 100 licenses, which exceeds the NRC suggested range of 1.0 to 1.5 FTE per 100 licenses.

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#### Christopher G. Atchison

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

I appreciate the courtesy and cooperation extended the NRC staff during the review.

Sincerely,

Richard L Bangast

Richard L. Bangart, 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 Stephen Brown, State Liaison Officer State Public Document Room NRC Public Document Room

bcc w/encls: The Chairman Commissioner Rogers Commissioner Remick Commissioner de Plangue

## 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 <u>Federal Register</u> 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 followup 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.

SUMMARY OF ASSESSMENTS AND RECOMMENDATIONS FOR THE IOWA RADIATION CONTROL PROGRAM FEBRUARY 22, 1993 TO DECEMBER 14, 1993

#### SCOPE OF REVIEW

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the <u>Federal Register</u> 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 policy statement. The review included an inspector accompaniment, discussions with program management and staff and technical evaluation of selected license and compliance files.

The program review meeting with Iowa representatives was held during the period December 6-14, 1993, in Des Moines. The State was represented by Donald Flater, Chief, Bureau of Radiological Protection, Daniel McGhee, Program Coordinator, Charlene Craig, Environmental Specialist and Mark Flickinger, Environmental Specialist. The NRC was represented by James Lynch, Region III State Agreements Officer (RSAO) and Kevin Null, Senior Health Physicist. Mr. Null accompanied Mr. Flickinger on a December 7, 1993, inspection of a medical licensee.

A summary meeting to present the results of the review was held with Christopher Atchison, Director, Iowa Department of Public Health (IDPH), David Fries, Director, Division of Administration and Planning, John Kelly, Director, Division of Health Protection, Donald Flater, Chief, Bureau of Radiological Health and Daniel McGhee, Program Coordinator. The NRC was represented at the meeting by John Surmeier, Acting Assistant Director, Office of State Programs, William Axelson, Director, Division of Radiation Safety and Safeguards, Roy Caniano, Chief, Nuclear Materials Safety Branch, Kevin Null, Senior Health Physicist and James Lynch, Regional State Agreements Officer.

#### CONCLUSION

The program for control of agreement materials is adequate to protect the public health and safety and is compatible with the regulatory program of the NRC.

# 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 Christopher Atchison dated May 6, 1993. Of the thirty program indicators, four were determined to be deficient at that time, three of those deficiencies were considered to be significant. All of these comments were satisfactorily resolved and were closed out during this review. These findings are presented below.

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

# Recommendations from the February 1993 Follow-up Review

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

#### Current Status

The Iowa radioactive materials inspectors appear to be competent to evaluate health and safety problems and to determine compliance with State regulations and requirements.

A casework review of 11 inspection files identified only minor errors, which were discussed with the Program Coordinator for correction.

An inspector qualification journal has been developed outlining training and inspections required for inspector qualification. Inspectors are accompanied, on at least an annual basis, by the Program Director or the Program Coordinator.

# 2. Status of Inspection Program (Category I Indicator)

# Recommendation from the February 1993 Follow-up Review

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

#### Current Status

Additional training in the area of inspection has been provided. Since the 1993 Follow-up review, the Region III State Agreements Officer and the State's consultant have provided inspection training to the technical staff. In addition, one-on-one training for inspectors and reviewers is provided by senior personnel and the consultant. Inspectors accompany, and are audited by, the Program Coordinator prior to receiving authorization to perform independent inspections. Inspector accompaniments are also performed by the Program's consultant. Qualification journals are used to schedule and monitor inspectors' progress.

The Iowa radioactive materials program, with current staffing, is capable of assessing licensee compliance with State regulations and requirements.

# 3. Staffing Level (Category II Indicator) Significant Comment

#### Recommendation from the February 1993 Follow-up Review

We recommended 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. Small programs have a proportionately greater overhead (i.e., regulations, procedures, guides, etc.) than a larger program. Thus, a higher staffing ratio is required for a small program.

