

DATED: DECEMBER 30, 1997

SIGNED BY: HUGH L. THOMPSON, JR.

Mr. Mark E. Weidler, Secretary
Environment Department
1190 St. Francis Drive
P.O. Box 26110
Santa Fe, NM 87502

Dear Mr. Weidler:

On October 23, 1997 and December 11, 1997, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New Mexico Agreement State Program. The IMPEP review was conducted July 14-18, 1997. The MRB had received for consideration the actions described in your letter of October 10, 1997 and William M. Floyd's letter dated December 3, 1997. The MRB found the New Mexico program adequate but needs improvement, and compatible with NRC's program. Because of the significance of the concerns, the MRB recommends heightened oversight of the New Mexico program. I request that monthly conference calls take place with the appropriate New Mexico and NRC staffs to discuss the status of the program. The Office of State Programs will coordinate the monthly teleconferences. I also request that written progress reports addressing the IMPEP team's suggestions and recommendations found in Section 5.0, page 19, of the enclosed final report be submitted to Richard L. Bangart, Director, Office of State Programs, every other month. The first progress report is requested by February 1, 1998.

Based on the results of the current IMPEP review, the follow-up review will be scheduled for July 1998. The follow-up review will cover the State's action on the recommendations from the July 1997 review.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review, to me and my staff during our December 4, 1997 meeting, and your continuing support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely, */RA/*

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Benito Garcia, NM
Ed Kelley, NM
William Floyd, NM

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 Deputy Executive Director
 for Regulatory Programs

Enclosure:

As stated

cc: Benito Garcia, NM
 Ed Kelley, NM
 William Floyd, NM

bcc: Chairman Jackson
 Commissioner Dicus
 Commissioner Diaz
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NEW MEXICO AGREEMENT STATE PROGRAM

July 14-18, 1997

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the New Mexico radiation control program. The review was conducted during the period July 14-18, 1997, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Washington. 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 August 13, 1994 to July 13, 1997, were discussed with New Mexico management on July 18, 1997.

A draft of this report was issued to New Mexico for factual comment on August 8, 1997. The State requested and received a month's extension for replying to the draft report. The State of New Mexico responded in a letter dated October 10, 1997 (Attachment 1). The State's factual comments were incorporated in the final report. The Management Review Board (MRB) met on October 23, 1997 to consider the proposed final report. At the time of the review, the review team found the State's performance to be satisfactory for the indicator, Technical Quality of Licensing Actions; satisfactory with recommendations for improvements for the indicators, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Staffing and Training; and unsatisfactory for the indicator, Response to Incidents and Allegations. The review team recommended that the New Mexico program be found adequate, but needs improvement, and compatible. Because of the significance of the concerns, the team also recommended that New Mexico be placed on probation and noted that heightened oversight is warranted. During the MRB meeting, three main issues were identified that New Mexico had to address in terms of programmatic improvements: (1) level of program staff and amount of resource support, (2) technical quality of staff and training needs, and (3) level of management support, involvement and oversight of New Mexico Agreement program activities. The MRB found the New Mexico program adequate, but needs improvement, and compatible with the NRC's program. The MRB concluded that it would be appropriate for NRC management to meet with upper management of the New Mexico program before the MRB voted on the recommendation for probation status for the program.

On December 4, 1997, Mr. Thompson, NRC and other NRC managers met with Secretary Mark Weidler, New Mexico Environment Department and his staff to discuss performance concerns associated with the New Mexico Agreement program. See Attachment 2, December 4, 1997 NRC/New Mexico Management Meeting Minutes.

On December 11, 1997, the MRB reconvened to discuss probation for the New Mexico program. Based on the New Mexico actions to date, and the commitments by Secretary Weidler, the MRB concluded probation was not warranted. Based on implementation of new procedures for response to incidents, the MRB directed the team to revise the finding for the common performance indicator, Response to Incidents and Allegations, to a satisfactory with recommendations for improvements. The MRB directed that the follow-up review be conducted

within one year of the IMPEP review, that monthly conference calls take place with New Mexico staff, and that written progress reports be submitted every other month.

The New Mexico Environment Department is the agency within the State of New Mexico that regulates, among other public health issues, radiation hazards. The New Mexico Environment Department Secretary is appointed by and reports to the Governor. Within the Environment Department, the radiation control program is administered by the Radiation Licensing and Registration Program (RLRP) under the direction of the Hazardous and Radioactive Materials Bureau (HRMB). The New Mexico Environment Department and HRMB organization charts are included as Appendix B. The New Mexico program regulates approximately 245 specific licenses, which includes a megacurie pool irradiator, manufacturers, broad academic programs, broad medical programs, nuclear pharmacies and industrial radiographers.

The review focused on the materials 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 New Mexico.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on April 10, 1997. New Mexico provided its response to the questionnaire on June 16, 1997. A corrected copy of the questionnaire was received on July 25, 1997. A copy of that response is included as Appendix C to this report.

