DATED: DEC 28, 1994; SIGNED BY: RICHARD L. BANGART

Mr. Thomas W. Ortciger, Director
Illinois Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

Dear Mr. Ortciger:

This is to transmit the results of the NRC review and evaluation of the Illinois radiation control program which was concluded on July 22, 1994. This review was conducted in conjunction with the pilot Integrated Materials Performance Evaluation Program (IMPEP) in which common performance indicators will be used to evaluate both NRC regional offices and Agreement State programs. The review was conducted by a team of NRC reviewers led by Jack Hornor, Region IV Agreement State Officer, Walnut Creek Field Office. This letter presents the results of the routine Agreement State review and should be considered as the findings of record for the review. The IMPEP pilot program review results will be presented in a separate document. The results of this review were discussed with you and your staff on July 22, 1994.

As a result of our review of your program and the routine exchange of information between the NRC and the State, we believe that the Illinois program for regulating agreement materials is adequate to protect the public health and safety. However, a finding that the program is compatible with the NRC's program is being withheld because the State has not adopted regulations equivalent to the NRC amendment for the "Emergency Planning Rule" (10 CFR Parts 30, 40, and 70) which was due April 7, 1993. Also, the State's regulations on financial assurance for decommissioning and certain provisions in the State's misadministration rule and Part 20 rule differ from those of the NRC and a determination of the significance of the differences was addressed recently in separate correspondence.

Please note that the format of this letter differs from that used in our previous review letters. This letter summarizes the guideline provisions and submits our findings in all 30 program indicators as opposed to including only those indicators in which 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. We request specific responses from the State on the findings and recommendations in Enclosure 2 within 30 days of this letter. We recognize the delay in our issuance of this letter; if you require more than 30 days to respond, please let us know. Your reply should address those recommendations that the State has not previously addressed in correspondence with NRC since the review. Please provide reference to other correspondence, as appropriate.

Enclosure 3 summarizes our findings for indicators which we believe satisfy the guideline provisions and there are no recommendations. A written response to the items in Enclosure 3 is not required.

I appreciate the courtesy and cooperation extended by you and your staff to the NRC review team during the review.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc: Paul Eastvold, Manager
Office of Radiation Safety
Illinois Department of Nuclear Safety

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cc: Paul Eastvold, Manager
Office of Radiation Safety
Illinois Department of Nuclear Safety

Distribution: See next page.

OFC	RSAO:RIV:WC	OSP:SPM	OSP:DD	RA		
NME	JHornor	KSchneider	PLohaus	JMartin		
DTE	11/17/94*	11/28/94*	11/28/94*	12/1/94*		

OFC	NMSS:D	OGC	OSP:D	DEDS	EDO	
NME	RBernero	FCameron	RBangart	HLThompson	JMTaylor	
DTE	12/2/94*	12/2/94*	12/07/94*	11/ /94	12/14/94*	

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DCD (SPO1) PDR (Yes_X__ NO___)
Illinois File

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 the 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 Category I comments are noted as significant, 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 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.

SUMMARY OF ASSESSMENTS AND RECOMMENDATIONS
FOR THE ILLINOIS RADIATION CONTROL PROGRAM
FOR THE PERIOD JANUARY 22, 1992 TO JULY 22, 1994

SCOPE OF REVIEW

The fourth regulatory program review with Illinois representatives was held during the period of July 18-22, 1994, in Springfield, Illinois. The 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 policy statement.

Illinois is one of three States that volunteered to participate in the pilot Integrated Materials Performance Evaluation Program (IMPEP) in which common performance indicators will be used to evaluate both NRC regional offices and the Agreement States programs. This review of the radioactive materials portion of the State's program was conducted in conjunction with the IMPEP review. The IMPEP review report, addressing only the common performance indicators, will be submitted in a separate report. The State's uranium mills and low-level radioactive waste programs were not evaluated during this review. Full review of those programs will be conducted at a later date.

The NRC review team was led by Jack Hornor, Region IV Agreement State Officer, Walnut Creek Field Office. Other team members included George Pangburn, Section Leader, and Scott Moore, Health Physicist, Office of Nuclear Materials Safety and Safeguards; Lloyd Bolling, Health Physicist, Office of State Programs; Craig Gordon, Region I State Agreements Officer; and Jacqueline Burks, Region IV License Reviewer.

The State was represented by Thomas W. Ortciger, Director, Gordon Appel, Deputy Director, Illinois Department of Nuclear Safety (IDNS), Paul Eastvold, Manager, Office of Radiation Safety, and Steve Collins, Chief, Division of Radioactive Materials.

The review included the evaluation of program changes made in response to our previous review recommendations, review of the State's written procedures and policies, discussions with program management and staff, technical evaluation of selected license and compliance files, review of the State's incident and allegation files, and the evaluation of the State's responses to an NRC questionnaire that was sent to the State in preparation for the review.

A summary meeting to present the results of the review was held with Mr. Ortciger on Friday, July 22, 1994.

CONCLUSION

The program for control of agreement materials is adequate to protect the public health and safety. However, a finding of compatibility is being withheld because the State has not adopted regulations equivalent to 10 CFR Parts 30, 40 and 70, "Emergency Planning Rule." Also, the State's regulations on financial assurance for decommissioning and certain provisions in the State's misadministration rule and Part 20 rule differ from the NRC's and a determination of the significance of the differences will be addressed in separate correspondence.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in a letter to Mr. Ortciger dated March 26, 1992. The State's program was found adequate to protect the public health and safety and compatible with the regulatory program of the NRC. The finding of compatibility was contingent on the Commission's evaluation of certain regulations involving the 1 millirem per year dose limit at the boundary of a low-level radioactive waste disposal facility, financial surety requirements for site reclamation, and medical misadministrations. The State's corrective actions in response to our findings were discussed with the State during the review visit conducted by James Lynch, Region III State Agreements Officer, between June 21 and July 29, 1993. The current status of each finding is as follows:

1. Status and Compatibility of Regulations (Category I)

The issue addressed in the following comment has not been satisfactorily resolved and cannot be closed out at this time.

Comment from the January 1992 Review

The State has adopted all regulations considered to be matters of compatibility within the three-year time period allowance specified in the guidelines. However, the State's regulations on financial assurance for decommissioning and certain provisions in the State's misadministration rule differ from those of the NRC.

Recommendation from the January 1992 Review

We recommend that the State document the reasons for these variances and provide a copy to the NRC for further review.

Current Status

Differences between the wording in the State's regulations and those of the NRC were identified and discussed during a meeting between the State and the NRC on June 16, 1993. Except for the NRC decision to approve the one millirem per year off-site doses in the Illinois low-level radioactive waste regulations, these issues are still under consideration. Because of the State's failure to adopt the emergency planning rule within the three-year time frame, the Status and Compatibility of Regulations indicator remains an open item, and is included in our current recommendations.