#### Current Status

Current technical staffing level is 3.4 FTE which was reached with a new hire on March 14, 1994. With a staffing level of 3.4 FTE and 216 licenses, the ratio is 1.57 FTE per 100 licenses. This exceeds the NRC-suggested range of 1.0 to 1.5 FTE per 100 licenses.

# 4. Management (Category II Indicator)

# Recommendation from the February 1993 Follow-up Review

We recommended that additional efforts be made by program management to assure that inspection and licensing documentation is sound.

#### Current Status

Each license or inspection letter is reviewed by the Program Coordinator, or in his absence, by two technical staff. Inspection letters and licensing actions are signed by the Program Director. These measures were implemented by management to maintain accuracy and consistency in work products.

# CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 program indicators were reviewed and the State fully satisfies 25 of these indicators. Minor deficiencies were noted

for 5 indicators and recommendations were made for three other indicators, as well. None of the comments are considered significant enough to affect the finding of adequacy and compatibility. A questionnaire containing the thirty policy guideline indicators with specific questions addressing each indicator was sent to the State prior to the review. The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the Program managers and staff members, review team observations, licensing and inspection casework file reviews, and an inspector accompaniment. Specific assessments and recommendations are as follows:

# 1. Status and Compatibility of Regulations (Category I)

#### NRC Guidelines<sup>1</sup>

The State should adopt regulations to maintain a high degree of uniformity with NRC regulations. 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 after the effective date.

#### Assessment

The State's regulations are compatible with NRC regulations. Iowa's regulations in Chapters 38 and 40 (136C) were revised to conform with the new 10 CFR Part 20 "Standards for Protection Against Radiation." The new rules are effective on January 1, 1994, as required.

In addition, as a matter separate from this review, we would like to bring to the State's attention other regulations that will be needed for compatibility. These rules are:

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) must be adopted by October 15, 1994.
- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 153) must be adopted by January 27, 1995.

<sup>&</sup>lt;sup>1</sup>The guideline statements are a summary of the guideline provisions provided in the May 28, 1992 policy statement, "Guidelines for NRC Review of Agreement State Radiation Control Programs."

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) must be adopted by July 1, 1996.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 (58 FR 39628) must be adopted by October 25, 1996.

# Recommendation

We recommend that the above rules and any others needed for compatibility, be promulgated expeditiously as effective State radiation control regulations.

# 2. Quality of Emergency Planning (Category I)

#### NRC Guidelines

The State radiation control program (RCP) should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc. Periodic drills should be performed to test the plan.

#### Assessment

Part IV of the Iowa Emergency Plan details response to incidents involving radioactive materials. The Department of Public Health is the lead agency for these incidents. The plan is reviewed each January by the Department of Public Safety which requests changes from the primary agencies with response responsibilities. The plan was last updated in December 1988 and a revision is in process of being finalized. The emergency personnel call list is updated annually, last in August 1993.

Drills of the emergency plan for radioactive materials are normally performed annually. Due to the extensive flooding in the State, the 1993 drill was rescheduled for Spring/Summer 1994.

#### Recommendation

We recommend that the radioactive materials drill be performed as scheduled in 1994.

# 3. Office Equipment and Support Services (Category II)

#### NRC Guidelines

The radiation control program (RCP) should have adequate secretarial and clerical support. States should have a license document management system that is capable of organizing the volume and diversity of materials associated with licensing and inspection of radioactive materials.

#### Assessment

One full-time secretary is employed by the radioactive materials program. Additional secretarial support is available within the Bureau, if needed.

The computer tracking system has eliminated may administrative duties such as licensing action tracking, let or preparation, fees, expiration notices, etc.

Each of the technical staff has a computer and can transmit correspondence and actions to the secretary for conversion to final form. Boilerplates and model citations and license conditions are available to staff.

