INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF TEXAS AGREEMENT STATE PROGRAM

JUNE 16 - 27, 1997

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Texas radiation control program. The review was conducted during the period June 16-27, 1997 by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 11, 1994 to June 27, 1997 were discussed with Texas management on June 27, 1997.

The Texas Agreement State program is administered from two State agencies, the Texas Department of Health (TDH), and the Texas Natural Resource Conservation Commission (TNRCC). Organization charts for both agencies are included as Appendix B.

The TDH, Bureau of Radiation Control (BRC) regulates approximately 1,540 materials licenses, and received regulatory authority for the 11e(2) uranium recovery program as of July 21, 1997. In addition to the radioactive materials program, TDH administers a laboratory program for environmental sciences under the Bureau of Laboratories.

The TNRCC regulates low-level radioactive waste burial sites, and the decommissioning of former burial sites. TNRCC also regulated the uranium recovery program during the period of September 1993 to the time of the review. Authority for the uranium recovery program transferred to TDH on July 21, 1997.

The review focused on the regulatory program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Texas.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to both agencies on April 18, 1997. Each agency provided a response to the questionnaire on May 22, 1997. A copy of each response is included in Appendix C to this report.

The review team's general approach for conduct of this review consisted of:
(1) examination of the responses to the questionnaire, (2) review of applicable Texas statutes and regulations, (3) analysis of quantitative information from the TDH and TNRCC licensing and inspection data bases, (4) technical review of selected licensing actions and inspections in each agency, (5) field accompaniments of nine materials inspectors, (6) a site visit of an uranium production facility, (7) the review of the low-level radioactive waste program, and (8) interviews with staff and management in both agencies to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and non-common indicator and made a preliminary assessment of the State’s performance.

A draft of this report was issued to Texas for factual comment on July 25, 1997. The State of Texas responded in letters dated August 26, 1997 and August 29, 1997 (Attachment 1). The State's factual comments were considered by the team and accommodated in the report, except

for the requests to reconsider the findings for the two non-common indicators Sealed Source and Device Evaluation Program and Low-Level Radioactive Waste Disposal Program. The MRB met on September 22, 1997 to consider the proposed final report. Based on the need to conduct two independent reviews for each sealed source and device evaluation and the performance of the State in an isolated case, the review team recommended that Texas' performance with respect to the non-common performance indicator, Sealed Source and Device Evaluation Program, be found satisfactory with recommendations for improvement. The MRB considered Texas response to the isolated case and the scope of the technical quality audits performed by the State and revised the team's recommendation to satisfactory for this indicator. For the Low-Level Radioactive Waste Disposal Program, the MRB supported the review team's recommendation that Texas' performance be found satisfactory with recommendations for improvement. The MRB did direct the team to revise the final IMPEP report to reflect that the team's review is not intended as a review of applicant's assessment or acceptability of the proposed site. The MRB found the Texas radiation control program was adequate to protect public health and safety and compatible with NRC's program.

Due to significant revisions to Section 4.3, Low-Level Radioactive Waste Disposal Program, a proposed final version of this section was issued to State for factual comment on November 5, 1997. The State of Texas responded in letters dated November 14, 1997 and December 18, 1997 (Attachment 2). TNRCC’s factual comments were considered by the team and a number, but not all, of the changes suggested were adopted into the final report.

Section 2 below discusses the State's actions in response to recommendations made following the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common indicators, and Section 5 summarizes the review team's findings, recommendations and suggestions. Suggestions made by the review team are comments that the review team believes could enhance the States program. The State is requested to consider suggestions, but no response will be requested. Recommendations relate directly to program performance by the State. A response will be requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on March 11, 1994, and the final combined results of the review were transmitted to both the Commissioner, TDH, and the Executive Director, TNRCC on December 28, 1994.

2.1 Status of Items Identified to TDH During the 1994 Routine Review

The 1994 review findings resulted in recommendations to TDH in three program indicators: (1) Status and Compatibility of Regulations; (2) Adequacy of Product Evaluations; and (3) Responses to Incidents and Alleged Incidents. TDH responded by letter dated February 9, 1995 and provided the Department’s response and comments to the recommendations. On April 10, 1995, the Office of State Programs (OSP), notified the TDH that their responses would be evaluated during the next review. The status of these recommendations are as follows:

(1) Status and Compatibility of Regulations. The regulation for "Notification of Incidents" was identified as being overdue for adoption, and NRC recommended that Texas regulations equivalent to 10 CFR Parts 31.3 and 31.5 be revised.

Current Status: TDH has adopted the equivalent regulations compatible to the "Notification of Incidents," 10 CFR 31.3 and 31.5. This recommendation is closed.

(2) Adequacy of product evaluations. NRC suggested that the State review a list of recommendations provided as an enclosure to the 1994 report.

Current Status: The State's corrective actions were evaluated during the IMPEP review. The State has developed template registration certificates and a safety evaluation checklist to assist the reviewers in including the items listed in the recommendation both in the evaluation and in the registration certificate. This recommendation is closed.

(3) Responses to Incidents and Alleged Incidents.

(a) The inspection manual refers to a 24-hour, 72-hour, and 10-day inspection requirements in response to incidents. Inspection criteria for the 24-hour and 10-day inspections are documented in the manual, but no criteria for 72-hour inspections are provided.

Current Status: The inspection manual procedure referred to is entitled "Incident and Complaint Investigation" and was effective September 7, 1988. The recommendation incorrectly states that the procedure requires 72-hour inspections. Under section B, "Complaints," of the procedure, there is a requirement to "initiate a response to each complaint within 72-hours of the time the complaint is received." A 72-hour inspection is not required and therefore criteria for such an inspection are not needed. As an added note, the above procedure was revised on May 14, 1997. The revisions retained the requirements for on-site investigations for significant incidents with the deletion of the 24-hour and 10-day time frames, and retained the 72-hour response to complaints. This recommendation is closed.

(b) One incident file revealed the following concern - a therapeutic misadministration of 675 to 750 rem to a patient's abdomen due to a dislodged source was not followed up by the TDH. The State should specifically follow up on this incident including a determination whether this incident was an abnormal occurrence.

Current Status: Follow up had been initiated prior to the March 1994 review but had not been completed. Since the 1994 review, an Abnormal Occurrence Report has been submitted to the NRC. This recommendation is closed.

(c) The Inspection Manual does not address misadministration.

Current Status: The inspection manual procedure referred to is entitled "Incident and Complaint Investigation" and was effective September 7, 1988. The May 14, 1997 revision to the procedure adds the requirement for on-site investigations when "information in an incident report causes Bureau concern for the health/safety of the public or medical patient." Discussions with the Technical Assistance Project Manager

on the misadministration issue verified that Texas conducts on-site investigations for all misadministrations. This recommendation is closed.

2.2 Status of Items Identified to TNRCC During the 1994 Routine Review

The December 28, 1994 review findings had recommendations for the TNRCC in seven program indicators: (1) Legal Authority; (2) Status and Compatibility of Regulations; (3) Administrative Procedures; (4) Staffing Level; (5) Technical Quality of Licensing Actions; (6) Inspection Procedures; and (7) Enforcement Procedures. The TNRCC responded by letter dated January 30, 1995. OSP notified the TNRCC by letter dated March 20, 1995, that the progress on each recommendation by TNRCC would be evaluated during the next review. On March 14, 1995, TNRCC notified NRC of additional progress made with respect to the 1994 recommendations. The current status of these recommendations is as follows:

(1) Legal Authority

(a) A recommendation was made for the State to take legislative action to revise the definition of low-level waste and the limitations on the disposal of transuranic concentrations greater than 10 nanocuries per gram.

Current Status: Legislation was introduced in the 1995 and 1997 legislative session; however, the legislation did not pass. Detailed discussion can be found under the non-common performance indicator, Legislation and Regulations, Section 4.1. This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(b) A recommendation was made for the State to revise the statutory definition of byproduct material to be compatible with 10 CFR Part 40.

Current Status: Legislation introduced into the 1997 legislative session was adopted and the statutory definition of byproduct material was made compatible with 10 CFR Part 40. This recommendation is closed.

(2) Status and Compatibility of Regulations. One regulation concerning self-insurance (Criterion 9) of 10 CFR Part 40, Appendix A needed to be adopted for the uranium program.

Current Status: This regulation was adopted by TNRCC in a rule package effective June 6, 1997. This recommendation is closed.

(3) Administrative Procedures

(a) A recommendation that the license renewal process be utilized to update both the reclamation/restoration plans and the associated cost estimates.

Current Status: TNRCC updated, and implemented a detailed written procedure for establishing financial assurance. This recommendation is closed.

(b) A recommendation was made for better documentation between the Texas Low-Level Radioactive Waste Disposal Authority (TLLRWDA) and the TNRCC.

Current Status: Standard documentation was developed and implemented for documentation between the TLLRWDA and the TNRCC. This recommendation is closed.

(4) Staffing Level. A recommendation was made for two additional technical staff members to help with the uranium recovery licensing backlog.

Current Status: TNRCC added four new technical staff and one new administrative staff positions, and established a two year time frame to overcome the licensing backlog. Considerable progress was made in reducing the backlog during the period. The licensing actions are being tracked and completed in accordance with the administrative procedure. Since the uranium program is being transferred to TDH, and given the progress made since the last review, this recommendation is closed.

(5) Technical Quality of Licensing Actions. A recommendation was made for the staff to identify the regulatory bases for requests to TLLRWDA for information and clarification by citing criteria and standards in the regulations.

Current Status: TNRCC implemented the citing of rules in their deficiency letters and correspondence. This recommendation is closed.

(6) Inspection Procedures. A recommendation was made for the TNRCC to update the Inspection Manual.

Current Status: TNRCC developed and revised the inspection procedures. This recommendation is closed.

(7) Enforcement Procedures. A recommendation was made to revise the handling of enforcement actions to assure a more expeditious transmittal of enforcement letters to licensees.

Current Status: A procedure for tracking enforcement actions and reports was implemented and the reports and associated enforcement actions are being transmitted in accordance with the administrative procedures. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Staffing and Training; (3) Technical Quality of Licensing Actions; (4) Technical Quality of Inspections; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The BRC's program for this common performance indicator is discussed in this section. Information for TNRCC in this area for the non-common performance indicators, low-level radioactive waste disposal program and uranium recovery program, is discussed in Sections 4.3.1 and 4.4.1.

The team focused on four factors in reviewing this indicator: inspection frequency; overdue inspections; initial inspection of new licenses; and timely dispatch of inspection findings to

licensees. This evaluation is based on Texas' questionnaire responses to this indicator, data gathered independently from the State's inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

BRC uses several data bases to manage the State's radiation control program. BRC uses the data to schedule those inspections that will become due in the next quarter. This inspection due list is forwarded to the regional offices for action. Regional managers also have access to similar information from a network server. Several checks and balances are in place to assure that inspections occur within three months of the planned date.

BRC conducts unannounced inspections, however, the BRC's general practice is to give short notice to medical facilities and certain other licensees before the inspection. BRC reported that this practice has been found to provide less disruption in patient care and effectively uses the inspector's time. BRC believes that announced inspections permit better use of inspection resources and that is a factor in maintaining a low number of overdue inspections in the program. The team did not identify from the casework or accompaniments, any difference in the quality of inspections or the number of findings because of this practice.

The team's review of the BRC's inspection priorities verified that the BRC's inspection frequencies for various types or groups of licenses are at least as frequent as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter (IMC) 2800. BRC requires more frequent inspections in some license categories as follows: waste processors were verified to be inspected on a six month frequency compared to the NRC one year frequency; processors of loose material are inspected every six months compared to NRC one year frequency for Type A broad manufacturers; rare-earth extraction and processing licensees are inspected every six month compared to NRC three year frequency; a specific licensee's low-level waste burial sites are inspected every six months compared to NRC one year frequency for commercial disposal; and industrial calibration and reference sources are inspected every four years where NRC does not have an unique category for this group of licensees.

In the questionnaire, BRC reported as of April 30, 1997, only six core inspections were overdue by more than 25 percent of the State's established inspection frequency. These licensees were overdue from 12 to 31 months beyond the 25 percent of the BRC's established frequency. These licensees are located in two western regions that did not have inspectors assigned at the time of the review. Inspectors from other regions are conducting inspections in these regions, workload permitting. Although BRC is hiring new inspectors to fill the existing vacancies, they expect to continue shifting inspectors to maintain inspection schedules in the western regions. The number of overdue core inspections is below the 10% evaluation criteria for satisfactory performance for this indicator.

BRC indicated that approximately 291 new licenses had been issued during the review period. The BRC's questionnaire response reported that 11 inspections of new licensees were overdue according to NRC's inspection frequency for new licensees. On review of these 11 licensees with BRC, the review team noted that the number of overdue new inspections reported in the questionnaire was incorrect. Only three inspections of new licensees are overdue. These licensees were overdue from 10 to 15 months beyond the NRC frequency for new licensees. Considerable inspection effort is dedicated to new license inspections. The team considered the overdues and noted that the three licenses overdue at the time of the review is acceptable when compared with the total number of new licenses issued.

The State reported in their response to the questionnaire that 115 licensees had submitted 1,919 requests for reciprocity during the review period, of which 80 were from licensees with inspection intervals of three years or less. The State reported that 74 reciprocity licenses were inspected, which exceeds the IMC 1220 guidance for conducting reciprocity inspections. In addition, the State conducted 122 additional non-reciprocity inspections of industrial radiography field sites.