The review team's general approach for conduct of this review consisted of: (1) examination of New Mexico's response to the questionnaire, (2) review of applicable New Mexico statutes and regulations, (3) analysis of quantitative information from the radiation control program licensing and inspection database, (4) technical review of selected licensing and inspection actions, (5) field accompaniments of three New Mexico inspectors, and (6) interviews with staff and management 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 performance indicator and made a preliminary assessment of the radiation control program's performance.

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 performance 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 possibly enhance the State's program. Recommendations made by the review team are comments the review team believes are areas to be addressed to maintain 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 August 12, 1994, and the results were transmitted to Judith M. Espinosa, Secretary, New Mexico Environment Department, on February 7, 1995. The review findings resulted in recommendations in two program indicators. The team's review of the current status of these recommendations is as follows:

- (1) At the time of the 1994 review, the New Mexico radiation protection regulations had last been amended on March 10, 1989. Compatibility was withheld because the State had failed to meet the three-year time frame required for adopting regulations equivalent to nine NRC regulations deemed matters of compatibility: (1) bankruptcy notification, (2) quarterly audit of the performance of radiographers, (3) well logging requirements, (4) National Voluntary Laboratory Accreditation Program (NVLAP) certification of dosimetry processors, (5) decommissioning requirements, (6) emergency plans, (7) safety requirements for radiographic equipment, (8) 10 CFR Part 20 equivalent regulations, and (9) notifications of incidents.

Current Status: New Mexico's regulations equivalent to the nine NRC regulations listed above were part of a package of regulations which were adopted on April 3, 1995, and which became effective on May 3, 1995. After reviewing the drafts of these proposed regulations, in a letter dated January 9, 1995, the Office of State Programs (OSP) offered the State a tentative finding of compatibility pending NRC review of the final, published regulations. The review team evaluated the published regulations against the equivalent NRC regulations. Pending review by NRC's Office of General Counsel (OGC), the team recommends that these regulations be found compatible with NRC requirements. This recommendation is closed.

- (2) The 1994 review recommended that the State review and compile internal procedures for staff use in the interest of maintaining consistency in licensing and compliance activities.

Technical staff members wrote procedures for licensing, inspection and allegation follow up. The procedures have not been shared with all staff members, however, creating program inconsistencies which are discussed in Sections 3 and 4 of this report. 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 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 the New Mexico questionnaire responses relative to this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

The team's review of the State's inspection priorities verified that the State's inspection frequencies for various types or groups of licenses are at least as frequent as similar license types or groups listed in the NRC Inspection Manual Chapter 2800 (IMC 2800) frequency schedule, with one exception. The New Mexico inspection frequency for nuclear pharmacies is 2 years as opposed to one year in IMC 2800. Staff indicated that this difference was due to an oversight as the State copy of IMC 2800 was out of date. The review team recommends that the nuclear pharmacy inspection frequency be modified from 2 years to 1 year.

In reviewing the State's priority schedule, the review team noted that none of the New Mexico inspection frequencies exceed 3 years. Specifically, examples of license categories in which the State requires more frequent inspections are as follows:

<u>Type of License</u>	<u>New Mexico Frequency (years)</u>	<u>NRC Frequency (years)</u>
Well logging	2	3
Medical institution	2	3 or 5
Medical private practice	2	3 or 5
Academic Type B broad	2	3
Veterinary	2	5
Portable gauges	2	5
Fixed gauges	3	5

In response to the questionnaire, New Mexico indicated that no inspections were overdue by more than 25% of the scheduled frequency. The team identified several inspections that were overdue compared to the State frequencies but would not be considered overdue with respect to IMC 2800 frequencies.

With respect to initial inspections of new licenses, the team evaluated the inspection tracking data system and verified that initial inspections were entered into the computerized tracking system together with existing licenses. Inspection due dates generated by the system for new licenses are combined by inspection priority with those for other materials licenses. A review of the inspection tracking system showed that initial inspections are not differentiated from routine inspections, since the tracking system does not display a six month due date for initial inspections. From interviews, team reviewers found that the inspection staff was generally able to identify licenses due for initial inspections by the license number. The higher-numbered licenses are new issues indicating an initial inspection is necessary.

A review of 25 license files, with initial inspections due during the review period, identified eight licenses which had initial inspections performed within 6 months. Nine licenses had initial inspections performed late, ranging from 1 to 21 months past the six-month window, and eight licenses were overdue for initial inspections at the time of the review, from 1 to 34 months past the six-month window. The review team recommends that initial inspections of licensees be performed within 6 months of license issuance or within 6 months of the licensee's receipt of material and commencement of operations, consistent with IMC 2800. Also, the review team recommends that the tracking system be revised to allow initial inspections to be readily identified to staff and management.