A minor problem with the tracking of licensee inspection responses was noted during the review. The tracking system does not alert staff to responses which are overdue, allowing tardy responses to go unnoticed by the Program Coordinator.

#### Recommendation

We recommend that the computer tracking system be updated to better track licensee responses.

# 4. <u>Staffing Level</u> (Category II)

Professional staffing level should be approximately 1 to 1.5 person-year per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel.

#### Assessment

Current technical staffing level is 3.4 FTE which was reached with a new hire on March 14, 1994. With a staffing level of 3.4 FTE and 216 licenses, the ratio is 1.57 FTE per 100 licenses. This exceeds the NRC-suggested range of 1.0 to 1.5 FTE per 100 licenses.

Impediments to hiring staff within the Department have been removed.

Cross-training of staff in other programs has been started, providing the program with greater flexibility and insurance against the loss of staff in the future.

#### Recommendation

We recommend that staff cross-training be continued for program security and enhancement.

# 5. Training (Category II)

#### NRC Guideline

Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices. The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology. The RCP staff should be afforded opportunities for training that is consistent with the needs of the program.

#### Assessment

Technical staff relies on NRC-sponsored training courses for formal training in health physics and radioactive disciplines. The Environmental Specialist hired in 1993 is scheduled to attend the 5-week health physics, inspection and licensing orientation, medical and radiography courses during the calendar year 1994.

The Program Coordinator has not attended the licensing orientation course. One of the Environmental Specialists has not attended the industrial radiography course.

As part of the previous effort to help Iowa regain an adequate program status, Region III licensing staff has provided extensive training in materials licensing over the past year. In addition, the Regional State Agreements Officer and the State's consultant have provided inspection training to the technical staff.

One-on-one training for inspectors and reviewers is provided by senior personnel and the consultant. Formal training courses are used to supplement in-house training. Junior new technical staff members are assigned a qualification journal to assist with and document accomplishments. These journals require attendance at NRC training courses.

#### Recommendation

We recommend that the Program Coordinator attend the licensing course. We recommend that the Environmental Specialist attend the industrial radiography course and we recommend that the newly hired Environmental Specialist attend all of the NRC core training courses as scheduled.

## 6. <u>Staff Continuity</u> (Category II)

#### NRC Guideline

The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications and should be comparable to similar employment in the geographical area.

#### Assessment

Staff turnover has been detrimental to the radioactive materials program over the past several years. In the past year, three technical staff left the program. One person left for a higher paying position at a utility company, another person was reassigned to another Bureau in the Department at his request, and a third individual was terminated. Similar technical staff turnover in recent years has affected the ability of the State to maintain an adequate program.

The staffing situation appears to be stable at this time. The Department recently filled the Environmental Specialist position, March 14, 1994. This additional individual will provide a measure of technical back up should another vacancy occur.

Salary levels appear to be comparable to similar employment in the same geographical area.

#### Recommendation

We recommend that the State continue in its effort to recruit and retain a highly qualifed technical staff.

# 7. 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.

#### Assessment

The technical quality of licensing actions has improved since the last review. The licensing staff is gaining experience and has received considerable assistance from the Region III staff.

To improve the quality of licensing actions, checklists are used routinely and licensing notebooks are available for the various types of licensed programs. All actions are checked for accuracy and content prior to review and signing by the Program Director.

The casework review performed by the NRC analyzed 22 licensing actions: 12 terminations, 8 renewals and 2 amendments. Errors were identified in several of the actions, none of which were significant. These issues were discussed with Iowa licensing staff. The terminated licenses were all determined to be adequately closed out, however, complete supporting documentation for a number of the actions was not available in individual license files. Material disposal records and radiation survey reports were found in other license files, inspection reports, etc. This information was also in various formats, making analysis more difficult.