The team evaluated the timeliness of inspection results issued to licensees. The team reviewed the results of 12 inspections. The typical procedure for issuing inspection results is as follows: (1) the inspector prepares field notes to transmit the inspection results to the Austin office; (2) a transmittal letter containing the inspection findings is prepared in the Austin office; (3) senior staff review the letter and inspection report, and (4) BRC transmits the letter to the licensee after management review. Generally, the inspection results are forwarded to the licensee within 30 days. Reviewers found that inspection files in Austin were generally well maintained with pertinent background information on the inspections available in the file. All files clearly showed that management had reviewed the inspection report and concurred with the inspector's findings.

BRC uses three interrelated data bases to help in the management of licensing, inspections and reciprocity activities. BRC can extract data on a State-wide and regional basis. Additionally, they can retrieve data on individual licensees, program codes or an individual inspector's activities. BRC quickly extracted information from the databases in response to questions posed by the team.

Based on the IMPEP evaluation criteria, the review team recommends that Texas' performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.2 Technical Staffing and Training

Except as noted in the discussion, the BRC's program for this common performance indicator is discussed in this section. Information for TNRCC in this area for the non-common performance indicators, low-level radioactive waste disposal program and uranium recovery program, is discussed in Sections 4.3.2 and 4.4.2.

Issues central to the evaluation of this indicator include the radioactive materials program staffing level, technical qualifications of the staff, training, and staff turnover. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed selected BRC and TNRCC managers and staff, and considered any possible workload backlogs in both agencies.

The BRC organization chart shows that the Bureau has a total of 138 positions. BRC has an Administrative Office with 24 positions, the Division of Licensing, Registration and Standards with 38 positions, the Division of Compliance and Inspection with 38 positions, and the Regional Health Department Offices (10) have a total of 38 positions for materials and x-ray inspections. The BRC organization was revised in January 1996 to reflect a flat matrix type of organization for the technical divisions which utilize the concept of Project Managers, and these Project Managers coordinate their work through the Deputy Directors on a daily basis. Only two recent vacancies were reported in the materials area, one had been filled by the time of the review, and interviews were ongoing for the other position during the review. These resources were determined to be properly balanced between licensing, inspection, and incident response, and the vacancy at the time of review had not adversely impacted the performance of the program as discussed under Section 3.1. Three individuals within the Division of Licensing also perform the

reviews of sealed sources and devices (SS&D). A discussion of SS&D personnel training is covered in Section 4.2.2.

The BRC has established qualifications for the Environmental Quality Specialist positions which includes the health physicists. Applicants are required to have a baccalaureate degree in a physical or (appropriate) life science. They are usually assigned basic responsibilities in the program until sufficient training and experience are obtained. They receive training in health physics, nuclear medicine uses, materials licensing, inspection procedures for radioactive materials or radiation producing devices, industrial radiography, well logging, emergency response, environmental monitoring, and transportation. Increased training warrants their assignment to more complex responsibilities.

BRC trains individuals on a case-by-case basis factoring in the individual's basic experience and program needs and uses a data base for planning, scheduling and monitoring individual training. Personnel in the Licensing Division are assigned increasingly complex licensing case work under the direction of senior staff. License reviewers also accompany experienced inspectors during compliance inspections of complex licenses to gain field experience and during pre-license inspections.

The inspection staff receives the same basic training as the licensing staff. Inspectors are required to demonstrate competence during accompaniments by the supervisor prior to being given permission to perform inspections independently. The BRC's inspector accompaniment process and the team's findings are discussed in Section 3.4. The review team determined that all staff utilized for the BRC's program were technically qualified by evidence of their training and experience.

Some licensing backlogs have been experienced in the BRC's Licensing Section. BRC management related that this issue had been discussed internally, and that BRC was looking for ways in which to streamline the licensing process and be more efficient. TNRCC also has some licensing and inspection backlogs in the uranium program which will be transferred to BRC effective July 21, 1997. BRC managers have already begun discussions internally and with the managers of TNRCC uranium program to assess the staffing and other resources needs to carry out the combined materials and uranium programs. Five FTEs will be transferred from TNRCC to BRC for maintenance of the uranium program, and TDH has agreed to add another three FTEs for the program.

The State continues to be committed to continued training as needed to allow the staff to carry out the duties and functions of the radiation control program. Training at NRC sponsored courses was provided by NRC during the previous years, and the State attempted to have monies appropriated for their training needs by the recent State Legislature that meets every two years. However, the legislation did not pass, and the State is continuing to look for training options that will allow for continued training, and for training at NRC sponsored courses.

Additional discussion of the TNRCC staffing and training for the low-level waste program and the current uranium program will be discussed under the respective non-common indicators.

Based on the IMPEP evaluation criteria, the review team recommends that Texas' performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.3 Technical Quality of Licensing Actions

The BRC's program for this common performance indicator is discussed in this section. Information for TNRCC in this area for the non-common performance indicators, low-level radioactive waste disposal program and uranium recovery program, is discussed in Sections 4.3.3 and 4.4.3.

The review team examined completed licenses and casework for 29 license actions in 21 specific license files, representing the work of five license reviewers and three licensing assistants. The license reviewers and supervisors were interviewed when needed to supply additional information regarding licensing decisions or file contents.

Licensing actions were reviewed for completeness; consistency; proper radioisotopes and quantities authorized; qualifications of authorized users; adequate facilities and equipment; and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy; appropriateness of the license and of its conditions and tie-down conditions; and overall technical quality. Casework was reviewed for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports; product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits; peer or supervisory review as indicated; and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

The license casework was selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The sampling included 26 of the State's major licenses and included the following types: medical broad scope, industrial radiography (temporary and fixed job sites); mobile nuclear medicine; class B waste processor; pool irradiator; and nuclear pharmacy. Licensing actions evaluated included 6 new, 1 renewal, 18 amendments, and 4 terminations. A list of these licenses with case specific comments can be found in Appendix D.

In general, the review team found that the licensing actions were thorough, complete, consistent, of acceptable or higher quality, and with health and safety issues properly addressed. Three of the four specific exemptions and one denial for an exemption, identified by the State in the responses to the questionnaire, were evaluated for this review period. All of them had valid justifications for acceptance or denial of the exemptions. Three of the exemptions were granted by amendment and the denial was finalized by letter. The licensee's compliance history appeared to be taken into account when reviewing renewal applications as determined from documentation in the license files and/or discussions with the license reviewers.

The review team found that terminated licensing actions were well documented, showing appropriate transfer records and survey records. The compliance branch conducts confirmatory surveys as needed prior to the termination being issued. Once an interoffice memorandum documenting the property for unrestricted use is received, the termination is issued. Sometimes there are periods of a year or more from when a termination request is received before a license is terminated.

Previously, BRC licenses were renewed by letter every five years and the licenses were renewed in their entirety every ten years. In an effort to utilize their technical staff more efficiently, and to

reduce the number of renewals, the renewal policy was revised in July 1996. The current policy is to renew all major licenses (in their entirety) on a seven year frequency, and all other licenses are renewed on a ten year frequency.

BRC has had a large backlog of renewal and amendment requests until last year. Each medical and industrial license reviewer has an average backlog of 54 licensing actions. BRC has placed more emphasis on the completion of the actions and over the past two years has dropped the backlog by over half. The actions are handled by the following priorities: (1) new, (2) terminations, (3) amendments, and (4) renewals. These priorities seem to be working; however, the review team suggests that amendments and renewals also be prioritized so that amendments which impact health and safety (i.e., new RSO because the previous one left the company; major proposed procedure changes which could effect radiation safety issues) are completed ahead of the amendments and renewals which are more routine (i.e., adding a source, or another user when ten sources or users are already on the license; renewal by letter).

The licenses issued by the Medical and the Industrial Sections receive another concurrence review and are signed by the respective Project Manager in each Section. The Project Managers can sign their own licenses, but the action does not require additional review except for the waste processor type licenses, which are reviewed and signed by the Division Director. The team did not identify any significant performance problems with this policy.

The review team found that the current staff is well trained and experienced in specialized licensing activities (medical, industrial, special and advanced licensing). The casework was reviewed for adequacy and consistency with the NRC procedures. BRC has official, written administrative procedures for licensing reviews. The team found that BRC follows their licensing guides and administrative procedures during the review process to ensure that licensees submit the information necessary to support the license. The licensing guides were similar to the NRC guides.

Also, under this indicator, the team reviewed the TNRCC program and procedures used for licensing the inactive non-uranium burial sites that were transferred from TDH and the TNRCC program for decommissioning sites. TNRCC reported that four former burial sites had been licensed. Three sites are no longer being used for burial of waste, and are under licenses issued by TNRCC for the possession, storage, control, and environmental monitoring activities. One licensee is an active site; however, TNRCC rules prohibit amendments or renewal of this license to allow any addition or expansion of the disposal facility. TNRCC managers related that these sites will be decommissioned, and that other sites will be identified and decommissioned in accordance with TNRCC procedures and regulations that became effective on June 6, 1997. TNRCC plans are to implement this program in January 1998.

Based on the IMPEP evaluation criteria, the review team recommends that Texas' performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.4 Technical Quality of Inspections

The BRC's program for this common performance indicator is discussed in this section. Information for TNRCC in this area for the non-common performance indicators, low-level radioactive waste disposal program and uranium recovery program, is discussed in Sections 4.3.4 and 4.4.4.

The team reviewed inspection field notes and inspection records for 28 materials inspections conducted during the review period, reviewed revisions to the Texas enforcement policy, and interviewed inspectors. At least two reports prepared by each current regional inspector were evaluated. Inspection casework records selected included higher priority inspections of various facility types including hospitals, nuclear medicine facilities, academic broad scope institutions, research and development facilities, industrial radiography and gauge use, well-logging facilities, nuclear pharmacies, and pool irradiator. Attachment E lists the inspection cases evaluated in depth with case-specific comments. Prior to the review, two team members performed accompaniments of nine region-based inspectors on separate inspections of high priority facilities throughout the State.

Inspection procedures and techniques utilized by BRC compliance staff were reviewed and determined to be generally consistent with the inspection guidance identified in NRC Inspection Manual Chapter 2800. The procedures were used to help inspectors identify root causes and poor licensee performance. Although field inspections were conducted, the revised inspection procedures do not direct temporary job sites to be inspected (per IMC 2800 guidance).

Use of inspection forms (field notes) is determined by regional inspectors. Different revisions (some outdated) of the State's primary inspection report form were noted to be used in regional offices. Forms were reviewed and found to be inclusive documents providing general inspection areas consistent with the types of information and data collected under IMC 2800 and 87100 documents. Except for an industrial radiography form, the State does not use separate supplements to the inspection report form for various license types. During inspection preparation, the form is supplemented by the inspector with information specific to the type of inspection to be performed. Copies of revised inspection field notes contained in IMC 87100 appendices covering the areas of industrial/research development, well logging, industrial radiography, commercial irradiator, medical broad-scope, well logging, and radiopharmacy were provided by the team to inspectors and Regional Health Physics Coordinators (RHPC) for use during inspections. To assist inspector preparation for inspections at different types of facilities, the review team suggests the State consider standardizing their primary and supplementary field note forms. These could be modeled after the NRC forms as discussed with BRC.

The review team found the level of detail provided in inspection reports was consistent with respect to scope of licensed program, licensee organization, management structure, radiation protection program, personnel protection, area posting and labeling, worker training, radioactive material control, and material transfer and disposal. For quality assurance of reports the State has three designated RHPCs in the central office who are assigned for senior technical review, comment, and issuance of final inspection reports and related enforcement actions identified by regional inspectors.

Field notes, inspection forms, and enforcement correspondence were found to be generally complete. Reports were evaluated for inspector documentation of operations observed, management and worker interviews, independent measurements, follow up to previous items of non-compliance, and discussion of inspection findings at exit interviews. Overall, the review team found inspection reports showed good technical quality. Reports contained a section which identified licensee personnel attending exit meetings but did not document a summary of inspection findings communicated to licensee management by inspectors. The review team suggests documenting in reports summary discussions of inspection findings with management at the conclusion of inspections. As noted in Appendix E, the team found reports contained only minor inconsistencies related to insufficient detail.

Documented inspection findings led to prompt regulatory actions and appropriate enforcement. Review of the revised enforcement policy (May 1997) showed it included consideration for emergency orders, management conferences, enforcement conferences, licensee requested hearings, monetary penalties, and civil and criminal penalties through court proceedings, and source impoundment. Team interviews with enforcement staff and review of cases involving escalated enforcement actions determined the State's enforcement policies were effective in achieving licensee compliance. Enforcement correspondence was timely for files reviewed by the team. Licensee responses to notices of violations were also timely and reviewed by central office RHPCs (technical reviewers) to ensure noncompliance issues were addressed. Information provided to the review team indicated several types of enforcement actions taken during the review period including civil actions referred to the State Attorney General, administrative (monetary) penalties, license suspension and revocation, issue of emergency orders, enforcement conferences, and provisions for impoundment of radiation sources. In cases where inspection results indicated a need for escalated enforcement action, enforcement conferences were held with licensees to discuss inspection findings and possible enforcement action against them.

The process for ensuring inspector feedback to licensing staff was not described, however the inspection reports are available to the licensing staff. As a regionalized function, inspection staff do not have the opportunity to provide inspection information affecting licensing directly to license reviewers in the central office. Inspectors discussed inspection findings with the RHPCs, who served as intermediaries between license and compliance staffs for information sharing.