In their response to the questionnaire, RLRP reported that 148 reciprocal licenses were issued; however, only about one-half of the reciprocity licensees filed notifications and received authorization to conduct activities during the review period. Of the 148 reciprocal licenses issued, 45 were industrial radiographers, 26 were well loggers and four were teletherapy/high dose rate afterloader source replacements. Approximately one-half of the reciprocities were for gauge or portable device uses. RLRP performed only three inspections of reciprocity licensees, two industrial radiographers and one gauge user, during the review period.

Reciprocity requests are recorded in a log and are available for review by inspectors but inspections are rarely performed. Both program management and staff indicated that short lead times and significant travel distances were impediments to performing reciprocity inspections. The review team recommends that the State increase the number of reciprocity inspections to better evaluate the health and safety implications of out-of-state companies working in New Mexico.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. For the inspection findings examined, the correspondence for nine inspections was sent to the licensee within 30 days of the inspection date. Eight inspections were "clear," and in several cases the inspection correspondence was sent within 1 to 2 days after the inspection. For three inspections, the correspondence was sent to the licensee greater than 30 days past the inspection date. All involved cases with deficiencies that were noted by the inspector. (New Mexico's definition of "deficiency" is identical to NRC's definition of "violation." In this report, the two terms are interchangeable.) Inspection deficiency letters to New Mexico licensees require a higher level of signature (Chief, HRMB), rather than the inspector. Two of the three letters were dispatched within 40 days of the inspection date. The third was issued 3 months after the inspection date. In the longest (3-month) case, the inspector was relatively new and did not understand the significance of quickly informing the licensee, in writing, of the inspection findings. While the New Mexico program has a few cases where inspection results were issued late (i.e., past the 30-day IMPEP criterion), the review team found that performance in this area was generally acceptable.

Based on the IMPEP evaluation criteria, the review team recommends that New Mexico's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory with recommendations for improvement.

3.2 Technical Staffing and Training

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 program management and staff, and considered any possible workload backlogs.

The RLRP Manager stated that all technical staff positions require a bachelor's degree in the sciences. Positions are classified as either Environmental Specialists, requiring 4 years experience or as Environmental Scientists, with 2 years experience.

The RLRP has a staffing level of one manager, five Environmental Specialists and one secretary. One of the Environmental Specialist positions was vacated on July 1, 1997, when a staff member retired. Another Environmental Specialist is expected to retire in 1997. This staff is responsible for the radioactive materials program, the Naturally Occurring Radioactive Material (NORM) program and the x-ray program. Approximately 55% of each Environmental Specialist's time is allocated for the Radioactive Materials Program. This equates to approximately 2.75 technical FTEs for the 245 license program. Based on review results, this staffing level appears to be a minimal level for a program of this size. With the recent departure of a retired staff member, the staffing level is even lower and raises concerns about the general effectiveness of the program.

The HRMB Chief indicated that the vacant position and the upcoming vacancy would likely be filled in the near future. The authority to fill these positions has been granted. The review team recommends that the State maintain the RLRP staffing level to at least the level which existed throughout the review period.

The radioactive materials staff is split between two offices, the main office in Santa Fe, with the RLRP Manager and two Environmental Specialists and an office in Albuquerque, with two (three until recently) Environmental Specialists. The RLRP Manager stated that he had tried to have staff perform inspection and licensing at both offices but he brought all of the licensing work back to the Santa Fe office to centralize and manage the licensing program more effectively. The Santa Fe office staff took full responsibility for licensing due to this reorganization of responsibility.

With the exception of the individual who recently left the program and one outstanding course for one staff member, technical staff have attended the core NRC training courses. Two areas of significant training need were identified during the review and inspector accompaniments. The first area is irradiator technology, particularly important as the State licensed a megacurie pool type irradiator last year. Only limited training was received by one Environmental Specialist from the irradiator vendor as the facility was brought on line. The other area in which additional training is needed is medical brachytherapy. New Mexico has several medical licensees who utilize various brachytherapy modalities, including high dose rate afterloaders. None of the program staff have attended a brachytherapy training course or have had any other significant training or experience in this area.

The RLRP Manager stated that, as New Mexico does not charge fees to its licensees and the general fund allocation for training is extremely limited, there is little chance that RLRP personnel will attend any conventional NRC training courses, unless NRC reassumes the cost for such training. Program management was directed to All Agreement States Letter

SP-97-040, dated June 9, 1997, which proposed criteria for States with financial need to receive training aid from NRC. The team believes that New Mexico may be a strong candidate for receiving funding from the NRC for training purposes. The team also discussed with the RLRP Manager potential alternative training methods which could be used to train staff in brachytherapy and irradiator technology. The review team recommends that the State provide training to technical personnel in the areas of medical brachytherapy and irradiator technology.