#### Recommendation

We recommend that license terminations be documented in one central location, the license file, as opposed to being dispersed in various files. In addition, to assist in the centralization, completeness and standardization of termination information, we recommend that licensees be required to complete a form similar to the NRC "Certification of Disposition of Materials." This form is used to certify that radioactive materials and/or contamination are not present at the facility at the time of a license termination and is used to document that appropriate radiation surveys have been conducted.

# 8. 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. When backlogs occur, management should develop and implement a plan to reduce the backlog.

#### Assessment

The Iowa radioactive materials program, with current staffing, is capable of assessing licensee compliance with State regulations and requirements.

The State does not have any inspection backlog in accordance with NRC criteria: inspections with an inspection frequency of three years or less that are overdue by more than 50% of their scheduled frequency or inspections with lower inspection frequencies that are overdue by more than 100% of their scheduled frequency.

The computer tracking system allows program managers to retrieve program statistics, on demand, allowing assessment of the inspection and licensing programs.

A list of inspections which are due or overdue within the next 60 days is produced monthly. Assignments to inspectors are made during weekly staff meetings.

Inspections of general licensees under reciprocity have not been a high priority for the State and none of the 37 reciprocity notices received in the past year were inspected. Following NRC's lead, Iowa is increasing efforts in this area, with a goal to inspect 50% of future reciprocity licensees, after the Environmental Specialist position is filled.

Field inspections of Iowa industrial radiographers were not performed during the past year. Facing a significant backlog of inspections, the State inspected most of the radiography licenses during the winter months, when radiography licensees were less active at temporary job sites, rather than to carry an inspection backlog. Although field inspections were not performed, demonstrations of equipment usage were part of the inspections. During the next inspection cycle (1 year), the State plans to modify the timing of inspections to allow field site inspections, when possible.

#### Recommendation

We recommend that the State perform reciprocity inspections and industrial radiography field inspections as a part of the inspection program.

# SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED BY THE IOWA RADIATION CONTROL PROGRAM FEBRUARY 22, 1993 TO DECEMBER 14, 1993

The assessments below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the Program managers and staff members, review team observations, licensing and inspection casework file reviews, and inspector accompaniments. The State fully satisfies the following indicators:

# 1. 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.

#### Assessment

Clear statutory authority exists which designates the Iowa Department of Public Health (IDPH) as the State radiation control agency with authority over agreement materials. Effective legislation in Iowa Administrative Code Chapter 17A and Code of Iowa Chapter 136C provides for promulgation of regulations, licensing, inspection and enforcement.

# 2. 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.

#### Assessment

The Iowa Radiation Control Program is located in the Department of Public Health. The Program Director is the Chief of the Bureau of Radiological Protection. Adequate access to appropriate levels of State management is maintained through the Director of the Department of Public Health.

ENCLOSURE 3

#### 3. 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.

#### Assessment

Lines of supervision from the Director, Department of Public Health, to the Director, Division of Health Protection, to the Chief, Bureau of Radiological Protection, are adequate for effective execution of program policy.

A program operating plan was developed in response to the February 1993 follow-up program review. The plan provides managers a short and long-term view of program goals and needs. The new materials tracking system also provides managers with immediate assessment capabilities for the licensing and inspection programs.

The Department has agreements (similar to Memorandum of Understanding) with two State agencies for services. The Emergency Management Division provides survey instrument calibration services which includes scheduling and picking up the instruments. The second agreement is with Iowa State University for laboratory services and radioactive material disposal.

#### 4. 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.

#### Assessment

The State Attorney General's office provides legal assistance to the program. This assistance includes review of proposed rules and enforcement cases. Program involvement was discussed with the Attorney General's office during the review.

# 5. 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.

#### Assessment

The Iowa radiation protection program does not use formal technical advisory committees. In lieu of such committees, the program calls upon experts for assistance as needs arise. In response to recent medical events, radiation therapy experts from various Iowa medical facilities assisted the Department in its investigation as to possible effects on patients. Conflicts of interest are avoided by using advisors from institutions not associated with particular cases.