2. Adequacy of Product Evaluations (Category I)

The issue addressed in the following comment has been satisfactorily resolved and is considered closed.

Comment from the January 1992 Review

Fourteen sealed source and device (SS&D) registration certificates were issued by the State during the review period. The State's reviews were sufficient to assure integrity of the sources and safety for its users. However, several minor comments were identified and discussed with your staff concerning NRC's current policy for evaluating sealed sources and devices and certificate documentation. We believe that the following recommendations will improve the documentation and avoid some potential problems in the future.

Recommendations from the January 1992 Review

(1) Separate and re-evaluate the registration (Certificate IL-136-S-289-S) for the Models VD and VD(HP) source. Request a completed, updated application from Amersham that better defines the source capsule size, isotopes, and activities. This recommendation was made in the form of a suggestion to your staff during the last program review.

(2) Prototype testing should be performed on all sources and devices. If a manufacturer states that the device has an assessed ANSI classification, then the manufacturer must submit information that allows the reviewer to make an independent determination. Further, if applicable, the manufacturer must demonstrate compatibility of their source design with competitor's equipment.

(3) The Environmental Conditions section of the certificate should include the uses of the sealed sources (and devices), and the conditions they will be subjected to under normal conditions of use. If known, the temperature, pressures, humidity ranges and other environs that the sources or devices are designed to withstand should be specified. Also, the expected working life of the product should be stated.

(4) In listing the external radiation levels, use the actual levels as measured by the manufacturer. If the manufacturer cannot provide the radiation levels, then conservative calculated levels should be listed. Care should be exercised when extrapolating beta measurements. In all cases, a theoretical calculation should be performed to check the manufacturer's measurements.

(5) The current policy on the labeling of sources includes the identification of the model of the source. If a model number were placed on all new sealed sources, lost sources could easily be identified as to manufacturer, isotope, activity, etc.

Current Status

(1) The Amersham Corporation models VD and VD(HP) well logging sealed source registration certificate has been placed on inactive status (see IL-136-S-830-S). This means that Amersham will no longer manufacture or distribute these model designations as new products. This does not, however, infer that existing models in use should be recalled or that their use should be restricted unless such action is warranted based on operating experience. IDNS still intends to collect updated information from Amersham on these existing models.

(2) A review of nine sealed source or device certificates indicates that prototype test data are being reviewed and that the reviewers are making independent determinations on the adequacy of the tests for the proposed use of the source or device. It was noted that Amersham assigns ANSI classifications based on actual prototype tests for some sources and by assessment (comparison) with similar sources. Those capsule designs utilizing similar materials, welding techniques and physical dimensions are assigned ANSI classifications for the same proposed use based on assessment or comparison to similar designs which were tested and certified. In these cases however, both capsule designs are evaluated and hold a valid Certificate of Radioactive Source Integrity from Amersham International in England and a valid Certificate of Approval of Design for Special Form Radioactive Material from the Department of

Transportation of United Kingdom of Great Britain. Both certificates are contained in each sealed source and device folder.

(3) Recently issued SS&D certificates contain adequate documentation of normal environmental conditions of use and for severe environmental conditions. IDNS' policy is to include the expected source life on the SS&D certificate. The review identified three certificates issued by IDNS which did not contain the expected source life. IDNS stated that these omissions were due to an oversight and corrections would be made.

(4) Actual radiological measurements or calculations of expected exposures were contained in each SS&D certificate reviewed. In all cases, independent calculations were performed by the staff.

(5) Amersham International has agreed to etch the serial number along the length and the radiation "Trefoil" on the side of each sealed source large enough to accept the etch (tube or cylinders). The smaller sources such as needles or seeds will continue to contain the appropriate safety information on the package label or attached to the source holder/ribbon. Amersham has stated that they can identify a source based on serial number alone.

3. Enforcement Procedures (Category I)

The issue addressed in the following comment has not been satisfactorily resolved and cannot be closed out at this time.

Comment from the January 1992 Review

The State does not have guidelines or a policy for the uniform handling of cases which involve or may involve escalated enforcement. It was noted during the program review that licensee non-compliances are handled on a case-by-case basis. In some cases, there were several rounds of correspondence between the State and a licensee involving inspection results. In other cases, there were management conferences. In others, there were statements about the possible use of escalated enforcement in the Notice of Violation. In another, there was a civil penalty. All appeared to be appropriate methods of enforcement, however, no guidelines exist to enable the staff to determine the appropriate level of enforcement associated with any given violation. Documented enforcement procedures are needed to insure consistency of application and uniformity of regulatory practices.

Recommendation from the January 1992 Review

We recommend that the State develop written procedures for handling escalated enforcement cases of varying degrees.

Current Status

In previous reviews, IDNS agreed to look into the use of specific severity levels for enforcement. In reviewing the State's written enforcement procedures, the review team found the procedures have not been modified to include specific severity levels. Although review of the inspection and incident files indicated that the State's enforcement actions were generally appropriate, specific severity levels would assist the staff in applying escalated enforcement actions in a consistent manner. This open item is included in our current recommendations.

The issue addressed in the following comment has been satisfactorily resolved and is considered closed.

Comment from the January 1992 Review

The State does not normally issue citations to licensees for violations associated with self-reported incidents involving the loss or inadvertent disposal of small quantities of radioactive materials. The State's position is that little is gained in the way of compliance when an enforcement action is initiated for loss of a small sealed source. Further, the State is concerned that such action may actually serve to discourage licensees from reporting lost sources in the future. When these situations occur, the State requires licensees to submit a report describing the incident, the most probable reason for its occurrence and the steps the licensee will take to prevent recurrence. The State is in the process of developing an enforcement policy on the loss of or inadvertent disposal of small quantities of radioactive material to ensure that the current practice is consistently applied among licensees, that reports are well documented and maintained in the license file, and that all pertinent staff is informed of the policy.

Recommendation from the January 1992 Review

We recommend that the State complete their enforcement policy on inadvertent disposal of small quantities of radioactive materials, and also provide a copy to our Region III Office for review and comment prior to implementation.

Current Status

The State submitted the formal policy memorandum regarding the disposal of small quantities of agreement materials to the Region III Office in their response to our March 26, 1992, letter to Mr. Ortciger. The procedure was reviewed without comment by the Region in March 1993. This closes the issue.

CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 22 of these indicators. Recommendations were made on the eight indicators discussed below. The remaining 22 indicators are discussed in Enclosure 3. A questionnaire containing the 30 indicators with specific questions pertaining to 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, review of the State's written procedures and policies, discussions with program managers and staff members, review team observations, and licensing and inspection casework file reviews.