The RLRP Manager stated that he provides on-the-job training to staff, explaining program procedures, and accompanies each inspector on at least two inspections per year. There is no

documented training and qualification program in place for the RLRP staff comparable to IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." As an example, the review team noted that licensing and inspection procedures had been developed by various staff members but that not all staff had been trained in these new procedures. The review team recommends that the State develop a formalized training program comparable to IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

Based on the team's finding and the IMPEP evaluation criteria, the review team recommends that New Mexico's performance with respect to this indicator, Technical Staffing and Training, be found satisfactory with recommendations for improvement.

3.3 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the reviewers for 11 specific licenses. Licensing actions were evaluated for completeness; consistency; proper isotopes 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 evaluated 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 cross-section sampling included several of New Mexico's major licenses and included the following types: nuclear laundry; pool irradiator; well logging; nuclear medicine; fixed gauge; academic research and development; veterinarian; and industrial radiography. Licensing actions evaluated included three new licenses, two renewals, one pending renewal, three amendments, and two terminations. In discussions with the RLRP Manager, it was noted that there were no major decommissioning efforts underway with regard to agreement material in New Mexico. Also, there were no identified sites with potential decommissioning difficulties equivalent to those sites in NRC's Site Decommissioning Management Plan. A list of these licenses with case-specific comments may be found in Appendix D.

The Interstate Nuclear Services (INS) license renewal was selected for review because the State has expended considerable staff resources with this renewal and is faced with opposition. A series of public hearings were held in 1996 culminating when the Secretary of the Department issued an order to renew the license subject to INS completing several conditions to the satisfaction of the Department. However, the main point of contention between the State and the opposition to renewal is the issue of "solubility" of radioactive particulates in liquid effluents discharged to the sewage system and whether the State will accept INS's proposed waste water treatment system. The State requested technical assistance from NRC. The State has sought to

identify potential contractors to evaluate the proposed waste water system and has queried other Agreement States to determine how the "solubility" criteria are being addressed in those States. INS has not yet submitted complete information to address all conditions of the Secretary's order. The license reviewer intends to require the licensee to consolidate the interim submittals into a final renewal package. A final license application review will be performed when the renewal package is complete. Issuance of this renewal is still pending.

With respect to the overall licensing program, the RLRP Manager stated that licensing quality had suffered when licensing actions were being handled out of two different offices. The RLRP Manager sought to improve licensing quality by bringing all licensing actions back to Santa Fe in early 1996. He also began performing many of the licensing reviews himself, concentrating on amendments and simple renewals to improve quality and consistency.

Licensing actions of all types appear to be completed in a timely fashion with most renewals being completed within 6 months of the expiration date. The RLRP Manager noted that "construction" visits were performed for the new panoramic, wet-storage irradiator and that an in-office consultation was held with another license applicant but there were no other pre-licensing visits for the few complex licenses that New Mexico had issued. The RLRP Manager estimated that as many as 50% of new licenses were hand delivered as a means of establishing open communications with new licensees.

Retention of supporting documentation is a program weakness. Required documents were found to be missing in 9 of 11 files evaluated. These documents included: licensee application submittals, a renewal request, a licensee's response to a compliance letter that required a licensing change, detailed schedules for testing and maintenance, evidence of named users' training and experience, verification that sources had been transferred properly, misfiled correspondence, and the results of close-out inspections. Documentation of the license reviewers work was particularly weak. Deficiencies identified by reviewers were apparently communicated by telephone in many cases with no record of the deficiency or its resolution unless the licensee's correspondence was clear. Reviewer checklists were present in new license files. The review team suggests that documentation of license reviewers' actions be maintained in license files.

All new licenses are reviewed and signed by the HRMB Director before being issued. All renewed licenses and amendments are reviewed and signed by the RLRP Manager. However, the RLRP Manager performs approximately one-half of all licensing actions and signs his own work without significant peer or supervisory review. No potentially significant health and safety issues were identified.

The review team found that, despite documentation deficiencies, the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues adequately addressed. Special license tie-down conditions were not observed. The licensee's compliance history was taken into account when reviewing renewal applications. New Mexico's licensing guides and license policy procedures were revised and updated after the last program review. New Mexico's licensing guides and license conditions were adopted directly from the NRC's. Reviews of licensing actions showed reviewers appropriately used the revised licensing

guides for new licenses and the absence of major findings indicates that the reviewers have a generally good understanding of applicable guidance.

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

3.4 Technical Quality of Inspections

The team reviewed the inspection reports, supporting documentation and correspondence to licensees for 12 materials inspections conducted during the review period. The casework included the State's four fully-qualified materials inspectors and one inspector who left the program during the review period (another inspector left the program early in the review period, and her work was not reviewed). Inspection reports were selected to cover the whole review period and to emphasize higher-priority licensees. The review team examined inspection casework of the following types of licensees: one medical institution; one pool-type irradiator; one nuclear laundry; one well logger; one nuclear pharmacy; one industrial radiographer; one portable gauge; two academic licensees; two research and development licensees (one of which "tagged" radionuclides to well logging tracers) and one broad medical that included a high dose rate (HDR) remote afterloader, brachytherapy, nuclear medicine, and academic research and development. Following the casework evaluation, the review team interviewed each of the four inspectors. Appendix E provides a list of the inspection cases evaluated in depth with case-specific comments.