At the time of the review, the State had 13 qualified field inspectors. Nine inspector accompaniments (six regional offices) were performed by two review team members. Two inspectors not accompanied were evaluated as acceptable in the previous NRC review and two inspectors were newly qualified. Inspection accompaniments were conducted during the weeks of April 14, May 20, June 9, and June 23, 1997 at the following types of facilities: nuclear pharmacy, hospital, industrial radiography, portable gauge, and well logging operation. Inspectors were well prepared and performed thorough inspections of licensee radiation safety programs. During the accompaniments inspectors generally showed sound inspection techniques, appropriate knowledge of the regulations, and demonstrated overall satisfactory technical performance. A summary of inspection accompaniments is identified in Appendix E.

BRC's policy calls for annual supervisory accompaniments of all qualified inspectors be performed either by RHPCs or senior inspection staff. In response to the questionnaire, BRC provided a table of supervisory inspection accompaniments performed during the review period. The table shows 12 of 13 inspectors accompanied at least once since 1994. However, from information in the table and interviews with RHPCs, none of the 12 inspectors identified in the table received an annual accompaniment each year for calendar years 1994 through 1997. RHPC reports of accompaniments indicated that inspector performance evaluations were complete and thoroughly documented. Since regularly scheduled supervisory accompaniments provide management with important insight into the quality of the inspection program, the review team recommends that the State adhere to the policy of annual supervisory accompaniments of all qualified inspectors.

The team noted an adequate supply of portable radiation detection instruments for use during routine inspections was calibrated and maintained by central office staff. Each regional inspector is issued a ratemeter with GM (side window and pancake) and gamma scintillation detectors, and a micro-R meter. Regional instrumentation is supplemented as needed with a multichannel

analyzer, alpha scintillation detector, low energy gamma scintillation detector, and low volume air sampler. At the central office inspector counterpart meetings held every six months, regional inspectors exchange assigned survey meters for newly calibrated instrumentation. Sufficient equipment was also available for emergency response activities.

The team toured the State's instrument calibration facility and noted survey instruments are calibrated with a collimated beam calibrator containing a cesium-137 source with activity of approximately 100 mCi. This relatively low activity system limits the calibration of some ion chamber instruments and some GM detectors on the high range (0-2 R/hr and higher). The review team recommends that all radiation detection instruments used for confirmatory surveys (field measurements) be calibrated on all ranges.

A tour of the State laboratory found it to include liquid scintillation spectrometers, gas flow proportional counters, and gamma spectrometers (multichannel analyzer) for full capability to analyze wipe, water, and soil samples for BRC activities. Impounded sources are maintained at the State's downhole storage area located near the State laboratory. From interviews with inspection and laboratory staff, laboratory processing time ranged from immediate to a few weeks and was acceptable for routine samples taken by inspectors.

Based on the IMPEP evaluation criteria, the review team recommends that Texas' performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.5 Response to Incidents and Allegations

The BRC's program for this common performance indicator is discussed in this section. Information for TNRCC in this area for the non-common performance indicators, low-level radioactive waste disposal program and uranium recovery program, is discussed in Sections 4.3.5 and 4.4.5.

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire regarding this indicator, reviewed the incidents reported for Texas in the "Nuclear Material Events Database" (NMED) against those contained in the Texas files, and reviewed the casework and supporting documentation for 12 material incidents and ten allegation files.

It was noted that the State informally defines the terms “incident” and "complaint." NRC does not have a definition for "complaints" but defines "incidents" and "allegations" in Management Directive 5.6.

The 12 incidents selected for review included one misadministration, one overexposure, one lost source, one potentially damaged source, two reported loss of control of radioactive material, and six equipment failures and are listed in Appendix F. Of the ten allegations reviewed, NRC Region IV office referred six to the State and the other four came directly to the State from allegers. In addition, the review team interviewed the Director and Deputy Director, Division of Compliance and Inspection, and the Technical Assistance Project and Complaint Investigation Project leaders.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with the Division of Compliance and Inspection. BRC procedures require on-site investigation for each significant incident and a timely response to allegations. The Technical Assistance

Program Manager discusses each incoming incident or allegation with staff and the response is coordinated with the appropriate field staff. If necessary, field staff and/or BRC staff conduct an on-site inspection. Incidents and allegations that have the potential for: (1) media involvement, (2) violations being issued, or (3) significant impact on public health and safety are brought to Director, Division of Compliance and Inspection attention promptly. All incidents and allegations are reviewed by management on at least a quarterly basis. The State summarized incident information is provided on printed copy to the OSP and to Idaho National Environmental Engineering Lab (INEEL) for entry into the NMED system.

The subject areas discussed with staff included the State's incident and allegation process, tracking system, file documentation, Open Records Act, and notification of incidents to other Federal and State agencies. Notification to the NRC Emergency Operations Center is made by the State for incidents that require immediate or 24-hour reporting by the State licensee. Although this notification requirement is understood by management, it is not specified in writing.

The review team found that with the exception of some equipment failure incidents, the Texas' responses generally were well within the performance criteria. Responses were prompt and well-coordinated, and the level of effort was commensurate with health and safety significance. Inspectors were dispatched for on-site investigations when appropriate. In general, the State took suitable corrective and enforcement actions, notified the NRC, other States, and other agencies as appropriate, and followed the progress of the investigation through until close out. Incident casework reviews were verified as cross-referenced to the corresponding license file. The review team noted that the BRC closed four of the six incidents related to equipment failure without forwarding any information on the potential for a generic design defect to other appropriate agencies. This issue was discussed with the Technical Assistance Program manager and his staff which recognized generic design defect problems needing to be evaluated and forwarded to the agency responsible for the product evaluation and registration certificate. In one additional case, there was no information in the file that indicated the manufacturer of the device was informed by the licensee or the State. (See discussion and suggestion in Section 4.2.3.)

All incidents and allegations are tracked by a numerical identification system. Discussions with the Technical Assistance Program Manager indicated that modifications to NMED were completed in January 1997 by INEEL. These modifications will allow Texas multi-user capability and the ability to utilize the State's current numerical identification system. BRC plans to fully implement the NMED system by the end of 1997. The team discussed the merits of the NMED system with the Technical Assistance Program Manager who added that they also plan to use NMED for Technical Assistance Requests, Complaints, and Close-outs. The review team suggests that the State initiate actions (through implementation of the procedures provided in the March 1995 Handbook on Nuclear Material Event Reporting in the Agreement States) to directly utilize the NMED system.

The review team also found good correlation of the State's response to the questionnaire, the incident information in the files, and the incident information reported on the NMED system printout for Texas. In most cases, the Texas numerical identification number was cross-referenced on the NMED report.

The team noted that two allegations referred to the State by RIV were categorized as "Technical Assistance" by Texas. The other eight allegations (four of which were referred by RIV) were responded to promptly with appropriate investigations, follow-up, and close out actions.

Complaints and technical assistance requests are documented on the same BRC form and are therefore handled in a similar manner. The definition differences do not impact the quality of BRC's handling of allegations. Information about the allegation, including the identity of a alleger, is not protected under the State's Open Record Act once the file is closed. During the initial telephone contact, the alleger is advised that their anonymity can not be guaranteed.

Based on the IMPEP evaluation criteria, the review team recommends that Texas' performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The team reviewed each non-common performance indicator as they apply to the Texas program.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

The legal authority for the BRC is found in the Texas Radiation Control Act, Health and Safety Code, Chapter 401. BRC is designated as the State radiation control agency with authority to regulate byproduct materials, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. TNRCC's legal authority for low-level waste activities is found in Chapter 401 and 402 of the same Act.

The State provided copies of legislation that affects the radiation control program. On June 20, 1997, Texas' Governor signed legislation transferring responsibility for the uranium recovery program from the TNRCC to the BRC. Both agencies are participating in ongoing meetings concerning details of the program's transfer. Based upon discussions with staff, the management, and a review of the State's response to the questionnaire, the review team confirmed that there are no legislative changes that would negatively affect the regulation of agreement materials, the low-level waste program, or the uranium recovery program. Except as noted below, the legislation is considered adequate to enable the State to protect public health and safety.

The team re-identified an open item from the 1994 review. The Texas Low-Level Radioactive Waste Authority Act (TLLRWAA) defines low-level waste as:

> "Low-level waste means any radioactive material that has a half-life of 35 years or less or that has less than 10 nanocuries per gram of transuranics and may include radioactive material not excluded by this subdivision with a half-life of more than 35 years if special criteria are established by the agency for disposal of that waste. The term does not include irradiated reactor fuel and high-level radioactive waste as defined by Title 10, Code of Federal Regulations."

Whereas, the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA) defines low-level waste as:

> "Low-level radioactive waste means radioactive waste that--(A) is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in section 11e(2) of the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)); and (B) the Nuclear Regulatory Commission, consistent with existing law and in accordance with paragraph (A), classifies as low-level waste."

Section 336.701(b)(3) authorization to dispose of transuranic radionuclides states the following:

> (b) A licensee authorized to dispose of radioactive waste under the rules in this subchapter shall not accept for disposal:
>
> (3) waste containing transuranic radionuclides in concentrations of 10 or more nanocuries per gram. This limit of 10 nanocuries per gram of transuranics shall not be equaled or exceeded in waste disposed of at a land disposal facility licensed under the rules in this subchapter, notwithstanding the concentration limits for transuranics specified in §336.362, Appendix E of this title (relating to Classification and Characteristics of Low-Level Radioactive Waste);

The NRC regulations in 10 CFR 61.55, "Waste Classification," limits the disposal of alpha emitting transuranics with a half-life greater than five years to 100 nanocuries per gram.

The team finds that the provisions of the Texas law and regulations cited are not compatible with the provisions of the LLRWPAA and NRC's regulations. This "jurisdictional gap" in the Texas legislation creates a situation where the State has not exercised its full authority to regulate low-level radioactive waste. This situation may create an orphan waste category for waste containing radioactivity greater than 10 nanocuries and less than or equal to 100 nanocuries per gram. The current authority does not prevent this radioactive waste from being disposed of at a site located in another State. TNRCC cannot change the provisions in its regulations without an essential change in the provisions of the TLLRWAA. The team found that the State attempted to change the definition of low-level radioactive waste; however, the House Bill did not pass during the 1995 and 1997 legislative sessions. TNRCC staff indicated that they will attempt to have the bill reintroduced during the next legislative session (in 1999).

In entering into an Section 274b agreement with Texas, NRC has transferred its authority over certain materials and activities to the State. By maintaining this gap in its law, Texas has failed to exert authority over all matters covered by the Agreement. Currently, this gap in legal authority is a problem only in theory because the State has yet to license a low-level radioactive waste disposal facility. However, it is the staff's understanding that TNRCC may license the low-level radioactive waste disposal site as early as 1998. Accordingly, the problems created by the "orphan waste" category may become a problem in fact. At the last program review, NRC withheld a finding of compatibility because the Texas definition was not compatible with NRC's definition. The report concluded that if the provisions are not corrected by the time of the licensing of the low-level waste facility in Texas, NRC will consider finding the Texas program incompatible with that of the NRC.

Consistent with this earlier review, the staff believes that the Texas program should be found not compatible with that of NRC if the gap in Texas law is not corrected by the time the State issues its final licensing decision. In addition, if the problem is not corrected by the time the facility begins to operate, it will be incumbent on NRC to consider appropriate action. Depending on the

circumstances surrounding the disposition of the “orphan waste” at that time, such action may include suspension or termination of part of the Texas agreement pursuant to Section 274j of the Atomic Energy Act. However, the staff emphasizes that such a decision will depend on the facts as they exist at that time.

The staff recognizes that correction to the law will depend on actions by the Texas legislature and not TNRCC. However, the staff notes that it is the State’s responsibility as a whole to maintain compatibility with NRC’s program, not just TNRCC. As such, the review team recommends that TNRCC vigorously pursue the changes necessary to make Texas law (statutes and regulations) compatible with those of NRC in the low-level waste area and, if necessary, raise this issue to higher levels in the State government. NRC will follow the State’s progress in this area at subsequent annual meetings.

4.1.2 Status and Compatibility of Regulations

The Texas Regulations for Control of Radiation (TRCR), found in Chapter 401, apply to all ionizing radiation, whether emitted from radionuclides or devices. BRC requires a license for all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. BRC also requires a registration for all equipment designed to produce x-rays or other ionizing radiations.

The review team examined the procedures used in the State's regulatory process and found that TDH offers the public the opportunity to comment on proposed regulations and participate in public hearings following the comment period. Procedures also require the proposed regulations, proposed hearing date, hearing comments and analysis be well publicized. Draft copies of the proposed regulations are provided to NRC during the rule development process. Final regulations are also placed on the TDH home page and the final regulations are submitted to NRC.

According to State law, when a rule is in the proposal phase of the adoption process, they may not propose additional changes to that rule until they adopt the initial rule. This fact and the time frames in the rulemaking process make it impossible to amend the TRCR with the same frequency that NRC amends its regulations.

The team evaluated TDH’s and TNRCC’s responses to the questionnaire and reviewed all regulations adopted by the State since 1993 to determine the status of the Texas regulations. This review included regulations required by the State to maintain compatibility through December 1997. The team also reviewed several regulations that are in the rulemaking process as a matter of convenience.

The TDH adopted two NRC regulation amendments that became effective since the 1994 review:

> “Notification of Incidents,” 10 CFR Parts 20, 30, 31, 34, 39, 40, 70 amendments (56 FR 64980) which became effective on October 15, 1991. The State’s rules became effective from September 1993 through October 1995. NRC has reviewed these rules and has found them to be compatible with NRC's regulations.
>
> “Licensing and Radiation Safety Requirements for Irradiators,” 10 CFR Part 36 amendment (58 FR 7715) which became effective on July 1, 1993. The State enacted

TRCR Part 36 in June 1996. NRC has reviewed this rule and found it to be compatible with NRC's regulations.

