

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

Dear Mr. Ortziger:

This refers to the discussion B.J. Holt held with you and Gordon Appel on January 21, 1992 following the review of the Illinois radiation control program for agreement materials.

Our staff has determined, as a result of the review and the routine exchange of information between our respective agencies, that the Illinois program for regulating agreement materials is adequate to protect the public health and safety and is compatible with the regulatory program of the NRC. The finding of compatibility is contingent on the Commission's evaluation of certain of your 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 NRC will be addressing these concerns at a later date.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs.

Enclosure 2 is a summary of our assessment and comments regarding your program. The comments and recommendations should be reviewed carefully by your staff. We request a response addressing each recommendation.

Your staff is to be commended on their initial review of the license application submitted by Chem-Nuclear Systems, Inc. for a low-level radioactive waste disposal facility. The review was found to be extensive and thorough and reflective of a professional and competent licensing staff. The current level of staffing resources and expertise should not be reduced during the licensing process. Any reduction in the licensing staff may negatively impact the quality and performance of the license application review efforts. Also, if not currently being addressed, consideration will need to be given to identifying the staffing and contractual resources required as the project moves forward from the design phase into actual construction and operation.

Your staff is also to be commended on other aspects of your Agreement State Program. The Office of Radiation Safety's Incident Review Committee is meeting regularly and has tackled some tough issues since its inception in mid 1991. The establishment and composition of this committee is a clear indication of management's concern for adequate review and follow-up of incidents involving radioactive materials. The secretarial/typing staff for the radioactive materials program provides a total quality service. Overall, your management and technical staffs both in Springfield and in your regional office appear to be highly motivated, well trained professionals.

Thomas W. Ortciger

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I appreciate the courtesy and cooperation extended to the NRC staff during the review and am looking forward to your staff's responses to Enclosure 2.

A copy of this letter and the enclosures are provided for placement in the State Public Document Room or otherwise to be made available for public information.

Sincerely,

Carlton Kammerer, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
Paul Eastvold, Manager
Office of Radiation Safety, IDNS
J. M. Taylor, Executive Director for
Operations, NRC
A. Bert Davis, Regional Administrator,
Region III
Roland Lickus, Chief,
State and Government Affairs, RIII
NRC Public Document Room
State Public Document Room

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cc w/encls:
The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque

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Application of "Guidelines for NRC Review
of Agreement State Radiation Control Programs"

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

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

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

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

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE ILLINOIS RADIATION CONTROL PROGRAM
FOR THE PERIOD
FEBRUARY 10, 1990 TO JANUARY 21, 1992

Scope of Review

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

The third regulatory program review meeting with Illinois representatives was held during the periods December 9-13, 1991 and January 13-17, 1992 in Springfield, Illinois. Discussions with and field accompaniments of the State's regional inspection staff were conducted during the months of November and December 1991 and January 1992. The review utilized a team approach which provided for a more in-depth examination of the Illinois program. The State was represented by Thomas W. Ortciger, Director, Illinois Department of Nuclear Safety (IDNS) and his management staff: Gordon Appel, Deputy Director; Paul Eastvold, Manager, Office of Radiation Safety; Richard Allen, Assistant Manager, Office of Environmental Safety; Steve Collins, Chief, Division of Radioactive Materials; Joe Klinger, Head, Licensing Section; Bruce Sanza, Head, Inspection and Enforcement Section; and Betsy Salus, Senior Staff Attorney. The NRC was represented by B.J. Holt, Region III State Agreements Officer. Assistance during the review was provided by NRC staff as follows: A review of the State's activities associated with licensing a low-level radioactive waste disposal facility was conducted by Joseph Kane, Mary Adams and Kristin Westbrook, all staff members of the Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety & Safeguards (NMSS). Reviews of sealed source and device evaluations were conducted by Thomas Rich and John Lubinski, staff members of the Source Containment and Devices Branch, NMSS. A review of the State's administrative procedures and general overall assistance during the program review were provided by Rita Hoskins, a staff member of the Office of Research on rotation in the Office of State Programs. A summary meeting regarding the results of the review was held with Thomas Ortciger and Gordon Appel on January 21, 1992.

ENCLOSURE 2

Conclusion

The Illinois program for control of agreement materials is adequate to protect the public health and safety and compatible with the regulatory program of the NRC. This finding of compatibility is contingent on the following: (1) the NRC's evaluation of your regulation regarding a 1 millirem per year dose limit at the boundary of a low-level radioactive waste disposal facility and (2) the NRC's evaluation of certain variances in the State's rules on financial assurance for decommissioning and (3) medical misadministration variances.

Status of Program Related to Previous NRC Findings

The results of the previous review were reported to the State in a letter to Thomas Ortziger dated June 27, 1990. All comments made at that time have been satisfactorily resolved by the State.

Current Review Comments and Recommendations

All 29 program indicators were reviewed and the State fully satisfies 26 of these indicators. Specific comments and recommendations for the remaining three indicators are listed below. Also included below is information provided to the staff for consideration during the on-going review of the license for a low-level radioactive waste disposal facility (Indicators 2 and 3).