Overall, the review team found that the inspector accompaniments and most inspection reports showed acceptable, but not strong, technical quality of inspections. Interviews with inspectors backed up the review team's findings that inspections were being conducted regularly, but moderate to significant areas that needed improvement were apparent in the State's inspection program.

Three inspector accompaniments identified in Appendix E were performed by a review team member on June 16-18, 1997. The other two New Mexico inspectors had been accompanied during past reviews. During the accompaniments, inspectors demonstrated a range in skills and abilities for the specific types of inspections they were performing. In two of the three accompaniments, inspection techniques were observed to be primarily records-review oriented, with missed opportunities when inspectors could have observed licensee operations. The accompaniments demonstrated that inspectors were not missing critical safety areas, but the inspections were not thorough, either. For example, on one accompaniment at a hospital, the inspector was not sufficiently trained in brachytherapy and missed opportunities to interview therapy technologists and ancillary personnel. In general, the inspections were adequate to assess the most significant radiological health and safety issues, although on some, the inspectors showed significant room for improvement.

Inspection reports were evaluated to determine if the reports adequately documented the scope of the licensed program, licensee organization, personnel protection, posting and labeling, control of materials, equipment, use of materials, transfer and disposal. The review team also evaluated

whether the reports adequately documented operations observed, interviews of workers, independent measurements, status of previous violations, substantiation of all violations and the substance of discussions during exit interviews with management. To assure consistency and quality of reports, the RLRP Manager provides review and signs inspection reports.

For 9 out of the 12 inspections reviewed, inspectors did not perform observations of licensee operations. In fact, on some inspection reports, the inspectors specifically noted that they had not observed licensee operations. In interviews, the inspectors asked the review team what type of operations should be observed, especially when conducting office inspections of industrial licensees and afternoon-inspections of diagnostic medical licensees. The review team noted that licensees can demonstrate actions (such as surveys, transportation practices, interlock checks, and so on), but the State inspectors did not indicate that such demonstrations or observations were being conducted on a routine basis during inspections. Even though the inspectors have attended the NRC inspection training course, the principal inspection effort seems focused on records review, which is contrary to the national (NRC and Agreement State) trend in inspecting for licensee performance. The review team recommends that the State inspectors attempt to observe licensee operations or demonstrations during all inspections.

On three of the inspections evaluated, inspectors did not conduct independent measurements. In one case, the inspector's survey instrument malfunctioned. The inspectors could not provide adequate explanation regarding why independent measurements were not conducted during the other two inspections. In other cases, independent measurements were performed but no specific results were indicated in inspection reports. Inspectors were knowledgeable that they should conduct independent measurements during inspections, and some inspectors even performed confirmatory measurements (i.e., side-by-side readings with licensee survey instruments), which is commendable. Conducting measurements for radiation levels should be an essential element of routine byproduct material inspections. The review team recommends that the State inspectors conduct independent measurements on all inspections.

The review team noted that, on a number of inspections evaluated, that the State was not examining complex, technical radiation safety/health physics issues in sufficient detail during inspections. For instance, on inspections of a medical institution using limited quantities of iodine-131 and on a tagging licensee, inspectors apparently did not review licensee effluent releases, even though the licensees had potential for material release. Similarly, inspectors did not regularly review bioassay adequacy or estimate doses (when licensees did not conduct bioassays), review Annual Limits on Intake and Derived Air Concentrations, provide dosimetry results on several inspection reports, and provide sufficient detail on a licensee's respiratory protection program. In addition to this lack of technical complexity and detail, the review team observed that many of the inspections omitted key program areas or were not sufficiently broad. For instance, the review team observed instances where RLRP inspections did not sufficiently close previous violations, address training, resolve emergency preparedness issues, address shipping or cover annual radiation protection program reviews. In response to these findings, the review team recommends that the State increase the rigor of reviewing technical health physics issues during inspections, and increase the breadth and scope of inspections. Additionally, the review team noted that few, if any, ancillary worker (such as facility housekeeping staff, students, administrative staff and medical assistants) interviews were conducted by the inspectors. The

review team suggests that the State inspectors attempt to interview ancillary workers during inspections.

On 8 of the 12 inspections evaluated, the inspector conducted exit meetings with the licensee's radiation safety officer (RSO) or a principal authorized user. In a few of these cases, the RSO was also a senior licensee manager. However, as determined through interviews, inspectors generally did not conduct exit meetings with senior licensee managers, or did not make substantial efforts to conduct exit meetings with senior licensee managers (i.e., managers who control the radiation safety program's authority, staffing, and resources). This is in conflict with the State's own policy that, "An exit interview with the highest available representative of administration or management shall be conducted by the inspector...." A cause of this may have been that few inspectors knew about the procedures. The review team recommends that the State inspectors attempt to conduct formal exit meetings with senior licensee management on all inspections.