The TDH has the following NRC regulation amendment that became effective since the 1994 review in the TDH's rulemaking process:

"Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement State flexibility to be more stringent (i.e., the State could choose not to adopt self-guarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provision for financial assurance that includes at least a subset of those provided in NRC's regulations, e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee). BRC has proposed this requirement in the development of transportation rules. It is in the second draft stage of promulgation. NRC found this proposed amendment to TRCR regulations to be compatible with NRC's requirement if adopted without change.

TNRCC adopted the following 11 NRC regulation amendments that became effective on June 6, 1997. In a letter dated January 7, 1998, NRC found these amendments to TNRCC regulations to be compatible with NRC's requirement.

"Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, 70 amendments (56 FR 64980) which became effective on October 15, 1991.

"Definition of Land Disposal and Waste Site Quality Assurance Programs," 10 CFR Part 61 amendment (58 FR 33886) which became effective on July 22, 1993.

"Decommissioning Record Keeping Documentation of Restricted Areas and Spill Sites," 10 CFR Parts 30 and 40 (58 FR 39628) that became effective on October 25, 1993.

"Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement State flexibility to be more stringent (i.e., the State could choose not to adopt self-guarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provision for financial assurance that includes at least a subset of those provided in NRC's regulations, e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee).

"Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," 10 CFR Part 40 amendment (59 FR 36026) that became effective on July 1, 1994.

"Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994.

"Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. This

rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement State the flexibility to implement more stringent requirements (i.e., the State could choose to continue to require annual medical examinations).

"Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. Agreement States are expected to have an effective rule on the same date.

"Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.

"Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.

“Termination or Transfer of Licensed Activities: Record Keeping Requirements,” 10 CFR Parts 20, 30, 40, 61, 70 (61 FR 24669) that became effective on May 19, 1996.

The following rules were not due during the review period but are in the TDH’s rulemaking process:

“Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards,” 10 CFR Part 40 amendment (59 FR 36026) that became effective on July 1, 1994. To assure continuous regulation of the uranium activities, the legislation transferring responsibility from TNRCC to BRC included a provision to permit the BRC to use the existing TNRCC regulations. A first draft of TRCR Part 43, “Licensing of Uranium Recovery Facilities” was being prepared for rulemaking to formalize uranium recovery activity licensing under BRC’s jurisdiction. This rulemaking package is scheduled to be submitted in July 1997. NRC found this proposed amendment to TRCR regulations to be compatible with NRC's requirement, if adopted without change.

"Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995. This requirement need not be in effect until November 24, 1998. BRC has proposed this requirement in the development of its transportation rules. It is in the second draft stage of promulgation. NRC found this proposed amendment to TRCR regulations to be compatible with NRC's requirement, if adopted without change.

“Termination or Transfer of Licensed Activities: Record Keeping Requirements,” 10 CFR Parts 20, 30, 40, 61, 70 (61 FR 24669) that became effective on May 19, 1996. This requirement need not be in effect until May 19, 1999. BRC has proposed this requirement in the development of its transportation rules. It is in the second draft stage of promulgation. NRC found this proposed amendment to TRCR regulations to be compatible with NRC's requirement, if adopted without change.

"Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994. It is in the second draft stage of promulgation of TRCR Parts, 11, 21, 41, and 44. This package is also scheduled for adoption in December 1997. NRC found this proposed amendment to TRCR regulations to be compatible with NRC's requirement, if adopted without change.

The review team identified two regulations that have not been put into effect in the BRC program:

> “Decommissioning Record Keeping Documentation of Restricted Areas and Spill Sites," 10 CFR Parts 30 and 40 (58 FR 39628) that became effective on October 25, 1993. It is in the second draft stage of promulgation of TRCR Parts, 11, 21, 41, and 44. The rulemaking package is scheduled for adoption in December 1997. The team reviewed the draft regulation. NRC found this proposed amendment to TRCR regulations to be compatible with NRC's requirement, if adopted without change.
>
> "Quality Management Program and Misadministration," 10 CFR Part 35 amendment (56 FR 34104) which became effective on January 27, 1992. BRC has not adopted the equivalent to the quality management and misadministration rule. As reported to NRC previously, BRC withheld adoption of this rule pending the outcome of the National Academy of Sciences report. NRC is continuing to defer compatibility findings for Agreement States that have not yet adopted a compatible Quality Management rule, until NRC issues a revised Part 35 rule, compatibility designations for the new rule are established, and an effective date for Agreement State implementation has been set.

Due to the constraints imposed by State law, BRC carefully plans future regulatory actions. It is the intention of BRC management to address the following regulations as quickly as possible. At the time of the review the following items are on the BRC’s regulatory agenda:

> "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995.
>
> "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. This rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement State the flexibility to implement more stringent requirements (i.e., the State could choose to continue to require annual medical examinations).
>
> "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
>
> "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.
>
> "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. Agreement States are expected to have an effective rule on the same date.
>
> “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Part 20.35 amendment (60 FR 48623) that became effective on October 20, 1995.
>
> “Termination or Transfer of Licensed Activities: Record Keeping Requirements,” 10 CFR Parts 30, 40, and 70 amendments (61 FR 1109) that became effective January 16, 1997.
>
> “Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act,” 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.

"Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective on January 13, 1997.

"Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Part 20.35 amendment (62 FR 4120) that became effective on January 29, 1997.

Based on the IMPEP evaluation criteria, the review team recommends that Texas's performance with respect to the indicator, Legislation and Regulations, be found satisfactory.

4.2 Sealed Source and Device Evaluation Program

In evaluating the State's Sealed Source & Device (SS&D) Evaluation Program, the review team examined the information provided by the State relative to this indicator in their response to the questionnaire, evaluated a sample of the actions completed since the last review, evaluated new procedures and guidance, and interviewed the TDH staff responsible for SS&D evaluations.

Since the last review, the State has developed template registration certificates and a checklist to assist in the review of SS&Ds and help to ensure that all pertinent issues are addressed. The staff has also adopted the use of the NRC's NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations" as standard reviewer guidance.

4.2.1 Technical Quality of the Product Evaluation Program

The review team evaluated 7 registration certificates out of the 16 registration certificates reported for the period since the last review. The SS&D sheets issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G. The review team suggests that the State consider the comments in Appendix G, and take action as the State deems appropriate. For 6 of the 7 cases reviewed, the overall quality of the evaluations was good, with minor comments that were addressed during interviews with the staff. However, for one case (TX-0246-D-103-S), the review team identified a number of inconsistencies and issues that appeared to be unaddressed in the review. Other unidentified review issues associated with this case may also exist. The issues identified by the review team are listed in Appendix G, and were discussed with both the initial and the concurrence reviewers.

Based on the limited evaluation performed by the review team and considering the team's experience with similar devices, the fact that the device must meet transportation dose rate requirements before shipment, the expected training level of the users, and the State's belief that there have been no devices distributed, the review team believes that the immediate health and safety risk to any potentially current users is low, possibly zero. However, the review team recommends that the State perform an evaluation to determine the safety significance of the issues identified by the review team pertaining to registration certificate number TX-0246-D-103-S and to identify any other issues that may exist, and re-evaluate the application, as necessary, to ensure that all pertinent safety and regulatory issues are adequately addressed. It was not possible to determine from the limited number of files reviewed whether the deficiencies noted in this evaluation was an isolated occurrence or if they may be present in other evaluations.

Therefore, the review team recommends that the State evaluate an adequate sample of additional safety evaluations to ensure that the deficiencies identified in TX-0246-D-103-S are adequately addressed in the additional cases, and to demonstrate that this was an isolated occurrence.

Through interviews with the staff responsible for performing the safety evaluations, the review team identified that the concurrence review is currently being performed as a review of the initial reviewer's evaluation, and is not an independent technical review. The review team recommends that the State review the issue of concurrence reviews[1] for SS&D safety evaluations and implement procedures that require concurrence review for all future evaluations. The review team notes that an independent technical review could have identified the issues involved in the case detailed in the previous paragraph.

4.2.2 Technical Staffing and Training

BRC reported that a two-person team with combined staff efforts equaling approximately 0.6 FTE is dedicated to performing safety evaluations. The balance of staff time is spent primarily in licensing actions. Both staff members responsible for performing safety evaluations are trained in health physics principles, and have engineering backgrounds. Both staff members have attended at least one SS&D workshop. BRC has begun training additional staff in this area, although at the time of this IMPEP review, no registration certificates have been signed by these additional individuals.

BRC reported that 16 registration certificates were issued or modified during the review period. The actions reported by BRC also included one action associated with Naturally Occurring or Accelerator-Produced Radioactive Materials (NARM). The review team noted that the initial review was performed by the same individual for all but one of the 16 registrations certificates completed during the review period. Since BRC has indicated that this primary initial reviewer plans to retire in the near future, the review team suggests that the State consider assigning safety evaluations to those staff members currently being trained to perform SS&D safety evaluations to enable them to gain enough experience and obtain registration certificate signature approval before the staff member currently performing the initial review retires.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The details regarding the review of incidents associated with SS&D product failures or problems is addressed in Section 3.5 of this report. The State adequately addressed the immediate issues involved relating to product failures or problems, but the review team suggests that the State take a more aggressive approach to forwarding information to the agency responsible for the

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[1] A concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the initial reviewer. The concurrence review includes evaluation of each area addressed during the initial review (e.g., construction of the product, labeling, prototype testing, etc.) but the concurrence review is not to the same level of detail as the initial review (i.e., it is not necessary to review every page of the applicant's submittal). The concurrence review must be focused upon ensuring that the product meets all applicable regulations, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implication resulting from the widespread distribution of sealed sources and devices.

product evaluation and registration certificate where there is a possibility that the failure or problem may be a generic issue.

Based on the IMPEP evaluation criteria, the review team recommends that Texas' performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste Disposal Program

The review team evaluated the State's responses to the questionnaire, compared Texas low-level radioactive waste (LLRW) statutes and regulations with those of the NRC, evaluated the qualifications of the technical staff and contractors, reviewed the State's written procedures and plans, examined parts of the LLRW disposal facility license application and interrogatories, reviewed parts of the environmental and safety analysis report, evaluated field reports and files, and interviewed staff, managers, and contractors assigned to the LLRW program.

In 1981, the Texas Legislature created TLLRWDA for the purpose of siting, developing, and operating a LLRW disposal facility. TDH was granted responsibility for licensing the facility. In March 1992, authority to regulate disposal of radioactive substances was transferred from TDH to the Texas Water Commission. In September 1993, authority was shifted to TNRCC. Within TNRCC, the LLRW program is administered by the Underground Injection Control (UIC), Uranium, and Radioactive Waste (UURW) Section within the Industrial & Hazardous Waste Division.

TNRCC received an application to license a LLRW disposal facility from the TLLRWDA on March 2, 1992. The initial application contained very little specific information on the proposed Sierra Blanca site; therefore, the application was declared incomplete. After nine submittals (called revisions by TLLRWDA), the application was declared administratively complete on May 12, 1995. After being declared complete, TNRCC was under statutory requirements to complete their review of the application within 15 months; however, based on familiarity with the application resulting from the completeness reviews, the TNRCC committed to completing the review by April 1, 1996. After the application was declared administratively complete, additional revisions were made based on interrogatories and meetings with TNRCC staff. The final revision (i.e., no. 20) is dated March 3, 1996. TNRCC completed its review of the application on March 29, 1996, and a draft, proposed license has been developed.

Currently, the licensing matter is in an adjudicative hearing with the State Office of Administrative Hearings (SOAH). At the conclusion of the hearing, the SOAH will prepare a recommendation to the TNRCC Commissioners, who will then make the final decision on whether to issue the license.

During the last program review of Texas, as noted in Section 4.1.1, NRC raised a concern with the compatibility between the State and NRC statutes and regulations on the definition of LLRW. The review team found that this issue has not been resolved.

4.3.1 Status of Low-Level Radioactive Waste Disposal Inspection

Under this part of the program indicator, the review team evaluated the State's ability and progress in doing periodic inspections of the LLRW disposal facility. TNRCC is planning to complete periodic inspections from the pre-operational phase through the post-closure phase, to

ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices.

The Texas LLRW disposal facility is in a pre-licensing phase; therefore, this program indicator is not applicable. However, the team notes that TNRCC has completed 14 pre-licensing site visits. Pre-operational (baseline) data have been collected on a quarterly basis for two years. Site visits have been made for the purpose of site familiarization, and collecting environmental samples and background radiation data for independent verification of data submitted in the application. TNRCC staff indicated that there will be regular inspections of the site during construction; however, the frequencies of the inspections have not been determined.

The team notes that baseline thermoluminescent dosimeter (TLD) data have been compared against data collected by TLLRWDA. Some discrepancies have been found. TNRCC staff investigated these apparent discrepancies and resolved them after the review (see August 15, 1997 memo). The review team notes that none of the baseline data have been put into a computer database. However, the data have been captured in a spread sheet by a member of the staff. The review team suggests that, if warranted by the amount of data, the baseline data should be entered into a computer database to facilitate its review and use.

4.3.2 Technical Staffing and Training

The team notes that there are currently five technical staff members supporting the LLRW program. All technical staff have bachelors' degrees or above. The team also notes that the following disciplines are covered within the program: health physics, civil engineering, chemical engineering, geology, and biology. Surface-water hydrology is currently not covered; however, temporary support can be obtained from other sections within the Division (although the details on this have not been worked out). The hydrologist who worked on the license review is still with the TNRCC and is expected to provide support during the license hearing.

During the license review, additional staff supported the LLRW program, including contractual support from the TDH and the University of Texas. This contractual support is still being provided. In total, approximately 12 technical persons were involved with the license review, with the following disciplines being covered: geology, hydrology, health physics, biology, geotechnical engineering, chemical engineering, civil engineering, and mechanical engineering.