The program also relies on the NRC's Office of State Programs, Region III personnel, and the Department's consultant for assistance with technically complex licensing or inspection problems.

# 6. <u>Contractual Assistance</u> (Category II)

#### hRC Guidelines

States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have procedures and mechanisms in place for acquisition of technical and vendor services necessary to support these functions that are not otherwise available within the RCP. The RCP should avoid the selection of contractors which have been selected to provide services associated with the low-level radioactive waste facility development or operations.

#### Assessment

This indicator is not applicable as the State does not regulate the disposal of low-level radioactive waste.

# 7. 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, follow-up 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 or rating 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.

#### Assessment

Funding is sufficient to support the radioactive materials program. The Program Director stated that there are no impediments to travel, equipment purchase or administrative support. The program generates licensee fees which go to the State's general fund. The Legislature approves appropriation from the general fund to the Department.

#### 8. 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.

#### Assessment

Laboratory services are readily available through Iowa State University in Ames and the University of Iowa Hygienic Laboratory in Iowa City. An agreement with Iowa State University provides for full radiological laboratory capability for a University exemption from fees. The Hygienic Laboratory charges the program a discounted rate for services. Immediate priority for sample analysis is available, if needed.

#### 9. 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, decommissioning and license termination, fee collection, contacts with communication media, conflict of interest policies for employees, exchange of information and other functions required of the program. Administrative procedures are in addition to the technical procedures utilized in licensing, inspection, and enforcement.

## Assessment

Written administrative procedures have been established and are in use by personnel. The procedures are located in the inspection manual, the tracking system procedure manual and in the secretaries' manuals. Procedures exist for preparation of licenses, mailing and filing, license termination, correspondence formats, fees tracking, refunds, reciprocity tracking, media communications, conflict of interest, exchange of information and other functions required of the program.

Personnel are kept informed of the procedures (and changes therein) through weekly staff meetings.

#### 10. 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). Supervisory review of inspections, reports and enforcement actions should also be performed.

#### Assessment

The Program Director has inspection and licensing status data available immediately from the computer tracking system. Monthly reports from the tracking system are generated which contain current and projected lists of inspections and license reviews which are due for action and provide milestor. tracking of those actions.

The management plan developed after the February 1993 follow-up program review is used as a tool by program management to plan long and short-term goals and to predict what resources will be needed to achieve those goals.

Each license or inspection letter is reviewed by the Program Coordinator, or in his absence, by two technical staff. Inspection letters and licensing actions are signed by the Program Director. These measures were implemented by management to maintain accuracy and consistency in work products.

Weekly meetings are held with staff to discuss casework, policies, goals and problems.

# 11. Public Information (Category II)

#### NRC Guidelines

Inspection and licensing files should be available to the public consistent with State administrative procedures. It is desirable, howeve, that there be provisions for protecting from public disclosure proprietary information and information of a clearly personal nature.

#### Assessment

Inspection and licensing files are available to the public per the Code of Iowa, Chapter 22 and Iowa Administrative Code 641-175. A written request and appointment are necessary to allow the Department to remove proprietary information from the files prior to public viewing.

Public hearings are held on all new rules.

#### 12. 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 including the director of the radiation protection program should be commensurate with the type of licenses issued and inspected by the State.

#### Assessment

Technical staff all have a bachelor's degree or have specific training in the use of radioactive materials (i.e., U.S. Navy Nuclear Medicine Technologist School).

The Program Director and the Program Coordinator have attended numerous technical training courses and have considerable experience with radiation safety programs.

Written job descriptions are available and may be used so that professional qualifications needed to fill vacancies can be readily identified (including the current Environmental Specialist vacancy).

A consultant with significant experience in inspection and enforcement is on contract with the Department and is available for advice and training.