1. Status and Compatibility of Regulations (Category I)

NRC Guidelines

The State must have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards, effluent limits, waste manifest rule and certain other parts), Part 61 (technical definitions and requirements, performance objectives, financial assurances) and those required by the Uranium Mill Tailings Radiation Control Act (UMTRCA), as implemented by Part 40. 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. The radiation control program (RCP) should have established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC. 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.

Assessment

The State was provided the latest chronology of NRC regulation amendments that are needed for compatibility. The Illinois regulations were compared with this chronology, and the amendments that were adopted by the State since the January 1992 review were reviewed for compatibility. With the exception of the "Emergency Planning Rule" (10 CFR Parts 30, 40, 70) which was due April 7, 1993, the State has adopted rules equivalent to the NRC amendments through the "Notification of Incidents Rule" which was due October 15, 1994. This includes the equivalent new Part 20, "Standards for Protection Against Radiation" which became effective January 1, 1994. The State contends failure to adopt the emergency planning rule is not a health and safety problem because contingency plans are required by license condition for all affected licensees. The State has verified by inspection that the three licensees requiring contingency plans have them implemented. The State also contends and NRC agrees that they were previously urged by the Office of State Programs to divert resources from other regulation promulgation efforts in order to have the equivalent rule to the new NRC Part 20 rule in place by January 1, 1994.

Also the State's regulations on financial assurance for decommissioning and certain provisions in the State's misadministration rule and Part 20 rule differ from those of the NRC and a determination of the significance of the differences will be addressed in separate correspondence. Differences in the wording of certain Illinois regulations and the equivalent NRC regulations were identified. The issues were addressed in correspondence dated December 19, 1994, from Richard L. Bangart, NRC, to Thomas W. Ortciger, State of Illinois.

Recommendation

We recommend that the State amend the emergency planning rule at the first opportunity.

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:

- "Quality Management Program and Misadministrations", 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992, and will need to be adopted by January 27, 1995.

- "Licenses and Radiation Safety Requirements for Irradiators", 10 CFR Part 36 (58 FR 7715) that became effective on July 1, 1993, and will need to be adopted by July 1, 1996.

- "Licensing Requirements for Land Disposal of Radioactive Waste," 10 CFR Part 61 amendment (58 FR 33886) that became effective on July 22, 1993, and will need to be adopted by July 22, 1996.

- "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993, and will need to be adopted by October 25, 1996.

- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70, amendments (58 FR 68726) that became effective on January 28, 1994 and will need to be adopted by January 28, 1997.

2. 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 statutes, and regulations.

Assessment

The Division of Radioactive Materials (DRM) has legal staff available for assistance in the Office of Legal Counsel (OLC) which is a part of IDNS. Although the review team did not discern any problems with routine legal assistance provided for the materials program, there was some concern over the timeliness of legal assistance provided relative to enforcement matters. In reviewing the June 1994 DRM report to the IDNS Director, the team found four cases in which delays in receiving legal assistance had hampered enforcement action. In two instances where DRM had requested legal assistance in issuance of civil penalties, DRM ultimately withdrew the request after some delay because the licensee had come into compliance in the interim. However, in two other cases, DRM requested the issuance of Orders relating to possession of radioactive material under an expired license. In the first case, the Order was not prepared for more than 6 months after requested by DRM and, at the time of the review, 7 months later, it had not been served on the licensee. In the second case, the Order was requested 9 months prior to the date of the review and had still not been issued. The review team did note that in cases where imminent health and safety concerns were present, DRM received prompt legal assistance in issuing orders. For this reason, the concern identified in this comment is not considered to be a significant finding.

Recommendation

The review team recommends that the State take appropriate action to assure that timely legal assistance is available to the agreement materials program.

3. 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, and inspection and enforcement.

Assessment

Administrative procedures reviewed by the review team included procedures for handling license applications, standard license conditions, entry of data into the licensing and inspection data base, use of word processing software for license generation, and various general procedures. As a result of the teams's review, the procedures were, except as noted, determined to be adequate to assure that the staff performs the duties required and to provide a high degree of uniformity and continuity in regulatory practices. During the 1993 review visit, it was noted that NRC Information Notices were not always received by the appropriate managers in IDNS, and thus were not consistently distributed to Illinois licensees. It was suggested that procedures be developed to correct the problem. During this review it was found procedures have not been developed to ensure the Information Notices are distributed to all appropriate licensees.

Recommendation

We recommend a procedure be developed and implemented to make certain the Information Notices are properly distributed to IDNS managers and to State licensees. The State agreed during the review to develop such a procedure.

4. 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 inspection program in all States should provide for the inspection of licensee's waste generation activities under the State's jurisdiction. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should include provisions for pre-operational, operational, and post-operational facility inspections. The inspections should cover all program elements which are relevant at the time of the inspection and be performed independently of any resident inspector program. In addition, inspections should be conducted on a routine basis during the operation of the low-level radioactive waste facility, including inspection of incoming shipments and licensee site activities. 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 versus junior staff, assignments to regions, identification of special needs and periodic status reports. When backlogs occur the program should develop and implement a plan to reduce the backlog. The plan should identify priorities for inspections and establish target dates and milestones for assessing progress.

Assessment

DRM maintains an integrated licensing and inspection data base capable of providing management with a variety of reports on status of the inspection program. Routine monthly reports are provided to the Inspection & Enforcement (I&E) section head which allow him to review status and serve as the basis for monthly inspection planning. Illinois uses a 25% criterion to determine if an inspection is overdue, although by the guidelines for review of Agreement State programs only speak to a 50% criterion for determining overdue inspections. In short, they hold themselves to a higher standard than

required. Using that higher standard, at the time of the review, there were 61 overdue inspections. These overdue inspections were the result of a large contamination incident at a licensed facility in May 1994 which occupied four inspectors full-time for approximately a month. In its response to the questionnaire, DRM indicated that it planned to deal with the overdue inspections by having the I&E section head spend one week per month in the Glen Ellyn office until the number of overdue inspections is within the guidelines. This plan was initiated in August 1994.

The review team also looked into initial inspections of new licensees. The NRC guidelines for frequency of inspections state that the minimum inspection frequency, including initial inspections, should be no less than that used by the NRC. NRC inspection procedures require that initial inspections be conducted within 6 months of license issuance. Of approximately 90 new licenses issued between 1/1/92 and 12/30/93, only three had been inspected within 6 months of license issuance. The review team examined a random sample of 10 of these new licenses to determine if there were any extenuating circumstances. However, in 9 of the 10 cases, there was no indication in the files of any basis not to inspect within 6 months. The I&E section head indicated that the cause of the problem was the computer program used to schedule all inspections.

Recommendation

The review team recommends that DRM take appropriate steps to modify the scheduling program to assure that initial inspections are conducted within 6 months of license issuance.

5. 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 recurrence (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.