The level of staffing was sufficient to allow review of the application within the mandatory 15 months. The review was completed by the target date (i.e., April 1, 1996); that is, several months ahead of the mandatory requirement. It should be noted that the State had received and reviewed various portions of the application prior to the declaration of administrative completeness. The team was informed that TNRCC staff worked extra hours to meet the target date.

TNRCC staff is allowed to pursue training as they see the need and as funds are available. The availability of training has been identified as a program weakness by TNRCC. TNRCC would like more support from the NRC in the form of free or inexpensive technical training because of limited available funds. In the LLRW area, TNRCC is especially interested in the availability of training in performance assessment. TNRCC maintains no consolidated compilation of training completed by staff. TNRCC Technical Training Academy maintains information on all in-house training of TNRCC staff. Through review of staff resumes, which are maintained current and reflect training received, the team notes that staff has undertaken additional on-site training,

outside training, and participated in workshops. The review team suggests that a consolidated training record be developed to enable assessment of training across the entire program.

The team found no apparent trends in the loss of staff that could adversely affect the program.

4.3.3 Technical Quality of Licensing Actions

The purpose of the review under this part of the program indicator is to confirm that the State has an acceptable program for licensing the LLRW disposal facility. To evaluate the technical quality of the licensing program, the team reviewed technical aspects of the licensing action, in particular the performance assessment. The team evaluated parts of the Environmental and Safety Analysis report, parts of the license application, interrogatories, file records, and staff files. In addition, the team interviewed staff involved with the license review.

The team notes that the license review utilized licensing guides such as "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility," NUREG-1200 and "Environmental Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility," NUREG-1300. TNRCC has developed a safety analysis report; the report required extensive effort by the team to conduct the review because of the need to refer to the application (i.e., the document is not self-contained). Further, the bases for staff findings (i.e., acceptance of the licensee's analysis) are not provided throughout the document. At the time of the review, the TNRCC staff was preparing additional documentation in the form of prehearing testimony to be submitted that will provide bases for staff findings. The review team suggests that TNRCC complete their efforts to document bases for all staff findings.

TNRCC sent out 31 different sets of interrogatories during the license review period. TNRCC staff also had numerous meetings with TLLRWDA staff; issues and resolutions discussed at these meetings are documented in the file records.

Assessment of the quality of the license review primarily concentrated on the key components of TNRCC's review of the TLLRWDA's performance assessment. No attempt was made to evaluate the performance assessment, itself. The performance assessment, which analyzes the long-term, post-closure doses from the site, is essential to the licensing decision. The team's review and comment on TNRCC's review of the TLLRWDA performance assessment are not intended as a review of TLLRWDA's assessment or the acceptability of the proposed site. Therefore, nothing in this report should be construed as a criticism or evaluation of the license application, the performance assessment, or the acceptability of the site. TNRCC reviewed the performance assessment by completing confirmatory calculations to test out individual models in the analysis. TNRCC also evaluated models and parameters used in the analysis against the literature.

TNRCC concludes that TLLRWDA performance assessment analysis is conservative in part because it is largely dependent upon water infiltrating into the disposal cells even though the site characterization data show that little or no recharge actually occurs at the site. Since the TLLRWDA analysis conservatively considers the possibility of water getting into the facility, the performance assessment analysis should be evaluated using a technically rigorous approach (i.e., the performance assessment analysis needs to be reviewed to ensure that appropriate parameter values were used in the analysis). The team found that in several important areas TNRCC could conduct additional analyses to ensure that the performance assessment used

appropriate input values and to ensure that the sensitivity to certain key input values was identified.

1. TLLRWDA analyzed infiltration into the facility by running a modified version of the HELP computer code which had been approved by the HELP code developer. TNRCC staff reviewed the input and made confirmatory runs.

   Sensitivity analyses performed by TLLRWDA show that a long-term average increase in rainfall by 50% leads to a threefold increase in percolation; however, such a long-term increase is deemed to be unlikely because it would represent a change in climate. No consideration was given to the sensitivity of the calculated infiltration to evapotranspiration. Evapotranspiration significantly effects recharge in arid areas. In reaching a proposed licensing decision, TNRCC relied solely upon TLLRWDA's sensitivity analysis which only addressed variation in precipitation. Although the needed increase in precipitation may be unrealistic, it is possible that a small change in evapotranspiration, which could be credible, could have the same effect on calculated infiltration as rainfall amounts.

2. In the source term analysis, TLLRWDA calculates releases of radionuclides from the facility as a first-order process that is a function of percolation and partitioning between the waste and the percolating water. The release model used is commonly cited in the literature. TLLRWDA uses a factor (f_L) to relate releases from a surface wash-off type process to a diffusion process. TLLRWDA relates the f_L factor to the contact time factor (t_c) in IMPACTS. Because of known concerns with the derivation and basis of the contact time factor in IMPACTS, TLLRWDA used a different approach to derive values for the f_L factor. Beginning with studies that were completed in support of the Fort Hancock site and continuing with Revisions 4 and 8 of the application for the Sierra Blanca site, the TLLRWDA estimated values for f_L by looking at the magnitude of t_c values from the IMPACTS methodology; then developed a methodology to calculate f_L values by using source terms from other models, including the DUST computer code (developed under agreement with Brookhaven National Laboratory for the NRC). DUST and other models were used to estimate appropriate f_L values by using the source terms generated from these other models in TLLRWDA's mass balance model to back calculate a range of equivalent f_L values. These values were then compared to TLLRWDA's original value for f_L and used as a basis for revising the TLLRWDA's f_L to an appropriately conservative value. Estimated f_L values derived for use in the analysis are:

Tc-99 and I-129	0.05
Cl-36	0.01
All other radionuclides	0.1

   In discussions with TNRCC staff, the team learned that these values were considered acceptable because they were several orders of magnitude larger than the t_c factors in IMPACTS. However, TNRCC did not review the input used in the DUST code or make any confirmatory runs. In fact, TNRCC did not have a copy of the input for the DUST code used by TLLRWDA. For example, the team questioned TNRCC staff about the basis for the assumed concrete diffusion coefficient of $1x10^{-9}$ cm^2/s; however, at the time of the discussion the staff did not know the basis for the value. Additional information was provided at a later date, but justification for the assumed value was not included. Because the value for the f_L factor can result in a 1-2 order of magnitude variation in

calculated doses, the team believes that TNRCC's review could be strengthened by checking the appropriateness of the derived values through either independent confirmatory analyses or review of the literature.

To further strengthen the technical analysis, TNRCC staff should review the specific literature cited by TLLRWDA in selecting distribution coefficients (K_d) for the waste area (source area) to ensure that the wasteform and chemistry are comparable to the proposed Texas facility. TNRCC staff reviewed distribution coefficients assumed for the soils, by comparing them against values in the literature. However, K_d's assumed for the waste area (K_d^w) are several orders of magnitude larger than for the soils for several key radionuclides (i.e., C-14, I-129, and Tc-99). Based on the approach used by TLLRWDA, K_d's for the soil should have little effect on the calculated dose. However, the K_d for the waste (K_d^w) can greatly impact the calculated dose. For example, the calculated ground-water concentration for C-14 (Class A waste) based on a K_d value used by TLLRWDA in an earlier submittal when compared with the K_d value for their last submittal, results in a two-order of magnitude reduction. TNRCC staff based their review of TLLRWDA's use of its waste distribution coefficients through their experience with distribution coefficients <u>for soils</u> in high pH environments, conversations with NRC staff, and by reviewing a research paper on waste distribution coefficients written by NRC staff.

3. In the environmental transport analysis, TLLRWDA calculated concentrations of radionuclides at receptor points along the water pathway by using a series of transfer functions that account for decay and dilution. TNRCC staff indicated that they had reviewed these equations and made confirmatory calculations to determine that they were appropriate and appropriately being used. Further, TNRCC staff indicated they had reviewed the parameter values used in the models against published information.

   To avoid double accounting for potential impacts, TLLRWDA arbitrarily assumed that 75% of leachate leaving the facility would be available to return to the surface (i.e., $f_{surface}$ = 0.75) and the remaining 25% would be available to travel to the ground water (i.e., $f_{aquifer}$ = 0.25). TNRCC staff questioned the basis for these factors, but accepted the use of them because they agreed that a ground water pathway analysis must be done, and recognized that any factors assumed for that analysis represent site conditions that do not exist and therefore must to some extent be arbitrarily defined. These factors have minimal effect on the calculated doses. For example, an arbitrary conservative increase in the $f_{aquifer}$ value from 0.25 to 1.0, increases the calculated dose by only a factor of four, but still well below the dose limit. However, if this factor is considered in combination with the f_L factor (discussed above), it can result in a significant variation in the calculated dose. As an arbitrary conservative illustration, the $f_{aquifer}$ factor ($f_{aquifer}$ = 1) combined with the f_L factor (f_L= 1) allow three-orders of magnitude increase in the calculated ground-water dose from exposure to Cl-36 . TNRCC representatives stated the peak dose occurs at approximately 50,000 years post closure, according to TLLRWDA estimates. The TNRCC statement was made during the Management Review Board meeting and no technical supporting basis for the 50,000 year estimate was provided. However, the team realizes that NRC does not recommend assessments of doses occurring after 10,000 years for the use as a basis for compliance with the performance objective. Although TNRCC staff correctly maintains that the $f_{surface}$ and $f_{aquifer}$ factors by themselves do not greatly affect the calculated doses, sensitivity analysis using these factors in combination with other factors or parameters should be considered.

TLLRWDA, in determining the dilution volume for contaminants returning to the surface, assumed a volume equal to the depth of the disposal unit (10.5 m for Class A and 7.75 m for Class B/C) multiplied by the total surface area of the facility (i.e., the area of Class A and Class B/C combined); however, releases from Class A are assumed to be initiated at 100 years, while releases for Class B/C are assumed to be initiated at 300 years. The surface area of the Class B/C units is only 1/4 that of the Class A units; therefore, use of the combined surface area is likely accounting for additional dilution of leachate released from the Class B/C units. TNRCC staff have indicated that the above assumptions were used in the inhalation exposure scenario which calls for an averaging of the surface contamination concentration to calculate air concentrations. In addition, the ingestion scenarios for the soil surface do not specify where on the site animals would graze or where vegetation would be grown. While TNRCC staff believe that it is prudent and conservative to use an average concentration, this conclusion was not supported by either a technical analysis of the difference in initial release times for Class A and Class B/C wastes or an analysis of the additional dilution reflected in the calculation methodology. Therefore, TNRCC staff should undertake analyses to evaluate the appropriateness of the approach used in determining the dilution volume.

4. TLLRWDA design of the interior of the disposal units calls for the placement of gravel between the waste canisters to provide stability for the cover. A layer of soil would be placed over the gravel and waste canister. The contrast in hydraulic properties between the gravel and soil has the potential of creating a capillary barrier, which would block water from moving down into the gravel and cause water to be channeled toward the waste, and needs to be further understood. The potential for this occurring should can be reviewed by modeling moisture movement within the facility.

The review team recommends that TNRCC ensure that well documented technical bases exist for the performance assessment. Sensitivity analyses could be completed to ensure that key aspects of the performance assessment analysis have been reviewed.

4.3.4 Technical Quality of Inspections

The intent of the review under this part of the program indicator is to evaluate the State in terms of the quality of its inspection of the LLRW facility. Because the LLRW facility is in a pre-licensing phase, this part of the program indicator is not applicable. However, the team notes that the TNRCC has completed 14 pre-licensing site visits. The site visits are thoroughly documented in terms of areas visited and features observed.

4.3.5 Response to Incidents and Allegations

Under this part of the program indicator, the State is evaluated in terms of its response to incidents, alleged incidents, and other allegations of safety concerns. The team notes that there have been no reported incidents, alleged incidents, or allegations of safety concerns with regards to the LLRW facility.

Based on the IMPEP evaluation criteria for the above five performance areas, the review team recommends that Texas performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, be found satisfactory with recommendations for improvement.

4.4. Uranium Recovery Regulatory Program

In the process of evaluating this performance indicator, the review team evaluated the State's responses to the questionnaire; reviewed information provided by the State regarding the status of licenses, status of the various sites, site inspection history, financial assurances, status of regulations; reviewed selected licensing and inspection files; evaluated the qualifications of the technical staff; and interviewed selected staff and managers working in the uranium recovery regulatory area.

Jurisdiction over uranium recovery activities was transferred from the TDH to TNRCC in September 1993, prior to the previous review. Since September 1993, TNRCC has been responsible for regulating the uranium recovery program which includes underground injection control, and decommissioning of uranium sites. During the 1997 legislative session of the Texas legislature, the regulatory responsibility for the uranium program was transferred (returned) to the TDH. The underground injection control program is an EPA-delegated program that will be retained by TNRCC. This transfer became effective on July 21, 1997. During the review, managers of TNRCC and TDH were in the process of working out the details of the transfer.

At the time of the review, Texas had 3 conventional mill licensees (3 sites) and 9 in-situ licenses (19 sites). All of the conventional mill licensed sites and all but 3 of the in-situ licensed sites are in various phases of closure. The active production facilities (in-situ) are Uranium Resources Incorporated (URI) sites identified as Kingsville Dome, and Rosita. The Vasquez facility has not yet been licensed.