## 13. 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.

#### Assessment

The Program Director and the Program Coordinator provide licensing and inspection guidance to junior personnel. Currently, all inspection letters and licensing actions are reviewed and signed by one of those individuals. Inspectors' work is monitored by review of their inspection preparation, a debriefing upon return and review of inspection reports and letters. License reviewers' work is monitored by a review of checklists, deficiency letters and licensing documents.

Inspection accompaniments are performed by the Program Coordinator and the consultant to train inspectors and to critique their development.

# 14. 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. 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.

#### Assessment

This indicator does not apply to Iowa at this time. The State has no manufacturing licensees; thus, no evaluations of sealed sources and devices are performed. If an application for such a manufacturing license is received, the Iowa staff would initiate review of the license application. Since this would be the State's first review, it would be anticipated that the State would identify specific areas needing technical assistance from the NRC.

#### 15. Licensing Procedures (Category II)

#### NRC Guidelines

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.

## Assessment

The Iowa radioactive materials program is developing regulatory guides for the various types of programs which are licensed. Medical, portable gauge and fixed gauge guides have been written thus far. If an Iowa guide is not available, NRC guides are used. Nine licensing notebooks which include review plans, guides, policies, information notices and license examples are available for the various types of licensed programs. Checklists are also used to improve the quality and consistency of products. Standard license conditions and boilerplate letters are available electronically.

Pertinent information notices are sent to licensees as they are available. NRC notices are generally rewritten to include Iowa regulatory references and then sent to licensees. NRC notices may also be forwarded to licensees.

#### 16. 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. The minimum inspection frequency including for initial inspections should be no less than the NRC system.

#### Assessment

Iowa performs inspections at the same hazard-based frequency as the NRC. Inspections are generally unannounced. The inspection priorities are listed in the Department's fee schedule and are updated as NRC Manual Chapter 2800 is modified.

Inspection frequency may be temporarily reduced or extended based on licensee performance, as allowed by NRC Manual Chapter 2800.

## 17. Inspector's Performance and Capability (Category 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.

#### Assessment

The Iowa radioactive materials inspectors appear to be competent to evaluate health and safety problems and to determine compliance with State regulations and requirements.

Inspections are currently being performed by the Program Coordinator and one junior-grade Environmental Specialist. Prior to receiving authorization to perform independent inspections, personnel are accompanied by the Program Coordinator and Program Consultant. The Regional State Agreements Officer also accompanies inspectors on an occasional basis and provides evaluations to the Program Director.

Mark Flickinger, Environmental Specialist, was accompanied on an inspection of a complex medical program during the review by Kevin Null of the NRC. The December 7, 1993, accompaniment was at Mary Greeley Medical Center, Ames, Iowa (License No. 0049-1-85-M1). Mr. Flickinger's performance was deemed to meet NRC guidelines for Agreement State inspectors.

A casework review of 11 inspection files identified only minor errors, which were discussed with the Program Coordinator for correction.

An inspector qualification manual has been developed outlining training and inspections required for inspector qualification. Inspectors are accompanied on at least an annual basis by the Program Director or Program Coordinator.

Investigational assistance in cases of potential wrongdoing is available through the State Attorney General's office.

# 18. Responses to Incidents and Alleged Incidents (Category I)

#### NRC Guidelines

Inquiries should be promptly made to evaluate the need for onsite investigations. 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.

#### Assessment

Incidents and allegations are promptly evaluated and investigated. Incident details and response actions are discussed with the Regional State Agreements Officer.

Medical and industrial consultants are consulted when assistance is needed in technical areas beyond the scope of the Department's expertise.

One potential medical misadministration occurred during the review period. The incident was investigated by IDPH and a determination was made that the misadministration criteria had not been met. The details were provided to the RSAO and to the Office of State Programs.

Two allegations were received during the review period. The first was forwarded to IDPH from the NRC Region III office. The allegation was promptly investigated and the results were communicated to the NRC for follow-up with the alleger. The second allegation received by IDPH prompted an extensive investigation. Results were forwarded to the alleger. The allegers' identities were kept confidential in both instances.