The review team examined the State's performance regarding follow up on previously cited violations (deficiencies). On one of the inspections, the licensee was cited for failure to calibrate survey instrumentation. In response, the licensee stated what it had done to correct the problem. However, the licensee did not state what would be done to prevent this type of deficiency from occurring again in the future. On the same inspection, the licensee was cited for an unauthorized user. The licensee was told to amend its license to add an individual as an authorized user (the individual apparently was using material at the time of the inspection), but the file does not indicate that the licensee ever submitted an amendment request. On the next inspection, the licensee was again given a deficiency for the same type of issue (i.e., told to amend its license to add authorized users). Similar licensing issues were identified on other inspections. These findings led the review team to conclude that New Mexico needs a mechanism to ensure that licensee responses to deficiencies are adequate to address the cited problems, and that the deficiency is closed and followed up on a future inspection. The review team recommends that the State develop a formal process for reviewing licensee responses to deficiency letters and closing open deficiencies. The State's inspection finding regarding the unauthorized user also indicates that the State does not have a formal mechanism for transfer of information from the inspector to the license reviewer, or vice versa, and the review team confirmed this in interviews. The closest that inspectors come to passing along information to the next license reviewer is by telling them verbally about needed licensing actions. In the case noted above involving the unauthorized user, this method apparently did not work or was not used. The review team suggests that the State develop a formal process for inspectors and license reviewers to document and transmit pertinent information to each other for follow up.

The review team also examined whether the State's inspection files were complete. On two of the inspection files reviewed, the files did not contain responses to the licensees acknowledging their responses and stating that the issues would be followed up on future inspections. Through interviews, the review team learned that occasionally the licensee's response is filed in the license file in Santa Fe, without being transmitted to the Albuquerque inspector for review. The review team suggests that the State develop a process for ensuring that inspection files are complete, that all appropriate State documents are prepared and filed, and that licensee responses are received and filed.

Also in the area of documentation, the review team examined the inspection casework for the State's new pool-type irradiator. The review team found that the first full, documented inspection was conducted on July 1, 1997. A site visit on October 28, 1996, was also documented in a note to the inspection file. However, the July inspection listed a number of previous trips to the licensee's site where inspection activity was performed, but not documented (e.g., November 1996 source loading, December 1996 review of system operations and product dosimetry, etc.). Follow-up interviews with the inspectors confirmed that the State had conducted site visits or inspections to the irradiator that were not documented. This is significant with respect to the pool irradiator, because it is a new operation in New Mexico involving an extremely large inventory of licensed material. The review team recommends that the State begin documenting all trips to licensees' or applicants' facilities when inspecting licensed activities, performing special inspections, or performing pre-licensing site visits during construction. This documentation should be filed in the State's official inspection file.

The review team identified a number of problems, covering both content and documentation, in New Mexico's inspection program. The review team concluded that the RLRP Manager, who signs each of the inspection reports as a reviewer, had the opportunity to identify many of these issues during the supervisory review of the inspection reports. The review team recommends that the State management exercise more stringent supervisory review of inspection reports.

In the area of the State's programmatic policy and management, the inspection procedures and techniques utilized by New Mexico were evaluated and determined to be generally consistent with, albeit in far less detail than, the inspection guidance provided in IMC 2800. Few of the inspectors were aware of the presence of inspection guidance within the State. Training on the State's internal procedures is discussed in Section 3.2.

The State's inspection report forms were reviewed and found to provide general inspection areas consistent with the types of information collected under NRC's Inspection Procedure (IP) 87100 field notes. On the two most complex inspection cases reviewed (the irradiator and an HDR), the State used NRC's field notes. On its own forms, the State already has developed an inspection report format with major subheadings and spaces for narrative responses, a move away from the checklist format, which is the approach that NRC is adopting for materials inspections. The State has been revising its inspection report for approximately the past 2 years, according to the inspector with lead responsibility for the inspection form revision, and in that interim time period RLRP inspectors have used a variety of "draft" inspection report forms that the review team observed in the inspection files. In interviews, the review team learned that RLRP inspectors select their own forms for the type of inspection they are performing; the review team did not identify any internal requirement or standardization within the State to use a specific report form for documenting inspections. The review team also concluded that, because the inspection report forms frequently determine the areas examined during an inspection, the forms themselves may have contributed to the State's lack of breadth and technical complexity during its inspections. The review team suggests that the State complete its revision of the inspection report forms, insuring that each set of forms covers all key areas for the type of licensee being inspected, and that RLRP inspectors begin using the standardized form(s).