Assessment

The State's enforcement procedures (Section III of IDNS Operating Procedures) were reviewed in detail. These written procedures, in addition to covering routine and escalated enforcement actions, contain instructions for management review, for providing feedback to the licensing section and for using the mechanism to move licensees that are recalcitrant to bring their programs into compliance. Model letters for eight possible situations are included.

Suggested escalated enforcement actions include telephone calls to the licensee, second notices of non-compliance, follow-up inspections, management conferences, license modifications, civil penalties, license suspension, revocations, and impound of radioactive material. In addition, IDNS has the use of the State Attorney General's office to obtain search warrants and prosecute criminal cases, if necessary.

The procedures do not, however, prescribe specific actions to be taken at varying severity levels of violations. The State's enforcement policy is performance based, rather than prescriptive, and as such, each action is based on management review and judgement with the goal of achieving compliance in the most expedient manner. Although the State's enforcement actions were, for the most part, satisfactory, review of the inspection files indicated that in two cases, escalated enforcement was not taken in response to licensee actions that met NRC severity level criteria for escalated enforcement.

Recommendation

Procedures for handling escalated enforcement cases of varying degrees can be written in such a fashion as to allow flexibility in judgement while providing a more consistent method of determining the appropriate enforcement action. We recommend that the State develop additional written guidance, to be used by management and staff, for specific action on enforcement cases with varying severity levels of violation.

6. 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. NRC 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, interviewing workers and observing operations, 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 supervisors 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.

Assessment

The State's inspection procedures were reviewed and found to be thorough and sufficient to provide guidance to inspectors on how to conduct inspections and document them. The review team determined through discussions with staff and review of compliance files, that the procedures are used by the inspectors. The inspection procedures, however, have not been updated with references to Illinois' new regulations, including Part 340 (Illinois' equivalent to 10 CFR Part 20).

NRC's inspection procedures are contained in Manual Chapter (MC) 2800, which is furnished to all Agreement States to use as guidance. NRC's position, as given in MC 2800, is that all materials inspections should be performed on a strictly unannounced basis, whenever possible, except for geographically distant locations. Illinois' policy on performing routine inspections, as

stated in their procedures, is that such inspections should be unannounced unless prior notification of no more than 48 hours would let the licensee assemble documents to be reviewed. Of the 13 inspection files that the team reviewed, eight were announced before the inspection. All eight of these were different types of inspections of a variety of different licensee categories. The Chief, Division of Radioactive Materials, explained that announced inspections are the result of a program management decision to reduce the number of overdue inspections as quickly as possible. Once the number of overdue inspections has been reduced to an acceptable level, his intent is to conduct unannounced inspections.

Although they differ slightly in wording, both the NRC's and the State's inspection procedures require the inspector to hold the exit meeting with the highest possible level of management. An appropriate manager would be someone who is the licensee's management representative on the Radiation Safety Committee or someone who has the authority to speak for the institution or obligate its funds. In a review of 13 inspection files, the review team found six cases in which the inspectors conducted exit meetings with the Radiation Safety Officer (RSO) or at the equivalent level. It appeared that in some of these cases, the inspector was not holding the exit meeting at a high management level. Notable among these was an inspection at Northwestern University, a broad-scope academic licensee, where the RSO was the highest university official present at the exit meeting.

In interviews with an inspector and with the I&E section head, the review team determined that it is IDNS' policy for inspectors to formally debrief with their supervisor on returning from an inspection trip. The I&E section head also reviews all sets of completed field notes and signs all inspection results as they are sent to licensees.

Recommendations

(a) We recommend the State update the inspection procedures to reference the new Illinois regulations, including Part 340.

(b) Once the number of overdue inspections is reduced to an acceptable level, we recommend that IDNS conduct routine materials inspections without advance licensee notice (that is, unannounced), unless resource considerations dictate otherwise for geographically distant locations.

(c) We recommend that IDNS' materials inspectors hold exit meetings at a high level of licensee management.

7. 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's 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.

Assessment

Thirteen inspection reports were selected for the casework review. The cases reviewed included reports from all five materials inspectors. The cases reviewed consisted of licensees in the following categories: broad-scope medical, specific medical, brachytherapy (storage only), fixed gauge, portable gauge, nuclear pharmacy, teletherapy, panoramic irradiator, wireline service, broad-scope research and development (Type A), industrial radiography, broad-scope academic (Type A), and specific manufacturer. The reviewer found that the inspection reports were generally well documented. All of the reports consisted of the inspectors' written comments on inspection field notes. Documentation of independent measurements made by the inspectors was included in the inspection reports.

In reviewing the irradiator inspection report, the review team found that the inspector used the inspection form (field notes) for fixed and portable gauges. The I&E section head said that the State has no inspection form specifically for irradiators. The reviewer compared Illinois' fixed/portable gauge inspection form with NRC's field notes for irradiators (pre-10 CFR Part 36), and found that several important safety areas were not covered on the fixed/portable gauge inspection form, including: water chemistry and pool sampling, demineralizer operation and radiological monitoring of the demineralizer, effluents, and emergency preparedness. Although the inspector performed a complete inspection, the inspector did not document the previously mentioned areas. The review team believes that the fixed/portable gauge inspection form is unsuitable for recording the results of an irradiator inspection, and that IDNS should develop an irradiator inspection form.

On reviewing the inspection files, the review team found that DRM materials inspectors were not routinely reviewing the area of gaseous effluents. In addition, the I&E section head indicated that this was not an area that the inspectors routinely examined, except on inspections of incinerators. In contrast, the State's procedures say that inspectors will look at airborne waste release records. In addition to incinerator inspections, for certain types of licensees such as radiopharmacies, broad-scope universities, major research and development licensees, certain types of manufacturers, it is prudent for inspectors to review gaseous effluent releases to determine compliance with the regulations (10 CFR Part 20 for NRC, or Part 340 for Illinois).

In reviewing the incident and allegations casework, it was noted that during the next inspection following an event, two inspection reports did not show whether the licensee met commitments for corrective actions or implemented program changes to prevent recurrence.

The reviewer developed isolated comments from the casework reviews, and these comments were not indicative of any generic issues or problems, beyond those explained above. The review team's comments were discussed with the I&E section head during the review.

Recommendations

(a) We recommend that the State develop a specific set of inspection forms for inspections of panoramic (i.e., not self-shielded) irradiators.

(b) We recommend that inspectors review gaseous effluent releases for all major users of unsealed, potentially airborne radionuclides.

(c) We recommend that inspectors review incidents that had occurred within the inspection interval with the licensee, verify corrective actions were taken, and document the results.