# 19. Enforcement Procedures (Category I)

# NRC Guidelines

Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Written procedures should exist for handling escalated enforcement cases of varying degrees.

#### Assessment

Enforcement actions similar to NRC's are available to the program through its regulations in Chapter 38 (136C). The review identified a specific inspection case in which only limited enforcement action such as confirmatory telephone calls were used. The Iowa program management thought that the State's efforts were effective and resulted in the desired corrective response from the licensee. The reviewer noted that more aggressive enforcement actions such as a conference and/or civil penalties may have been appropriate, in accordance with the State's enforcement policy. It was suggested to the Department that the enforcement policy be used to its best advantage.

Enforcement letters clearly specify violations and concerns and are generally issued within 30 days following inspections. Responses to enforcement letters are reviewed by the inspector and Program Coordinator.

The Department may choose to impound radioactive material and has an agreement with Iowa State University to dispose of such material.

#### 20. Inspection Procedures (Category II)

## NRC Guidelines

Inspection procedures and 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.

#### Assessment

The Bureau has developed an inspection procedures manual which is consistent with NRC procedures and guidance. The manual establishes policies for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, interviewing workers and observing operations, assuring exit interviews with management, and issuing appropriate notification of violations or health and safety problems.

Inspectors debrief with the Program Coordinator upon return from inspections. Significant inspection findings are related to licensing personnel during weekly staff meetings and are noted on special forms in the license file.

# 21. Inspection Reports (Category II)

#### NRC Guidelines

Inspection 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 also show the status of previous noncompliance and the independent physical measurements made by the inspector.

#### Assessment

Eleven field note inspection reports were reviewed for appropriate documentation of inspection results. All of the reports uniformly and adequately documented inspections. Minor errors identified in several reports were identified and reported to the Program Coordinator for correction.

Inspection reports adequately closed out violations from previous inspections. Standard violations are maintained in the Bureau's enforcement manual. No narrative reports were generated during the review period.

# 22. Confirmatory Measurements (Category II)

#### NRC Guidelines

Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensees measurements.

#### Assessment

Confirmatory measurements are a component of each inspection. Measurements are sufficient in number and type to confirm licensee control of radioactive materials. Instrumentation is adequate for program needs. Available instrumentation includes GM survey meters with end window and pancake probes, ion chambers, sodium iodide detectors, alpha detectors and neutron meters. Air sampling equipment is available from university laboratories, if needed.

The Department has an agreement with the State's Emergency Management Division for calibration of all of the instruments listed above. Instruments are calibrated at frequencies equivalent to those required for licensees.

# SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

Mr. Surmeier, Mr. Axelson, Mr. Caniano, Mr. Null and Mr. Lynch presented the results of this program review to Mr. Atchison, Mr. Fries, Mr. Kelly, Mr. Flater and Mr. McGhee during a summary meeting held on December 14, 1993.

The State was informed that the radioactive materials program had improved to the point where the NRC could consider the program adequate and compatible.

The staffing level was discussed with the State. The NRC representatives noted that, at the time of the review, the technical staffing level was 2.4 FTE with one full-time vacancy. With a staffing level of 2.4 and 216 licenses, the ratio for the State was 1.11 FTE per 100 licenses. This staff level was within NRC guidance; however, with this technical staff level, the program was vulnerable and in danger of failing if one or more key personnel should leave the program. It was recommended that the State continue to pursue filling the Environmental Specialist vacancy so that the radioactive materials program is staffed at 1.57 FTE per 100 licenses when the vacancy is filled.

The NRC committed to continue providing assistance to the Iowa program.

The NRC recommended that the State use its enforcement program to its full potential to encourage compliance with radioactive materials rules and regulations.

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

# **ENCLOSURE 5**