Most inspection forms, correspondence, and documents were found in the files. Documented inspection findings generally led to appropriate deficiency letters. In interviews with the inspectors, none could recall any escalated enforcement cases during the review period. Of the files reviewed, the State cites deficiencies on about one third of its inspections.

In response to the questionnaire, the State reported that supervisory inspector accompaniments were performed at least twice per year by the RLRP Manager for each inspector since the previous review. Performance evaluations are discussed with the inspector and the accompaniments documented. Accompaniments of less-experienced staff are also performed by senior inspectors.

The review team noted that RLRP has a sufficient number of calibrated, portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. The State also has available the services of the State's Scientific Laboratory Division in Albuquerque, which appeared to provide exceptional services on one of the inspections reviewed.

Based on the IMPEP evaluation criteria, the review team recommends that New Mexico's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory with recommendations for improvement.

3.5 Response to Incidents and Allegations

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 relative to this indicator and evaluated the incidents reported for New Mexico in the "Nuclear Materials Events Database (NMED)" against those contained in the New Mexico casework and license files. The team evaluated casework in the license files maintained in the Santa Fe office and in files from the Albuquerque office which were delivered to the review team. The team compiled a list of 31 incidents that had occurred in the State during the review period, examined the list for possible trends or generic issues, and chose 11 of the more significant incidents for in-depth review. The team also evaluated the State's response to the only two allegations reported by the State. A list of the incidents with comments is included in Appendix F.

The review of the incident casework revealed five serious generic deficiencies in RLRP's response to incidents. First, circumstances in 5 of the 11 incidents indicated the need for onsite response from the State; however, only one of the five received an onsite response, and it was not documented, and thus could not be confirmed. The review team recommends that the State make onsite, documented investigations of incidents, allegations, or misadministrations with potential health and safety effects (i.e., source disconnects, possible overexposures, lost sources, contamination, etc.).

Second, in all cases, documentation of the State's response was either missing or incomplete. The team found that the State has no procedures or forms in place to record information obtained in the incoming calls, to track the progress of the investigation, to document management involvement, or to close out the incident investigation. In evaluating the casework, the team

found that in five cases, the individual taking the incident report was not identified. In addition, none of the files contained the investigator's signature, evidence of management involvement or review, or any notation that the investigation was completed and closed out. The review team recommends that the State create an incident and allegation reporting form that would, at a minimum, identify the person taking the initial report, list the name and telephone number of the reporting party, provide the details of the incident or allegation as reported, record the State's conversation with the licensee or individual, describe corrective actions taken by the licensee, describe the investigation conducted by the State and the results, list citations or other regulatory actions, show the date the investigation was closed out and justification for closure, show date(s) incident was reported to the NRC or other agencies, and provide spaces for the signatures of the investigator and supervisor. A copy of the form should be maintained in the incident file and in the license file.

Third, none of the casework contained any indication that the State evaluated the licensee's response or corrective actions. It appeared the State relied entirely on the licensee's reports of the incident and their corrective actions. The review team recommends that the State establish a protocol for making independent investigations and evaluations of the licensee's actions.

Fourth, generic deficiencies were noted in five cases where the incident should have been followed up at the next inspection, but was not. The review team recommends that the State initiate procedures to ensure incidents are followed up at the next inspection to verify that the licensee's corrective actions have been implemented.

Last, the team found that in five cases, licensees may have failed to comply with regulations but were not cited. The review team suggests that when evaluating incidents, the State cite appropriate deficiencies when applicable.

New Mexico does not have an incident tracking system. RLRP does not keep a central log of incident or allegation reports and does not maintain a separate incident file. Incidents may be reported by the licensee directly to the Albuquerque inspector assigned to their territory, or they may be reported to the RLRP office in Santa Fe and documents involving incidents may be kept either place. From interviews with staff, the team found that events are assigned to the inspector normally responsible for the licensee involved. The inspector then routinely requires the licensee to investigate the incident and furnish a report with the details and corrective actions. That licensee's report is used when necessary to complete the NRC Event Report (Form 565) and then filed in the license file. The State has no provision to file reports for incidents that do not involve New Mexico licensees. In conducting the file reviews, the team had difficulty in assembling information necessary to evaluate the State's incident response because documents could not be located and staff could not remember details of investigations. The review team recommends that the State (a) set up a separate incident and allegation file system in the Santa Fe office, keeping all documents and records pertaining to an incident in one location, with the data cross-referenced to the license/inspection files there and in the Albuquerque office, and (b) establish a system to centrally log and track the progress of incidents and allegations.

The New Mexico statewide emergency plan is the responsibility of the Department of Public Safety. If other State agencies encounter incidents or emergencies related to radioactive

materials, the responsibility is delegated to the RLRP. The team found through interviews with staff and management that RLRP has no written internal procedures for incident response other than a November 1995 memorandum explaining the NRC event reporting criteria. In interviews with the review team, the inspectors stated that they were not aware of any emergency procedures and that they had not been trained in emergency response. The review team recommends that the State develop and implement written procedures for responding to events involving radioactive material and conduct training sessions until all technical staff are fully trained and qualified in emergency response. These procedures and training should address the use of the forms and tracking system recommended above.