8. 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 licensee's measurements. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, access to testing should be available on an "as needed" basis for confirming licensees' and applicants' programs for measurements related to nonradiological aspects of facility operations such as soils and materials testing and environmental sampling and analysis to demonstrate compliance with 10 CFR Part 61 or compatible Agreement State regulations and ensure facility performance. Conditions for nonradiological testing should be prescribed in plans or procedures. RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samplers, lab counting equipment for smears, identification of isotopes, etc.). RCP instrumentation should include the following types:

GM Survey Meter: 0-50 mr/hr
Ion Chamber Survey Meter: up to 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 µCi/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 of the licensees being inspected.

(Note: Additional types of instrumentation that are highly desirable are thin window plastic or NaI detectors for low energy gammas and "micro-R" meters with audio signal for searching for lost gamma emitter sources.)

Assessment

The inspection reports were reviewed for documentation concerning confirmatory measurements and independent measurements. The team reviewer determined that inspectors were performing independent measurements. Independent measurements were particularly well documented in the inspection reports.

The reviewer determined that survey meters are being calibrated on an annual frequency. The reviewer discussed the equipment calibration procedures with the inspection and calibration staff and pointed out that certain types of licensees require calibration of their survey meters on a more frequent basis. For instance, radiographers must calibrate their survey meters at least quarterly. The reviewer performed a spot check of the calibration dates for survey meters used on radiography inspections during the review period and found several instances where the instruments had not been calibrated within the preceding 3 months. The review team concluded that IDNS was not

calibrating its instrumentation as frequently as some types of licensees. This practice contrasts to the Illinois' inspection procedures which state that the inspector will use survey instruments that have been calibrated within the time interval required for the licensee's survey instruments.

IDNS calibration facility is well equipped, and its calibrations are traceable to the National Institute of Standards and Technology.

Recommendation

We recommend that the State calibrate all survey instrumentation at a frequency at or more frequent than that required of the licensee being inspected, or only use instruments on inspections that have been calibrated within the standards applicable to the licensee. For instance, survey meters used on inspections of radiographers should be calibrated within the past 3 months.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

On Friday, July 22, 1994, Richard L. Bangart, Director, OSP, and the review team met with Mr. Ortciger and his staff to present the results of the review. The meeting was also attended by Guy Arlotto, Deputy Director, Office of Nuclear Material Safety and Safeguards, Roy Caniano, Chief, Nuclear Materials Safety Branch, and James Lynch, State Agreements Officer, Region III.

It was explained to the State that the review of the State's low-level waste and uranium mill program would be scheduled for a later date.

The State representatives were advised that, although the final determination of adequacy and compatibility of an Agreement State program rests with the Commission, the finding of compatibility may not be granted because of the State's failure to adopt the Emergency Planning rule within the three-year time frame.

The State was informed that their program fully satisfies 22 of the 30 indicators, and our recommendations for the remaining eight indicators were presented and discussed. The problem in obtaining timely legal assistance in enforcement cases was discussed at length. The State representatives were told that the Commission may reconsider the finding of adequate enforcement procedures because of IDNS' difficulty in obtaining orders. The review team reminded the State that the terms of several technical advisory committee members had expired. They suggested that IDNS ask the Governor to extend the terms or appoint other members.

Mr. Ortciger was informed that the results of the review would be reported in a letter to him from Mr. Bangart and that a written response would be requested.

The NRC representatives thanked the State for participating in the IMPEP pilot program. The common performance indicators concept and the IMPEP review process were explained, and the differences between the OSP and IMPEP reviews were discussed. The State was advised they will be asked to comment on the draft version of the IMPEP report before the final version is presented to the Management Review Board of the National Program Review. They were also told that an Illinois representative will be invited to attend that presentation. It was explained that the Board makes the final determination of adequacy for the National Program Review.

Mr. Ortciger and the other Illinois representatives were thanked for their cooperation and commended on their professional and conscientious staff.

In reply, Mr. Ortciger thanked the team for their comments and said he felt outside reviews were beneficial to any program. He indicated the State would consider our recommendations and advise us of their plans for corrective actions in their response.

SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED
BY THE ILLINOIS RADIATION CONTROL PROGRAM
FOR THE PERIOD JANUARY 22, 1992 TO JULY 22, 1994

The assessments below are based upon information provided in the State's written response to the NRC questionnaire mailed to the State in advance of the review, review of the State's written procedures and policies, comparison with previous review information, discussions with program managers and staff members, review team observations, licensing and compliance 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. 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. States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulations for low-level waste management and disposal. The statutes should also provide regulatory program authority and provide for a system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur.

Assessment

The Illinois Department of Nuclear Safety (IDNS) is currently designated as the State's radiation control agency under the provisions of the Radiation Protection Act of 1990 [420 ILCS 40/1 - 40/44 (1992)] as amended. The regulations are published in Title 32, Chapter II, of the Illinois Administrative Code. These documents, which were reviewed by the staff, provide clear statutory authority for the control of agreement materials.

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

NRC Guidelines

The radiation control program (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. Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Assessment

The Department of Nuclear Safety is a cabinet level agency within Illinois State government. The Director is appointed by and reports directly to the Governor and, accordingly, has access to appropriate levels of State management. The Office of Radiation Safety (ORS), which includes the Division of Radioactive Materials (DRM), and the Office of Environmental Safety (OES), which includes the Division of Low-Level Waste Management, report directly to the Department Director.

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. Where regional offices or other government agencies are utilized, the lines of communication and administrative control between these offices and the central office (Program Director) should be clearly drawn to provide uniformity in licensing and inspection policies, procedures and supervision.

Assessment

Organization of DRM is appropriate for execution of the major program functions. The Division Chief has organized the Division into two sections: (1) Licensing; and (2) Inspection and Enforcement (I&E). Both sections are managed by a section head who reports directly to the Division Chief. The licensing section has a materials licensing group (four license reviewers) and a Low-level radioactive waste and mill tailings licensing group (four license reviewers). The I&E Section has a regional component in the form of four inspectors located in the Glen Ellyn office (one of whom serves as a supervisor) as well as one inspector in the Springfield office. The Glen Ellyn office handles all licensees located north of Interstate Highway 80, while the Springfield inspector handles all licensees located south of Interstate Highway 80. This organizational arrangement is basically unchanged since the last program review.

4. 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.

Assessment

The State has four technical advisory boards. Two of these are established by statute: the Radiation Protection Advisory Council (RPAC) and the Radiologic Technologist Accreditation Advisory Board (RTAAB). These bodies are charged with advising IDNS on policies, programs and regulations developed by IDNS as well as such other matters as may be requested. In addition, the RPAC has two subcommittees — the Industrial Use Advisory Board and the Medical Use Advisory Board — which provide recommendations specific to their areas of expertise. The RPAC met once during the review period and the Medical Use Advisory Board met three times. Members of the RPAC and RTAAB are appointed by the Governor and members of the two subcommittees are appointed by IDNS. Review of the membership of these various boards indicated that the terms of many of the

members had expired. The review team pointed out that IDNS should ask the Governor to extend these terms or take other appropriate action.