4.4.1 Status of Uranium Recovery Program Inspection

The TNRCC program initially set the inspection priorities for mill sites at one year frequencies to be consistent with the inspection frequencies called for in IMC 2800 and IMC 2801. However, due to other programmatic priorities such as the Low-Level Waste Program, development of regulations, and licensing backlogs, the program established additional priorities for the uranium site inspections which were based upon potential health and safety issues, and environmental considerations. Program managers related that in order to address health and safety issues while managing the inspection backlog, emphasis is placed (in decreasing order) for response to incidents, the inspection of active operations and decommissioning activities, and finally to those sites that had been decommissioned but still requiring regulatory monitoring and observations. At the time of the review, 12 sites were on a one year inspection frequency. For 10 sites, TNRCC has established a two year frequency, and documented the justification for the frequency change for these facilities which are in restoration/reclamation mode since their activities did not warrant the same level of attention as facilities with a greater potential to adversely affect the health and safety of the workers and the public. The review team noted that the two year sites are not consistent with IMC 2800.

The State reported that four licenses were overdue for inspection (overdue by more than 25% of the NRC frequency). A review of the tracking system and the inspection files confirmed this information and noted that the four overdue sites had inspection frequencies of one year. The review team recommends that an action plan be developed and implemented by TDH to overcome the inspection backlog in the uranium recovery program.

At the time of the review, none of the operational production sites were due for inspection. Therefore, in lieu of inspector accompaniments, the reviewer accompanied the Section manager

to the URI, Kingsville Dome facility for a visit to a production site. This visit was conducted on June 4, 1997. TNRCC initially reported in the questionnaire that no annual supervisory accompaniments of inspectors had been performed; however, documentation was reviewed showing that the lead inspector was accompanied by the supervisor in March 1997. The other two inspectors work under the supervision of the lead inspector during team type inspections. The team considered the content of the report documenting the accompaniment, interviewed the supervisor and the inspector, and determined the accompaniment to be satisfactory.

All inspection reports are reviewed and signed by the supervisor prior to issuance. Notice of violations were confirmed to be transmitted to the licensee within the 30 days limit established by administrative procedures. The program has a tracking system for management of inspection reports, issuance of notices of violation, and escalated enforcement actions.

4.4.2 Technical Staffing and Training

The Manager (Registered Professional Engineer) of the UURW Section has the Section organized into three teams; the UIC Permitting Team, the Licensing Team, and the Inspections and Compliance Team. The Licensing Team handles the uranium, LLRW and buried sites for specific licensees, and consists of a Team Leader and eight other professionals. The team is made up of two engineers (PE's), one Ph.D. biologist, four health physicists, two geologists, and one vacant hydrologist position. The Team Leader also has many years experience in the uranium industry.

The Inspection and Compliance Team consists of a Team Leader and seven other professionals which includes two engineers (one PE), two geologists, and three health physicists. The Team Leader is also a geologist with several years experience. Two of the health physicists are still in training and are being scheduled for NRC training as the space becomes available.

The review team examined the training, education, and experience of the staff members and found that the qualifications of the technical staff are commensurate with the expertise identified as necessary to regulate uranium recovery and 11e(2) byproduct material.

Additional support is provided by the UIC Permitting Team and the Division staff in environmental surveillance , environmental monitoring, verification surveys, accounting and finance, systems analysis, legal staff, and sample analysis on an as needed basis. TDH Laboratory is under contract to provide sample analyses as needed, and was visited by the review team and found to be a state-of-the-art facility which participates in laboratory inter-comparison programs. Additional details of the laboratory can be found in Section 3.4.

4.4.3 Technical Quality of Licensing Actions

The evaluation of this area focused on a review of the licensing process and the evaluation of health physics type issues. Three recent licensing actions were evaluated as a sample of work performed by the Section's Licensing Team, and included licensing actions performed by each of the three project managers on the Licensing Team. This casework is identified as: (1) Chevron Resources, Panna Maria Project, (RW2602), which is a conventional mill tailings pond under reclamation/closure; (2) Everest Exploration, Inc., Hobson (RW 3626-000), McBryde (RW 3626-001), Tex-1 (RW 3626-003), and Mt. Lucas (RW 3626-005) sites, which are in-situ sites that are all under restoration/reclamation; and (3) Uranium Resources, Inc., Kingsville Dome (RW 3653-000), Rosita (RW 3653-001), and the Vasquez (RW 3700) sites.

The detailed licensing process includes a tracking system covering the administrative and technical review of all applications. Each phase and step of the process were found to have documentation relative to the issues under review, and reviewed and concurred upon by the appropriate technical disciplines and representatives of the licensing team, the inspection/ compliance team, and management. The review team noted that the team approach is effective in getting peer review and the necessary expertise applied to the specific review.

In examining the license and selected background information in the file, the review team found that the licenses included appropriate license conditions for the reclamation/closure operations at the facility. Detailed procedures have been tied down by license conditions.

4.4.4 Technical Quality of Inspections

The review team examined the compliance summaries prepared for each licensee identified under the above Section (4.4.3), and the latest inspection report and enforcement action prepared for the licenses. The documentation for these activities show that inspections and audits adequately covered the scope, completeness, and technical accuracy necessary to determine compliance with regulations, license conditions, and available guidance. The reports were narrative type reports with good detail, and with well documented and referenced violations as appropriate. Appropriate enforcement actions were taken given the scope of the violations noted.

The inspection reports and enforcement actions are also tracked in the system, and the reports receive appropriate review and concurrence by other members of the inspection team, the licensing team, and managers. Any enforcement actions going beyond a notice of violation must also be reviewed by the Legal Section and be signed by the Commission.

4.4.5 Response to Incidents and Allegations

The State reported seven incidents (four sites listed in TNRCC’s questionnaire response) but there were no allegations pertaining to the uranium recovery activities. The incidents were addressed in a timely manner and the documentation was complete and timely. The evaluations and actions taken by the States were determined to be satisfactory. The documentation was located in the license file and the lead inspector’s incident file.

TNRCC has one staff person who has received training under the NMED system and the Section has received the software for implementation. TNRCC summarized incident information is provided on printed copy to the OSP and to INEEL for entry into the NMED system.

Based on the IMPEP evaluation criteria for the above five performance areas, the review team recommends that Texas' performance with respect to the indicator, Uranium Recovery Program, be found satisfactory with recommendations for improvement.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance with respect to each of the common performance indicators and the non-common indicators, Legislation and Regulations and Sealed Source and Device Evaluation Program to be satisfactory. The review team found the State's performance with respect to the Low-Level Radioactive Waste Disposal Program and the Uranium Recovery Program to be satisfactory with recommendations for

improvement. Accordingly, the team recommended, and the MRB concurred in finding the Texas program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for consideration by the State.

1. The review team suggests that amendments and renewals be prioritized so that amendments which impact health and safety (i.e., new RSO because the previous one left the company; major proposed procedure changes which could effect radiation safety issues) are completed ahead of the amendments and renewals which are more routine (i.e., adding a source, or another user when ten sources or users are already on the license; renewal by letter). (Section 3.3)

2. The review team suggests the State consider standardizing their primary and supplementary field note forms. These could be modeled after the NRC forms as discussed with BRC. (Section 3.4)

3. The review team suggests documenting in reports summary discussions of inspection findings with management at the conclusion of inspections. (Section 3.4)

4. The review team recommends that the State adhere to the policy of annual supervisory accompaniments of all qualified inspectors. (Section 3.4)

5. The review team recommends that all radiation detection instruments used for confirmatory surveys (field measurements) be calibrated on for all ranges encountered by inspectors. (Section 3.4)

6. The review team suggests that the State initiate actions (through implementation of the procedures provided in the March 1995 Handbook on Nuclear Material Event Reporting in the Agreement States) to directly utilize the NMED system. (Section 3.5)

7. The team recommends that TNRCC vigorously pursue the changes necessary to make Texas law (statutes and regulations) compatible with those of NRC in the low-level waste area and, if necessary, raise this issue to higher levels in the State government. (Section 4.1)

8. The review team suggests that the State consider the comments in Appendix G, and take action as the State deems appropriate. (Section 4.2.1)

9. The review team recommends that the State perform an evaluation to determine the safety significance of the issues identified by the review team pertaining to registration certificate number TX-0246-D-103-S and to identify any other issues that may exist, and re-evaluate the application, as necessary, to ensure that all pertinent safety and regulatory issues are adequately addressed. (Section 4.2.1)

10. The review team recommends that the State evaluate an adequate sample of additional safety evaluations to ensure that the deficiencies identified in TX-0246-D-103-S are adequately addressed in the additional cases, and to demonstrate that this was an isolated occurrence. (Section 4.2.1)

11. The review team recommends that the State review the issue of concurrence reviews for SS&D safety evaluations and implement procedures that require an independent technical review for all future evaluations.(Section 4.2.1)

12. The review team suggests that the State consider assigning safety evaluations to those staff members currently being trained to perform SS&D safety evaluations to enable them to gain enough experience and obtain registration certificate signature approval before the staff member currently performing the initial review retires. (Section 4.2.2)

13. The review team suggests that the State take a more aggressive approach to forwarding information to the agency responsible for the product evaluation and registration certificate where there is a possibility that the failure or problem may be a generic issue. (Section 4.2.3)

14. The review team suggests that, if warranted by the amount of data, the baseline data should be entered into a computer database to facilitate its review and use. (Section 4.3.1)

15. The review team suggests that a consolidated training record be developed to enable assessment of training across the entire program. (Section 4.3.2)

16. The review team suggests that TNRCC complete their efforts to document the bases for all staff findings. (Section 4.3.3)

17. The review team recommends that TNRCC ensure that well documented technical bases exist for the performance assessment. Sensitivity analyses could be completed to ensure that key aspects of the performance assessment analysis have been reviewed. (Section 4.3.3)

18. The review team recommends that an action plan be developed and implemented by TDH to overcome the inspection backlog in the uranium recovery program. (Section 4.4.1)

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APPENDIX A
IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Richard L. Woodruff, RII	Team Leader Technical Staffing and Training Uranium Recovery Program
Michelle Burgess, NMSS	Sealed Source and Device Evaluation Program
Elizabeth Drinnon, GA	Technical Quality of Licensing Actions
Craig Gordon, RI	Technical Quality of Inspections
James Myers, OSP	Status of Materials Inspection Program Legislation and Regulations
Thomas O'Brien, OSP	Response to Incidents and Allegations
Mark Thaggard, NMSS	Low-Level Radioactive Waste Disposal Program

APPENDIX B

ORGANIZATIONAL CHARTS

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE - RESPONSE

APPENDIX D
LICENSE FILE REVIEWS

File No.: 1
Licensee: Offenhauser Company License No.: L03109
Location: Houston, TX Amendments No.: 17, 18, and 19
License Type: Industrial Radiography (Fixed) Reviewer: DF, TG, BDB
Date Issued: 02/24/95, 07/01/96, 08/06/96

Comment:
a) Changed the RSO in July 1 amendment. Exemption was granted for the RSO. He did not have the required high school diploma or GED. Good documentation was in the file to support the exemption.

File No.: 2
Licensee: University of Texas Medical Branch License No.: L01299
Location: Galveston, TX Amendments No.: 43, 44, 45, 46, and 47
License Type: Broad Medical Reviewer: PM
Date Issued: 01/19/96, 04/02/96, 05/09/96, 07/11/96, 08/28/96

Comments:
a) Although amendments completed, the license has been under timely renewal since December 1992.
b) Amendment 44 was a correct copy issued to Amendment 43 adding letters in the tie-down condition that were left off of Amendment 43.
c) Exemption requested to a license condition about record keeping requirements at a storage only location. Justification well documented and exemption granted. Amendment 46 captured the exemption.

File No.: 3
Licensee: Central Pharmacy (formerly Sholars Drug) License No.: L04785
Location: Orange, TX Amendment No.: 6
Licensee Type: Nuclear Pharmacy Reviewer: DW
Date Issued: 05/29/97

Comments:
a) Requested an exemption under Sholars Drug not to provide internal dose monitoring. The licensee did not provide adequate justification for the request and the exemption was denied.

File No.: 4
Licensee: Gulf Coast Inspection License No.: L04934
Location: Ingleside, TX New; and Amendment No.: 1 and 2
License Type: Industrial Radiography (Fixed) Reviewer: DF, SW, LK
Date Issued: 03/14/96, 03/28/96, 05/29/97

File No.: 5
Licensee: Camco Incorporated License No.: L03303
Location: Houston, TX Amendments No.: 10
License Type: Industrial Radiography (In-Plant) Reviewer: WS
Date Issued: 08/08/96

File No.: 6
Licensee: MacGregor Medical Associates License No.: L04646
Location: Houston, TX Amendment 3
License Type: Nuclear Medicine (Diagnostic and Therapy) Reviewer: PM
Date Issued: 11/21/95

File No.: 7
Licensee: University of Texas at San Antonio License No.: L01962
Location: San Antonio, TX Amendment No.: 32
License Type: Research and Education Reviewer: DJ
Date Issued: 04/22/97

File No.: 8
Licensee: Joe Arrington Cancer Research & Treatment Center License No.: L04881
Location: Lubbock, TX Amendment No.: 8
License Type: HDR and Therapy Reviewer: PM

File No.: 9
Licensee: Lockheed Fort Worth Facility License No.: L01866
Location: Fort Worth, TX Termination
License Type: Research and Development Reviewer: FH
Termination Issued: 06/09/95

File No.: 10
Licensee: Ybarrondo & Associates - Scientech, Inc. License No.: L04435
Location: Carrollton, TX Termination
License Type: Calibration and Reference Sources,
Unsealed Radioactive Material Reviewer: DF
Termination Issued: 06/20/95

Comment:
a) Had to request additional information and conduct field inspection prior to releasing site.