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

Comment

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. The major differences are as follows:

Decommissioning Rule

The State uses the term reclaiming instead of decommissioning. Reclaiming means returning property to a condition or state such that the property no longer presents a public health or safety hazard or threat to the environment.

The State's rule exempts all educational institutions, nuclear pharmacies and medical institutions. State, local and other governmental agencies are exempt from the requirements unless they are major processors or waste handling licensees.

There are no provisions in the rule for recordkeeping requirements.

Misadministration Rule

The State uses the term "reportable event" instead of misadministration. The definitions are the same.

The "wrong route of administration" is a criteria for a reportable event involving a radiopharmaceutical dosage greater than 30 microcuries of I-125 or I-131.

The State's rule speaks to "ascertaining and confirming" that a reportable event has occurred. The NRC uses the term "discovery" of a misadministration.

Licensees are required to notify the patient of the reportable event within 15 days after the licensee ascertains and confirms that a reportable event has occurred.

Recommendation

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

2. Technical Quality of Licensing Actions (Category I Indicator)

Comment

The efforts extended by the State and its consultants during the initial review of the application for the low-level radioactive waste disposal facility have been extensive and thorough. Over 1200 review interrogatories and comments have been provided by the State to the applicant. The comments appear to comprehensively address review items that need to be resolved. The Program review identified some items which were discussed with the licensing staff and should be considered by the State during the on-going review of the license application.

Recommendation

We recommend that the following items be considered as discussed with your staff.

The applicant should submit the omitted Section 3.1.2.1.1 in Volume 4 related to the monitoring of the primary infiltration collection and detection system (ICD) (p.3.3-14).

The applicant should identify the specific construction controls to be required for placement moisture content on soil fill materials.

The applicant should provide legible drawings with clear topographic contours to assist in the assessment of the 100 year flood and probable maximum flood (PMF) levels on the performance of the disposal facility.

The applicant should conduct "state of the art" field permeability tests in a test fill on the low-permeability soils to verify that established design values for hydraulic conductivity can reasonably be attained with the planned construction equipment and procedures.

The applicant should assess the long-term performance of facility drainage structures after closure, particularly with regard to their erosion resistance and the potential undermining of the northernmost disposal modules.

The applicant should assess the performance of the proposed drainage sumps, which because of their indicated depths and in recognition of the high water table elevation, may require long term active maintenance. This would be in conflict with current State regulations.

The applicant should develop a clear plan with sufficient drawings and sectional views of proposed borrow fill excavation operations to ensure that soil materials with the required engineering properties are available and deliverable under expected construction operations.

The licensing staff should reassess certain information requests from the consultants to verify the reasonableness and importance of their comments in reaching regulatory conclusions on facility licensing and safety issues.

Each consultant should cite the appropriate regulatory sections that provide the basis for the information requested from the applicant in a format similar to that used by Envirodyne.

3. Licensing Procedures
(Category II Indicator)

Comment

The State has developed a "Low-Level Waste Licensing Review Manual." The manual is currently in draft form and contains the acceptance rationale and procedures to be used by the licensing staff in determining the acceptability of the license application and in supporting the decision to issue or not issue a license. A major portion of the manual is similar to the NRC's Standard Review Plans in NUREG-1200, but it differs in format with emphasis on demonstrating compliance with individual State regulations.

Recommendation

Because of the significance of the "Low-Level Licensing Review Manual" in support of the ultimate licensing decision, we encourage the State to finalize the development of this document.

Comment

The State has developed a draft conceptual plan on construction oversight. The draft describes the objectives of the construction oversight and touches on needed staffing and inspection resources along with identification of major construction activities to be inspected. The licensing staff is to be commended for its foresight in the initial planning and addressing of this licensing activity.

Recommendation

We recommend that the draft conceptual plan be expanded and developed into complete inspection procedures that will help ensure that the Low-Level Radioactive Waste Disposal Facility is constructed as designed and approved.

4. Adequacy of Product Evaluations
(Category I Indicator)

Comment

Fourteen Sealed Source and Device 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.

Recommendation

The following recommendations are provided for your consideration:

Separate and re-evaluate the registration (Certificate No. 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.

Prototype testing should be performed on all sources and devices. If a manufacturer states that the device has as 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.

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, pressure, and 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.

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.

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

5. Enforcement Procedures
(Category I Indicator)

Comment

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 threats 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

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

Comment

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

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.

Summary Discussion with State Representatives

A summary meeting to present the results of the regulatory program review was held with Messrs. Ortziger and Appel on January 21, 1992 in the NRC Region III Office. The meeting was also attended by Carl Paperiello, Deputy Regional Administrator, Region III, and by Roland Lickus, Chief of State and Government Affairs, Region III.

The State was commended on the efforts of its managerial, technical and administrative staffs in administering the Agreement State Program. The scope and findings of the review were discussed.

Mr. Ortziger requested a timely issuance of the report of the program review.