5. Contractual Assistance (Category II)

NRC Guidelines

Because of the diversity and complexity of low-level radioactive waste disposal licensing and regulation, 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

The State's manual, "IDNS Contract Formation and Management Guide" (1990), provides guidance for all IDNS contracts. The guide, which is approved by the Office of Legal Counsel (OLC), includes sections on conflict of interest, bribery, Illinois contract law, disclosure, and all other agency contractor dealings. Every contract must have OLC review before approval is granted. Staff interviews indicated the procedure is strictly followed. Although the low-level waste program was not reviewed, the procedures and mechanisms for using vendor services are in place.

6. 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.

Assessment

The NRC was provided a copy of the emergency plan, "Illinois Plan for Radiological Accidents (IPRA), Volumes 1-10," which covers all radiological emergencies including those at fixed nuclear facilities. The portions of the plan pertaining to radioactive materials accidents are contained in Part B of Volume 1 (Concepts of Operation) and in Volume 10 (Transportation). Controlled copies are sent to all appropriate Federal and State agencies including the NRC. Although the NRC may comment on the plan, the last revision was provided after the fact. It was, however, evaluated during the review and found to be satisfactory. Sections of Part B include: directions for accident classification; discussion of types of emergencies (overexposures, release of radioactive material, lost or stolen sources, etc.); assigning responsibility for direction and control, assessing the need for emergency response and assigning specific agencies and personnel

responsible for response actions; procedures for obtaining medical services; and provisions for exercises and drills.

IDNS maintains 24-hour "Radiological Assistance" telecommunications centers for reporting emergencies. When a center receives a call involving radioactive materials, the Office of Radiation Safety duty officer assumes responsibility for determining the correct response. The duty officer assignment is rotated among qualified personnel who are provided with the "ORS/OES Duty Officer Manual of Standard Operating Procedures." This document includes the procedures used to evaluate and respond to events, complaints, and allegations, as well as the requirements for incident notifications. It also provides guidance on how to perform appropriate surveys. These procedures were also reviewed and found to be comprehensive and clear. Briefly, in the event of an accident, the nearest materials inspector is dispatched to the site. After appraising the situation the inspector confers by phone with the duty officer to evaluate the need for further action. It was verified by interview and observation that potential responders have copies of the plan and procedures and are well-versed in incident response. It was also verified that the emergency call list is regularly updated. The plan is in place, working, and satisfies the guidelines for this indicator.

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 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. States regulating the disposal of low-level radioactive waste facilities should have adequate budgetary resources to allow for changes in funding needs during the low-level radioactive waste facility life cycle. After appropriations, the sources of program funding should be stable and protected from competition from or invasion by other State programs. 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.

Assessment

Funding is sufficient to support the radioactive materials program. The total budget for fiscal year 94 for IDNS is $32.8 million and the radioactive materials program was allocated approximately $1.5 million of this budget; this figure does not include the management and administrative aspects of the program. The Division collects fees from licensees to recover costs of licensing actions; annual fees and inspection fees are not collected from licensees. The materials program is 26 percent funded by fees.

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. In addition, States regulating the disposal of low-level radioactive waste facilities in permanent disposal facilities should have access to laboratory support for radiological and non-radiological analyses associated with the licensing and regulation of low-level waste disposal, including soils testing, testing of environmental media, testing of engineering properties of waste packages and waste forms, and testing of other engineering materials used in the disposal of low-level radioactive waste. Access to laboratory support should be available on an "as needed" basis for nonradiological analyses to confirm licensees' and applicants' programs and conditions for nonradiological testing should be prescribed in plans or procedures.

Assessment

IDNS has its own laboratory, which provides support to the Division of Radioactive Materials and the rest of IDNS. The radiochemistry laboratory is able to analyze environmental samples of many types, including air, milk, water, soil, and vegetation samples. Inspectors' wipe samples are evaluated by the laboratory, as well as samples involving disposal of low-level radioactive waste. In addition to the in-house analysis capability, IDNS has a mobile laboratory that can analyze many environmental samples on-site. The Chief of the Division of Radiochemistry indicated that the laboratory is able to analyze routine bioassay samples, but this service has not been requested in the past. Interviews with an inspector, the I&E section head, and laboratory management indicated that the laboratory is able to analyze inspectors' samples on a priority basis when the inspection staff indicates that they need results quickly. Inspection staff are satisfied with both the quality and speed of results from the laboratory. The State indicated in response to the questionnaire that there have been no problems in obtaining timely and accurate results. Review team members, during a tour of the laboratory, observed that the laboratory is extremely well equipped for both in-house and on-site analysis. The reviewers determined that laboratory support satisfies this indicator.

9. 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, low-level radioactive waste disposal facilities, large scope-Type A Broad, and those which have the potential for significant releases to the environment) should receive second party review (supervisory, committee, consultant.) Supervisory review of inspections, reports and enforcement actions should also be performed. For the implementation of very complex licensing actions, such as initial license review, license renewals and licensing actions associated with a low-level radioactive waste disposal facility, there should be an overall Project Manager responsible for the coordination and compilation of the diverse technical reviews necessary for the completion of the licensing action. The Project Manager should have training or experience in one or more of the main disciplines related to the technical reviews which the Project Manager will be coordinating such as health physics, engineering, earth science or environmental science. When

regional offices or other government agencies are utilized, program management should conduct periodic audits of these offices.

Assessment

The section heads provide monthly data on licensing, inspection and other program activities to the Division Chief for inclusion into a monthly report for the IDNS Director. The section heads also review and sign off on all licensing and inspection actions prior to issuance. In discussions with technical staff as well as examination of licensing and inspection files, the review team confirmed that these sign offs were taking place. In addition, the Division Chief also reviews selected licensing actions prior to issuance, specifically those which are complex or potentially controversial. As an independent check, the Assistant to the Division Chief periodically reviews a sample of completed licensing actions conducted by the license reviewers. The review team concludes that DRM management is adequate with respect to this indicator.

10. 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. 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. Professional staff should not be used for fee collection and other clerical duties.

Assessment

DRM has a comprehensive, integrated licensing and inspection data base which tracks the status of licensing and inspection actions and generates a variety of management reports. Ability to change data resides with only a selected number of key positions; most staff have read-only authority. All Springfield personnel have personal computers and are interconnected by a LEON (local area network). The LEON extends to the regional office at Glen Ellyn, but that office has only one personal computer for the four inspectors there. Licenses are generated and maintained by word processing software using macros with license formats and having search capability. Secretarial and clerical staff support is adequate for routine program functions.

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, however, that there be provisions for protecting from public disclosure proprietary information and information of a clearly personal nature. Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws during the process of major licensing actions associated with UMTRCA and low-level radioactive waste in permanent disposal facilities.