File No.: 11
Licensee: 3M Company/Health Physics Services License No.: L03843
Location: St Paul, MN (Austin, TX) Termination
License Type: Fixed Gauges Reviewer: WS
Termination Issued: 05/14/96

File No.: 12
Licensee: LogTech Wireline Services, Inc. License No.: L02501
Location: Tyler, TX Termination
License Type: Well Logging Reviewer: DF
Dated Issued: 12/12/95

File No.: 13
Licensee: South Texas Utility Contractors License No.: L05065
Location: Mercedes, TX New
License Type: Portable Gauges Reviewer: DF
Date Issued: 06/06/97

Comment:
a) Did not include the standard condition for leak testing.

File No.: 14
Licensee: Jagoe-Public Company License No.: L05042
Location: Denton, TX New
License Type: Portable Gauges Reviewer: WS
Date Issued: 06/03/97

File No.: 15
Licensee: Health Images Inc.
D.B.A. Health Images Medical Center License No.: L05005
Location: Houston, TX New & Amendment No.: 1 and 2
License Type: Diagnostic Nuclear Medicine Reviewer: PM
Date Issued: 09/20/96, 04/08/97 and 04/16/97

File No.: 16
Licensee: Northeast Medical Center Radiology License No.: L02926
Location: San Antonio, TX Renewal
License Type: Private Practice Nuclear Medicine & Therapy (<30mCi) Reviewer: DW
Date Issued: 03/05/96

Comment:
a) This was a renewal in entirety and not by letter.

File No.: 17
Licensee: Cardiology Care Consultants License No.: L05045
Location: El Paso, TX New
License Type: Private Cardiology Reviewer: DW
Date Issued: 05/01/97

File No.: 18
Licensee: Texoma Medical Center License No.: L01624
Location: Denison, TX Amendment No.: 45
License Type: Institutional Nuclear Medicine,
Therapy and Brachytherapy Reviewer: PM
Date Issued: 05/27/97

File No.: 19
Licensee: Nacona General Hospital License No.: L04977
Location: Nacona, TX New
License Type: Mobile Nuclear Medicine Reviewer: DRJ
Date Issued: 09/11/96

File No.: 20
Licensee: Nuclear Sources & Service, Inc.,
D.B.A. NSSI/Recovery Services, Inc. License No.: L01811
Location: Houston, TX Amendment No.: 43
License Type: Waste Processor-Class B Reviewer: PS
Date Issued: 04/19/96

Comment:
a) Condition 9 stated that Attachment 1 was attached to the license and was a part of the license. Attachment 1 was not with the amendment. This was corrected as soon as it was brought to the reviewer's attention.

File No.: 21
Licensee: Johnson & Johnson License No.: L01870
Location: Sherman, TX Amendment No.: 16
License Type: Pool Irradiator Reviewer: TG
Date Issued: 08/23/95

APPENDIX E
INSPECTION FILE REVIEWS

File No.: 1
Licensee: Mundy Contract Maintenance, Inc. License No.: L04360
Location: Pampa, TX Inspection Type: Unannounced/Routine
License Type: Industrial Radiography Priority: 1
Inspection Date: 01/23/97 Inspector: RA

Comments:
a) Unable to determine whether previous NOV followed up or corrected.
b) No description of findings related to management.
c) Inspector area surveys and maximum range of licensee personnel dosimetry not in report.

File No.: 2
Licensee: Don and Sybil Harrington Cancer Center License No.: L03053
Location: Amarillo, TX Inspection Type: Unannounced/Routine
License Type: Medical Brachytherapy Priority: 1
Inspection Date: 04/19/96 Inspector: RA

Comments:
a) Maximum range of licensee personnel dosimetry not in report.
b) Cannot determine whether licensee performed operational checks for inspector.
c) Dates of leak test records checked prior to date licensee received all sources.

File No.: 3
Licensee: Amarillo Diagnostic Clinic License No.: L04085
Location: Amarillo, TX Inspection Type: Unannounced/Routine
License Type: Medical Priority: 2
Inspection Date: 05/17/96 Inspector: RA

Comments:
a) License authorizes diagnostic use only but report indicates therapy also performed.
b) Instrument calibration expired but not identified.
c) NOV issued for dosimetry records not maintained but report indicates records available through 04/96.

File No.: 4
Licensee: X-Cel Group, Inc. License No.: L03548
Location: Corpus Christi, TX Inspection Type: Unannounced/Routine/Partial
License Type: Industrial Radiography Priority: 1
Inspection Date: 05/09/95 Inspector: DC

Comment:
a) No description of inspection findings related to management.

File No.: 5
Licensee: Bay Area Healthcare Group, Ltd.
License No.: L09723
Location: Corpus Christi, TX
Inspection Type: Initial/Partial
License Type: Eye Applicator
Priority: 2
Inspection Date: 01/08/97
Inspector: DC

Comment:
a) Unable to determine whether inspection announced or unannounced.

File No.: 6
Licensee: Star-Jet Services, Inc.
License No.: L02214
Location: Corpus Christi, TX
Inspection Type: Unannounced/routine
License Type: Well-logging
Priority: 1
Inspection Date: 10/16/96
Inspector: DC

Comment:
a) No description of inspection findings related to management.

File No.: 7
Licensee: Boart Longyear
License No.: L04302
Location: Houston, TX
Inspection Type: Unannounced/Routine
License Type: Gauge service
Priority: 2
Inspection Date: 06/28/96
Inspector: LC

Comment:
a) Several NOV's identified in 1994 but not issued until 1996 inspection.

File No.: 8
Licensee: Houston Northwest Radiotherapy Center
License No.: L02916
Location: Houston, TX
Inspection Type: Announced/Routine
License Type: Teletherapy
Priority: 1
Inspection Date: 08/29/95
Inspector: LC

File No.: 9
Licensee: Scott & White Memorial Hospital
License No.: L00331
Location: Temple, TX
Inspection Type: Announced/Routine
License Type: Nuclear medicine
Priority: 3
Inspection Date: 12/19/96
Inspector: CD

Comment:
a) Unable to determine whether emergency instructions to workers inspected or employee interviews performed.

File No.: 10
Licensee: H&H X-Ray Services, Inc. License No.: L02516
Location: Tyler, TX; Bryan, TX Inspection Type: Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 02/27/97 Inspector: CD

File No.: 11
Licensee: Reinhart and Associates, Inc. License No.: L03189
Location: Austin, TX Inspection Type: Announced/Routine
License Type: Industrial radiography Priority: 1
Inspection Date: 12/13/96 Inspector: CD

Comment:
a) No observation of licensee field operations.

File No.: 12
Licensee: Cleveland Regional Medical Center License No.: L02055
Location: Cleveland, TX Inspection Type: Announced/Routine
License Type: Nuclear medicine w/therapy Priority: 1
Inspection Date: 02/06/97 Inspector: HD

Comments:
a) Physician using radioactive material not named on license.
b) No description of inspection findings related to management.
c) Closeout of previous NOV not clearly documented.

File No.: 13
Licensee: Blood Center of Southeast Texas, Inc. License No.: L04399
Location: Beaumont, TX Inspection Type: Unannounced/Initial
License Type: Irradiator Priority: 2
Inspection Date: 04/29/97 Inspector: HD

Comment:
a) Survey meter not required to be available by license; unclear how licensee monitors during emergencies.

File No.: 14
Licensee: Syncor International Corp. License No.: L02048
Location: Dallas, TX Inspection Type: Announced
License Type: Pharmacy Priority: 1
Inspection Date: 03/13/97 Inspector: RE

Comments:
a) Inspector surveys or independent measurements not documented.
b) Field note form outdated.

File No.: 15
Licensee: Physician Reliance Network, Inc. License No.: L05019
Location: Sherman, TX Inspection Type: Announced/Initial
License Type: Brachytherapy Priority: 1
Inspection Date: 02/27/97 Inspector: RE

Comments:
a) Field note form outdated.
b) Report indicates no dosimetry badges available but sources transferred on 2/19/97.

File No.: 16
Licensee: Corpus Christi Inspection & Engineering Inc. License No.: L04379
Location: Houston, TX Inspection Type: Unannounced/Initial
License Type: Industrial Radiography Priority: 1
Inspection Date: 10/16/96 Inspector: EF

Comment:
a) No description of inspection findings related to management.

File No.: 17
Licensee: University of Texas Health Science Center License No.: L02774
Location: Houston, TX Inspection Type: Announced/Routine
License Type: Broad medical Priority: 1
Inspection Date: 03/18-20/97 Inspector: EF

Comments:
a) Field note form outdated (1986).
b) Inspection overdue.
c) Inspector smears did not include laboratory sink areas where small amounts of tritium disposed.

File No.: 18
Licensee: SPL Wireline Services, Inc. License No.: L01983
Location: Granbury, TX Inspection Type: Unannounced/Routine
License Type: Well-logging Priority: 1
Inspection Date: 04/09/96 Inspector: CL

Comment:
a) Emergency equipment not checked in 1995 or 1996 reports.

File No.: 19
Licensee: Sterigenics International, Inc. License No.: L03851
Location: Fort Worth, TX Inspection Type: Announced/Routine
License Type: Pool irradiator Priority: 1
Inspection Date: 05/03/96 Inspector: CL

Comment:
a) Cannot determine whether licensee performed operational checks for inspector.

File No.: 20
Licensee: BPB Instruments, Inc. License No.: L04405
Location: Kilgore, TX Inspection Type: Announced/Routine
License Type: Well-logging Priority: 1
Inspection Date: 05/16/97 Inspector: MV

Comment:
a) Report indicates material used 11/96, but license not issued until one month later.

File No.: 21
Licensee: East Texas Medical Center License No.: L00977
Location: Tyler, TX Inspection Type: Announced/Routine
License Type: Medical - Diagnostic & therapy Priority: 1
Inspection Date: 01/30-31/97 Inspector: MV

Comments:
a) Unable to determine how 2 misadministrations followed up during inspection.
b) Response to NOVs not in file.

File No.: 22
Licensee: Baylor University License No.: L01290
Location: Dallas, TX Inspection Type: Announced/Routine
License Type: Broad medical Priority: 1
Inspection Date: 03/12/96 Inspector: RW

File No.: 23
Licensee: Bonded Inspections, Inc. License No.: L00693
Location: Garland, TX Inspection Type: Announced/Routine
License Type: Industrial radiography Priority: 1
Inspection Date: 04/14-15/97 Inspector: RW

Comments:
a) No observation of licensee field operations.
b) Worker interviews not documented.

Inspection accompaniments:

Accompaniment No.: 1
Licensee: Bonded Inspections, Inc. License No.: L00693
Location: Garland, TX Inspection Type: Announced/Routine
License Type: Industrial radiography Priority: 1
Inspection Date: 04/14-15/97 Inspector: RW

Accompaniment No.: 2
Licensee: Denton Regional Medical Center License No.: L02764
Location: Denton, TX Inspection Type: Announced/Routine
License Type: Hospital Priority: 2
Inspection Date: 04/16/97 Inspector: RE

Accompaniment No.: 3
Licensee: Longview Inspection License No.: L01774
Location: Longview, TX Inspection Type: Announced/Routine/Complete
License Type: Industrial Radiography Priority: 1
Inspection Date: 04/17/97 Inspector: MV

Accompaniment No.: 4
Licensee: Syncor International Corporation License No.: L03398
Location: Amarillo, TX Inspection Type: Unannounced/Routine/Complete
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 05/20/97 Inspector: RA

Accompaniment No.: 5
Licensee: Syncor International Corporation License No.: L02117
Location: Austin, TX Inspection Type: Unannounced/Routine/Complete
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 05/21/97 Inspector:

Accompaniment No.: 6
Licensee: Gulf Coast Inspection License No.: L04934
Location: Ingleside, TX Inspection Type: Routine/Unannounced
License Type: Industrial Radiography Priority: 1
Inspection Date: 06/11/97 Inspector: DC

Accompaniment No.: 7
Licensee: Associated Testing Labs, Inc. License No.: L01553
Location: Corpus Christi, TX Inspection Type: Routine/Announced
License Type: Gauge Priority: 2
Inspection Date: 06/11/97 Inspector: DC

Accompaniment No.: 8
Licensee: MacGregor Medical Associates
License No.: L04646
Location: Houston, TX
Inspection Type: Routine/Unannounced
License Type: Nuclear Medicine
Priority: 2
Inspection Date: 06/12/97
Inspector: DS

Accompaniment No.: 9
Licensee: CAMCO
License No.: L03303
Location: Houston, TX
Inspection Type: Routine/Unannounced
License Type: Industrial Radiography
Priority: 1
Inspection Date: 06/12/97
Inspector: DS

Accompaniment No.: 10
Licensee: Santa Rosa Health Care Corporation
License No.: L02237
Location: San Antonio, TX
Inspection Type: Routine/Unannounced
License Type: Nuclear Medicine & Brachytherapy
Priority 1
Inspection Date: 06/24/97
Inspector: RW

APPENDIX F
INCIDENT FILE REVIEWS

File No.: 1
Licensee: Unknown
License No.: NR
Location: Midland, TX
Date of Event: 08/18/95
Type of Event: Release of Radioactive Material
Summary: A State inspector found Ir-192 contamination near a concrete wash bay at a truckwash. An area of ground read 3 mrem/hr on contact.

Comments:
a) The State could not determine who was responsible for the contamination.
b) The contaminated dirt was removed and transferred to a local company (authorized for radioactive material storage) to be held for decay.