Assessment

Illinois has a Freedom of Information (FOIA) act which governs all State agencies. IDNS has a paralegal within OLC who acts as FOIA coordinator before requests for information are released. Inspection forms and license reviewer checklists are considered draft material and are not releasable under FOIA requests. Members of the public may come in and review agency licensing and inspection files, but proprietary and/or personal information is protected from disclosure.

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. For States regulating uranium mills and mill tailings, staff training and experience should also include hydrology, geology, and structural engineering. For programs which regulate the disposal of low-level radioactive waste in permanent facilities, staff training and experience should include civil or mechanical engineering, geology, hydrology, and other earth science, and environmental science. In both types of materials, staff training and experience guidelines apply to available contractors and resources in State agencies other than the RCP. Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Assessment

The review team interviewed the Assistant Division Chief, who indicated that all materials personnel have bachelor's degrees in physical or life sciences. Position descriptions for all technical and managerial positions were reviewed. The training and experience of the technical staff, including the managers were reviewed and found to be commensurate with the licenses issued and inspected by the State.

13. Staffing Level (Category II)

NRC Guidelines

Professional staffing level should be approximately 1-1.5 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. 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 in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978. States which regulate the disposal of low-level radioactive waste in permanent disposal facilities should allow a baseline RCP staff effort of three-four professional technical person-years (in addition to the two professionals for the basic RCP indicated in the first sentence of this indicator). However, in some cases, the level of site activity may be such that a lower level is adequate, particularly if contractor support is on call. In any event, staff resources should be adequate to conduct inspections on a routine basis during operations of the low-level radioactive waste facility,

including inspection of incoming shipments and licensee site activities and to respond to emergencies associated with the site. During periods of peak activity additional staff or specialty consultants should be available on a timely basis.

Assessment

The Division has 11.5 technical FTE for approximately 785 licenses which equates to 1.5 FTE/100 licenses. This meets the NRC criterion of 1.0-1.5 FTE/100 licenses and appears to be adequate for most routine and non-routine licensing and inspection demands of the program. The staffing for the low-level radioactive waste and mill program was not examined during this review.

14. 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

A review of the training and experience of the first line supervisors indicates that these personnel are qualified to provide guidance to junior personnel. DRM staff generally self-assign work, but supervisors monitor the distribution of and progress on work assignments. As noted above, supervisors also review the completed inspection and licensing actions and, based on discussions with the technical staff, provide timely and adequate feedback to the responsible staff.

15. Training (Category II)

NRC Guidelines

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 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

Licensing staff have taken the four core courses, with the exception of one individual who is presently scheduled to take the industrial radiography course. The inspection staff have all taken three of the four core courses, with the exception of the licensing course. Due to the segregation of the inspection and licensing function in IDNS, the licensing course is not considered necessary for the senior inspection staff. Discussions with DRM management as well as staff demonstrated a commitment to training beyond the core courses, which is shown by a high percentage of staff having taken other courses such as well-logging, transportation, gauges and the NRC's five-week health physics course presented at the Oak Ridge National Laboratory. Management also supports continued professional development through courses

outside the radiation area (such as environmental impact preparation) and participation in professional society meetings.

16. 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.

Assessment

Staff turnover during the review period was minimal. Two persons departed the program: one for family reasons and another for a radiation safety staff position at a licensed facility. One of the positions (license reviewer) was filled; the other (regional inspector) was transferred to the low-level radioactive waste licensing portion of the program where the need was more urgent. Salary levels within the Illinois program are adequate and favorable when compared to those of other Agreement State programs.

17. 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. Additionally, in States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet State licensing requirements for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be adequately documented including safety evaluation reports, product certifications or similar documentation of the license review and approval process. 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.

Assessment

The State processed a total of 789 new licenses, renewals in entirety and terminations during the review period. In addition 1,147 amendments were issued during the same period. Sixteen license files were selected for casework review including four new licenses, four amendments, four renewals in entirety and four license terminations. All license reviewers were included

in the review. License types included two source material processors, one well logger, three in-vitro laboratories, two industrial radiographers, one research and development laboratory, one self contained irradiator, one veterinary medicine, two institutional medicals, one institutional medical with teletherapy, one manufacturer and one teletherapy service firm.

The licensing actions were reviewed for completeness, consistency, proper isotopes and quantities, qualifications of authorized users, adequate facilities, operating and emergency procedures, and authorized user training sufficient to establish the basis for the licensing action. Casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of the basis for the licensing decision, and consideration of enforcement history on renewals. The files were checked for orderliness and retention of necessary documents and supporting data.

The licensing actions were found to be thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. Tie-down and specific conditions were clearly stated, backed by information contained in the file and considered to be inspectable. Questions developed during the casework reviews were resolved in discussions with IDNS staff.

18. 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 on 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. Approval documents for radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste for disposal should be complete and accurate as to the use, capabilities, limitations, and site specific restrictions associated with each product.

Assessment

Thirty-four sealed source and device (SS&D) registration certificates were issued by IDNS during the review period. The following nine certificates (26 percent) and their associated background files were reviewed:

Registration	Manufacturer	Radionuclide	Type of Use
IL-412-D-133-B	ROSEMOUNT, INC.	241-Am:Be	NEUTRON GAUGE
IL-136-S-163-S	AMERSHAM CORP.	241-Am	GAMMA GAUGE
IL-136-S-250-S	AMERSHAM CORP.	60-Co	RADIOGRAPHY
IL-136-S-343-S	AMERSHAM CORP.	60-Co & 137-Cs	GAMMA GAUGE
IL-136-S-191-S	AMERSHAM CORP.	137-Cs	WELL LOGGING
IL-136-S-337-S	AMERSHAM CORP.	125-I	BRACHYTHERAPY

IL-136-S-338-S	AMERSHAM CORP.	125-I	BRACHYTHERAPY
IL-136-S-353-S	AMERSHAM CORP.	137-Cs	BRACHYTHERAPY
IL-422-D-101-S	LIXI, INC.	241-Am & 125-I	RADIOGRAPHY

The sealed source and device registration certificates and their associated background files were reviewed for technical quality and consistency in the following areas: format, description, labeling, diagrams, conditions of use, prototype testing, radiation levels, quality assurance and control, limitations of use, and the basis for determining that the source or device design was deemed acceptable for licensing purposes. These evaluations were found to be adequate and no deficiencies were found. Minor questions posed by the review team were resolved during the review.

IDNS program for evaluation of sealed sources and devices is an integral part of the radioactive materials licensing program. The licensing program, staffed by four health physicists and an engineer from another section of IDNS, is consulted as needed on matters such as engineering drawings, compatibility of materials and product test criteria. Evaluations are reviewed by one of two senior health physicist/managers who co-sign every registration certificate issued.

The program has adequate staffing, equipment and administrative procedures to conduct independent evaluations of data submitted in support of SS&D applications. Each staff member has a 386 PC which is used to generate licensing actions. The staff developed a set of comprehensive sealed source and device manuals which contain current guidance such as the draft regulatory guide on establishing QA programs for SS&D manufacturers/distributors, policy and guidance directives, information notices, NRC regulations, ANSI & ISO test criteria and checklists. These manuals also contain valuable historic information including "lessons learned" reports from several incidents and the original Users Handbook on the Automated System for Registry of SS&D, dated July 1982.

Enforcement of vendor SS&D commitments is covered under the tie-down statement on the manufacturer's license and is further referenced on each registration certificate.

IDNS has the authority to withhold proprietary information identified by applicants. Documents requested under the State's Freedom of Information Act receive technical and legal staff review and the appropriate personal or proprietary data are withheld. Although there is no specific IDNS regulatory equivalent to NRC's Part 21, licensed SS&D manufacturers are expected to and do report product defects and incidents to IDNS in accordance with the general provisions of the State's regulations and the terms of their license. Three of the four staff members conducting SS&D evaluations have attended the last NRC sponsored SS&D workshop. The consensus among the staff and the managers is that further training in this area is needed. It was recommended that two levels of training be considered. First, a basic course to explain the system and its features for new staff as system users. A second course would cover more complex casework for devices such as high dose rate afterloaders and the gammaknife.

19. Licensing Procedures (Category II)

NRC Guidelines

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should have program specific licensing guides, plans and procedures for license review and policy memoranda which relate to specific aspects of waste disposal. The program should include the preparation of safety evaluation reports, product certifications, or similar documentation of license review and approval process. 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.

Assessment

The license files are complete and are maintained in an orderly manner allowing for easy retrieval of information. Each file contains adequate licensing and compliance information and adequately supports the most recent licensing action.

Licensing manuals and checklists have been developed for the major classes of licensees, including medical, industrial and gauging systems. IDNS standard license conditions have been revised to reflect amendments to their regulations. This change has allowed IDNS to issue licenses with fewer standard license conditions while focusing on the more explicit regulations to highlight specific safety requirements. License templates are contained on the IDNS computer network. Each reviewer has a 386 PC which is used to generate a completely new document each time a license is amended. All changes are reflected in bold lettering on the new document. Licensing actions are tracked by IDNS managers via a "Blue Sheet" which is attached to each application. These blue sheets are prepared by an administrative assistant who also enters critical application data onto the IDNS computer network. The review of selected license files indicates that the blue sheets are effective for tracking the progress of individual licensing actions for fees, technical evaluations, telephone calls, deficiency letters, responses, acknowledgement letters, mailing dates and supervisory reviews. Each licensing action receives a supervisory review and is signed by a program manager. This same blue sheet information is used to generate periodic internal reports via the IDNS computer network. These reports are used to identify licensing actions by type, program code, date, licensee name and reviewer name.

Licensing procedures require that the reviewers consider the licensee's compliance history before authorizing new users or uses. This practice was confirmed during the review of selected license files. Applicants are provided copies of guides for the preparation of applications for the specific category of license for which they are applying. IDNS provides copies of licenses and other licensing related information, such as the IDNS Newsletter,

to NRC as part of the Exchange-of-Information commitment in their Section 274 Agreement.

20. 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 including for initial inspections should be no less than the NRC system.

Assessment

The review team compared the inspection frequencies utilized by the State and those utilized by NRC. The State uses inspection frequencies which are as or more frequent than NRC's. For instance, the State's inspection frequency for well loggers is 2 years, compared to NRC's three-year frequency; and IDNS inspects Research and Development - Type A Broad licensees each year, compared to NRC's two-year frequency. The only class of licensees that the State does not inspect as frequently as NRC is Storage Only licensees, a category of licensee that NRC just recently created. IDNS was unaware of the new storage category in Manual Chapter 2800 and agreed to review their inspection frequencies.

21. 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. For the inspection of complex licensed activities such as permanent low-level radioactive waste disposal facilities, a multidisciplinary team approach is desirable to assure a complete compliance assessment. 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.

Assessment

All State materials inspectors were accompanied by their supervisor or IDNS management at least once during 1993, and some inspectors were accompanied two or three times during the year. The I&E section head indicated that all inspectors will be accompanied by a supervisor or manager during the remainder of 1994. The IDNS goal is annual management accompaniment of inspectors, either by the I&E section head, the inspection supervisor in the Glen Ellyn office or by upper level managers within IDNS. The I&E section head plans to meet this goal, in part, during his upcoming trips to Glen Ellyn to reduce the inspection backlog.

No inspectors were accompanied as part of this review. However, the Region III Regional State Agreements Officer (RSAO) accompanied all five of the materials inspectors during June and July 1993, during his visit. Information on those accompaniments follows:

radiation injuries. The RCP should use other technical consultants for special problems when needed.

Assessment

This assessment is based on the State's answers to the questionnaire; review of the "Investigations and Special Surveys" section of the State's operation procedures which describes actions the State takes for response to incidents, allegations, or other inquiries affecting radioactive materials; review of casework of 18 incident and allegation files; and discussions with management and staff.

According to the answers provided on the questionnaire, 91 reports of materials incidents or allegations were received during the review period. Of these, 58 on-site investigations were conducted by the State. The 1993 Annual Event Summary was sent to the NRC Office of State Programs on June 14, 1994.

The State's investigations of event circumstances were thorough, addressed safety issues, and were well documented.

In most cases, the State's response actions to incidents and alleged incidents were timely. These included both 10 CFR 20.403 (10 CFR 20.2202 in the revision to 10 CFR Part 20 published May 21, 1991) type reportable events, incidents requiring immediate action, and less significant events followed-up during the next scheduled inspection.

Enforcement actions were primarily limited to notices of violations for reporting requirements and appeared adequate. Although therapeutic misadministrations were identified during the review period, the State has not adopted the Quality Management rule to permit citations against medical treatment plans. There was one case of equipment failure or defects which could affect other licensed operations. Testing is presently being conducted by an NRC contractor on the source to determine if there are any inherent defects in the design. The testing has not yet been completed. In at least three reviewed cases of overexposures and misadministrations, advice was obtained from a State authorized medical consultant and was beneficial to the State's investigations on hospital use of radioactive materials. IDNS submitted two Abnormal Occurrence Reports to NRC during this review period.

One concern was identified and is addressed under "Inspection Reports" in Enclosure 2. During the next inspection following an event, two inspection reports did not indicate the licensee met commitments for corrective actions or implemented program changes resulting from the event, or whether the inspector followed-up on licensee commitments.

The State's incident response procedures and actions are adequate to meet the guidelines.