File No.: 2
Licensee: Texas A&M University.
License No.: 42-09082-09
Location: College Station, TX
Date of Event: 10/12/94
Type of Event: Release of Radioactive Material
Summary: A dog injected with 17 mCi of Tc-99m voided contaminated urine resulting in contamination being spread to several locations of the clinic before nuclear medicine staff became aware of the event. The clinic did not notify the Radiation Safety Office until the day after discovery of the event. The licensee provided detailed documentation of the event to Texas. Several violations were issued.

Comment:
a) An on-site investigation was not conducted due to the short half-life of the radionuclide involved.

File No.: 3
Licensee: Kooney X-Ray
Location: Barker, TX
License No.: NR
Date of Event: 02/08/95
Type of Event: Loss of Radioactive Material
Summary: A 33 Ci Ir-192 radiography camera was reported lost by the licensee. It was found by an individual who reported it to authorities.

Comment:
a) Camera had fallen off a truck. No apparent damage occurred. The licensee was cited for violations.

File No.: 4
Licensee: Midland Inspection and Engineering
Location: Odessa, TX
License No.: NR
Date of Event: 03/24/95
Type of Event: Equipment Failure
Summary: A 20 Ci Ir-192 source became disconnected due to a worn ball on the end of the drive cable and resulted in a 18 mrem dose to the RSO during source retrieval.

Comment:
a) The cable was sent to the manufacturer for repair. No analysis of the failure was documented in the file.

File No.: 5
Licensee: Petroleum Industry
Location: Houston, TX
License No.: NR
Date of Event: 09/12/95
Type of Event: Equipment Failure
Summary: A 56 Ci Co-60 radiography source could not be retrieved back into the camera due to apparently worn bearings in the crank handle. The source was retrieved by manually pulling the source cable. There were no excessive exposures.

Comments:
a) Although the crank had been inspected two weeks earlier and no problems were noted, the licensee believes the crank handle bearings had become pressed together due to daily wear and tear.
b) There was no evaluation of whether the failure was a user problem or product problem. No information of the failure was sent to the manufacturer.

File No.: 6
Licensee: Quantum Chemical
Location: Deer Park, TX
License No.: NR
Date of Event: 04/10/96
Type of Event: Equipment Failure
Summary: A nuclear density gauge 3 Ci Cs-137 was left in the open position due to the gauge's rusted handle/shaft breaking off when shutter closure was attempted.

Comments:
a) The gauge was replaced by a service company.
b) The State did not investigate the root cause of the severe rusting with respect to the conditions of use or type of material used in the handle/shaft.
c) The State did not notify the gauge manufacturer of the failure.

File No.: 7
Licensee: H and G Inspection Company
Location: Houston, TX
License No.: NR
Date of Event: 03/27/95
Type of Event: Equipment Failure
Summary: The automatic locking device on a radiography camera would not allow the radiographer to crank the source out to an exposed position. The RSO cleaned the locking device and the device operated correctly.

Comments:
a) The NMED event date is incorrectly listed as 03/27/75.
b) The licensee determined that a stiffer housing on the crankout device corrected the problem and notified the manufacturer of the problem.

File No.: 8
Licensee: X-Cel Group, Inc.
Location: Corpus Christi, TX
License No.: NR
Date of Event: 08/23/94
Type of Event: Equipment Failure
Summary: A 29 Ci, Ir-192 source became stuck in the guide tube of a radiography camera. Two radiographers retrieved the source without contacting the RSO. No overexposures resulted.

Comments:
a) A violation was issued for not following emergency procedures.
b) A rusted cable was the apparent cause of the source jam.
c) The State did not evaluate the conditions of use that may have led to the excessive rusting.

File No.: 9
Licensee: TN Technologies, Inc.
Location: Round Rock, TX
License No.: 42-01485-04
Date of Event: 03/27/95
Type of Event: Equipment Failure
Summary: A retaining ring on a gauge source holder assembly failed and allowed the source capsule containing 100 mCi of Cs-137 to fall out of the gauge during an attempt to turn on the gauge. The area was secured and the licensee was notified. The licensee repaired the source and shutter assembly.

Comments:
a) No overexposures occurred during the event.
b) Although it was determined that no generic problem or design defect caused the failure of the retaining ring, the assembly was redesigned to eliminate future failures.
c) The State did not evaluate the root cause of the retaining ring failure.

File No.: 10
Licensee: University of Texas
Location: San Antonio, TX
License No.: NR
Date of Event: 09/12/95
Type of Event: Misadministration
Summary of Incident: A 50 mCi Cs-137 source was inadvertently left on the patients bed at the time of loading. It remained on the patients bed for 22 hours before it was discovered.

Comments:
a) The therapy plan was revised to obtain the prescribed dose to the area of interest.
b) The worst case skin dose scenario calculated to be 17,600 rad.
c) Texas conducted an on-site investigation and concurred with hospital's corrective and preventive actions.

File No.: 11
License: K. G. Taylor, Co.
License No.: NR
Location: Odessa, TX
Date of Event: 06/09/94
Type of Event: Potential Source Damage
Summary: A local health department notified Texas of a fire in a wooden storage shed involving a 250 mCi Am-Be calibration source. Texas conducted an on-site inspection and determined there was no contamination and no damage to the source

File No.: 12
License: BIX Testing Laboratory
License No.: NR
Location: Odessa, TX
Date of Event: 03/23/94
Type of Event: Overexposure
Summary: A radiography trainee who was not qualified to perform radiography attempted to take some radiographs on his own while the other radiographer was developing films. When the trainees dosimeter was observed to be off-scale, the film badge was processed and indicated a 21.36 rem whole body dose.

Comment:
a) The State immediately performed an on-site inspection and issued violations and proposed an administrative penalty.

APPENDIX G
SEALED SOURCE AND DEVICE REVIEWS

File No.: 1
Registry No.: TX-0642-D-101-B
Licensee: Tremetrics Chromatography Group, Finnigan Corporation
SSD Type: Electron Capture Detector Cell
Date Issued: 08/08/94

Comments:
1. The 08/8/94 action was a name change only. The request letter lists Finnigan Corporation, Tremetrics Chromatography Group, but the registration certificate lists it TCG, FC. The same appeared on TX-0642-D-102-B and TX-0642-D-801-B. The review team suggests that all three registration certificates be corrected at the next amendment.
2. With the 05/16/94 action for the wipe test procedures, it states " Place the blank inspection sheet and a copy of your license along with...." This is apparently directed toward Specifically Licensed Users (SLs). Since the procedure would apply to all users including Generally Licensed Users (GLs), it may be confusing to GLs since they may not know what to do about the "copy of their license." The review team suggests that the procedures be rewritten to apply accurately to GLs as well as SLs at the next time that the file is opened.

File No.: 2
Registry No.: TX-0642-D-102-B
Licensee: Tremetrics Chromatography Group, Finnigan Corporation
SSD Type: Electron Capture Detector Cell
Date Issued: 08/08/94

No comments.

File No.: 3
Registry No.: TX-0642-D-801-B (was 642/103)
Licensee: Tremetrics Chromatography Group, Finnigan Corporation
SSD Type: Electron Capture Detector Cell
Date Issued: 08/08/94

Comments:
1. The review team did not find a request letter from the distributor requesting that the registration certificate TX-0642-D-103-B be changed to inactive. The reviewer could not find the letter either and believes that the Tremetrics RSO transmitted the request via phone, and that the phone call was not documented. The review team suggests that all requests be documented.
2. With regard to taking a registration certificate inactive, the reviewer said that the distributor states that there were no changes to the device, therefore the only change made to the registration certificate was to change the product number in the registration certificate number. The review team suggests that when a registration certificate is taken inactive, that the reviewer determine the total number of units distributed, the number of units still in the field, and ensure that all letters listed in the REFERENCE section of the registration certificate are in the file (with attachments). The review team also suggests that the registration certificate be changed to past tense as appropriate (i.e. change "the model XX is authorized for distribution to specific licensees" to "as of x/x/xx, the model XX

is no longer authorized for distribution." The reviewer says that State procedures for amendments to active registration certificates includes ensuring that the material in the file is up to current standards, so that if there has been a change in what is required or the level of detail required for the file, the distributor will be asked to provide it. The review team suggests that this procedure be extended to requests to make a registration certificate inactive as far as practicable.

File No.: 4
Registry No.: TX-0634-D-169-B
Licensee: TN Technologies Inc.
SSD Type: X-Ray Analyzer
Date Issued: 04/25/94

No comments.

File No.: 5
Registry No.: TX-0634-D-131-B
Licensee: TN Technologies Inc.
SSD Type: Fixed Gauge
Date Issued: 01/11/96

Comments:

1. The 05/12/95 registration certificate added the 5034A to use a 2 ft belt vs a 3 ft belt (same source and source holder as already approved for the 5034), and removes a protective screen for this model. The deficiency letter asks the applicant to justify having no guard. The applicant's response says that they will use a guard, but then the next document in the file is the SS&D which says there is no guard and that the vertical distance will be 7.5 inches or less. It is not apparent from the file where the applicant stated that there would be no guard, and that the vertical distance between the source housing and the detector would be restricted to a maximum of 7.5." Upon discussion with the reviewer, the reviewer stated that he thought the applicant may have provided that information in a phone call. The review team suggests that all information pertaining to the design or limitations of an item, or to applicant commitments, be adequately documented.
2. There appears to be a letter missing between TN's 04/28/95 response and the SS&D dated 05/12/95, and a 08/14/95 letter missing which may address the issue of the screen guards. During interviews with the reviewer, the reviewer could not find the documents either.
3. The SS&D indicates that the vertical distance between the source housing and the detector will be no more than 7.5." Since the approval of this device for use without guard screens by generally licensed users is based on this restriction, the review team suggests that this be included as an item in the LIMITATIONS section of the registration certificate to ensure that the restriction is clear.
4. The registration certificate dated 07/19/95 added the 5038A, which is the 5038 widened an extra 12" and raised 7," and still has guard screen for distribution to GLs. The request letter says that "in the event that the 5038A is distributed to a plant where an individual is able to enter the area between the detector and source housing (i.e., no GL guards provided)" that lock-out procedures will be provided. The registration certificate should

indicate that the model 5038A can be distributed without the guards to specifically licensed users only and require that lock-out procedures be provided.

File No.: 6
Registry No.: TX-0634-D-138-B
Licensee: TN Technologies Inc.
SSD Type: Fixed Gauge
Date Issued: 01/11/96, corr. pg 01/25/96

Comment:
1. The reviewers completed but the file did not document that the reviewer evaluated the impact that the reduced wall thickness resulting from enlarging the inside of the source holder would have on the integrity of the holder. The review team suggests that this be documented.

File No.: 7
Registry No.: TX-0246-D-103-S
Licensee: Oceaneering International Inc.
SSD Type: Industrial Radiography
Date Issued: 11/09/95

Comments:
1. Texas regulations state that "31.53 (a) Radiographic exposure devices and associated equipment shall meet the criteria set forth by ANSI N432-1980. (1) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after 09/01/93, shall comply with the requirements of this part." This device does not appear to meet these requirements. The review team suggests that the registration certificate reflect this to assist license reviewers using the registration certificate. (examples of what it does not meet - 31.53(b)(3))
2. The external radiation levels listed in the application and the registration certificate do not obey I1 D1 D1 = I2 D2 D2. The distance from the source to the outside surface of the head is 1.855." Section 31.50(a)(1) of the Texas regulations states that for any exposure device measuring less than 4" from the source storage position to the surface of the device shall have no radiation level in excess of 50 mR/hr at 6 inches from any exterior surface of the device." Using the values given for the external radiation levels to calculate the external radiation level at 6 inches (15.24 cm) from the surface of the device, gives values ranged from 3.079-5.788 mR/hr using the 5 cm value, to 54.74-71.46 m/hr using the 100 cm value. The range results from whether the 5/30/100cm distances were measured from the surface of the gauge or from the source. The values at 6 inches using the 100 cm value all exceed the 50 mR/hr max required in the regulations. The review team recommends that the manufacturer be contacted for corrected information.
3. Quality assurance/control checks only for mechanical and electrical function. The review team recommends that the State obtain commitments from the manufacturer to ensure that external radiation levels are checks on all units and that a program be developed to ensure that these devices are fabricated according to the drawings submitted in support of the evaluation.
4. "DIAGRAM: See Attachments" is on the registration certificate twice.

5. When the transit cover or the actuator is removed from the head, the depleted uranium (DU) shield is exposed, allowing direct contact with the surface of the DU shield and allowing any loose DU contamination and DU corrosion products to escape. The DU shield is not coated or painted. There is no limitation that requires that actuator removal be performed in an area where contamination from the loose DU can be controlled. The review team recommends that the State evaluate this issue to determine whether the design should be required to encase the DU shield, or a Reviewer Note be placed on the registration certificate and procedures be placed in the manual which address this.
6. The tube inside the DU shield does not extend to the end of the hole in the DU shield. The review team recommends that the State review this issue to determine whether the damage to the DU shield that might result during source exchange or replacement would justify requiring a design change to extend the end of the sleeve to outside the DU shield.
7. Drawings referenced by the licensee providing information regarding materials, assembly methods, and source containment were not provided to the State (ex. Dwg 401 as referenced in Dwg 004A.) The review team recommends that the State obtain all referenced drawings, and ensure that questions regarding materials, assembly methods, and source containment are adequately addressed.
8. Dwg 004A refers to Dwg 401, but the drawing for part 401 does not look like what is shown in Dwg 004A. The review team recommends that the State review the drawings to ensure adequacy of design and compatibility of components.
9. The safety evaluation was performed assuming that device was a mobile unit. The device as registered is less than 50 lbs. and may be considered portable. The device as used (and leased) is mounted on a crawler and could be considered mobile. The review team recommends that the State review this issue to determine whether the evaluation should be performed on the device as registered or as used.