The State does have brief written procedures for investigating allegations. It is their policy to thoroughly investigate all allegations, including those made anonymously, to seek out and interview corroborative witnesses, to investigate the reasons for confirmed events, and to document all conversations. It is also their policy to respect anonymity to the highest possible extent. The team noted, however, that New Mexico law does not protect the identity of individuals making allegations. The review team suggests that the State keep expanding the allegation procedures to include procedures for notifying the person making the allegation of the results of the investigation and including the allegation procedures in the event reporting form, tracking system, and emergency response procedures.

The team evaluated the two allegations that occurred in the State during the review period. In both cases, the team found that the allegations were promptly evaluated to determine the validity and safety significance of the claims. Onsite investigations were conducted promptly in both cases. In one case, there was evidence that the State kept the individuals making the allegations informed of the resolution of their concerns; in the other, there was not. In one complex and lengthy case, the State held public hearings on the renewal of the license at the request of the alleging parties.

Except for the period between July 1995 and May 1996, the State provided quarterly event reports to the NRC even though NRC has requested monthly reports. During the period between July 1995 and May 1996, the State did not provide reports to the NRC, and little to no documentation of events exists. Two incidents that should have been reported were inadvertently omitted through oversights. The team instructed the State to report the events to NMED on the next monthly report. In the one case of a leaking source, the NRC and regulating agency of the manufacturer were both advised.

As discussed above, the team found frequent examples of incomplete, inappropriate, poorly documented, or delayed responses to incidents, and as a result, potential health and safety problems may exist. Therefore, at the time of the review, based on the IMPEP evaluation criteria, the review team recommended that New Mexico's performance with respect to the indicator, Response to Incidents and Allegations, be found unsatisfactory. In response to the draft report, the State issued new procedures on response to incidents that appeared adequate to address the concerns. The MRB noted that the new procedures appeared adequate to address the concerns and if these procedures are properly implemented, New Mexico would receive a rating of "satisfactory with recommendations for improvement" for this indicator. At the time of the October 23, 1997 MRB, no incidents had been reported since the new procedures were put into place. During the December 11, 1997 MRB, it was noted that New Mexico had implemented new procedures for three incidents. Based on the implementation of the new procedures, the MRB directed the finding to be revised to satisfactory with recommendations for improvement.

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 Operations. New Mexico's agreement does not cover uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

Along with their response to the questionnaire, the State provided the review team with copies of legislation that affects the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in New Mexico Statutes, 1978 Annotated, Chapter 74, Environmental Improvement, Pamphlet 120 with 1989 Replacement Pamphlet, Article 3, Radiation Control Act, Sections 74-3-1 through 74-3-16. In the Act, the New Mexico Environmental Department is designated as the State's radiation control agency. The review team evaluated the legislation which had not changed since the previous review and found State legislation to be adequate.

4.1.2 Status and Compatibility of Regulations

The review team compared the State's regulations against the latest Chronology of Amendments and found that the State had adopted equivalent rules for all amendments which were due for adoption by the Agreement States through July 1, 1996. However, the State had failed to revise their equivalent regulations to the following NRC regulations identified as compatibility items:

- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993, and which became due on October 25, 1996.
- "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, and which became due on January 28, 1997. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States 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 provisions for financial assurance that include 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).

From reviewing the State's promulgation process and from interviewing program management, the review team found that the time frame for adopting revised regulations is at least 11 months from the date the process begins. The State advised the review team that the Decommissioning Recordkeeping and Self-Guarantee regulations are in planning stages and are expected to be adopted by May 30, 1998.

The State was alerted that the following regulations will become due during the next 12 months:

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994, and which will become due on August 15, 1997.
- "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, is under review and is expected to become effective by the due date of January 1, 1998.
- "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, and which will become due on March 1, 1998. The NRC delayed its effectiveness until the State could adopt compatible requirements so that the national manifest system will go into effect at one time.
- "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, and

which will become due on March 13, 1998. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).

Each of the listed regulations and amendments are scheduled to be adopted by May 30, 1998. The review team recommends that the State expedite promulgation of the compatibility-related regulations now overdue and those which are due within the next 12 months.

The State was reminded of the following amendments which will need to be addressed:

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995, and which will become due on August 14, 1998.
- "Medical Administration of Radiation and Radioactive Materials" 10 CFR Parts 20 and 35 amendments (60 FR 48623) that become effective on October 20, 1995, and which will become due on October 20, 1998.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995, and which will become due on November 24, 1998.
- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996, and which will become due on April 1, 1999. NRC delayed the effective date of this rule until April 1, 1996, so that the Department of Transportation (DOT) companion rule could be implemented at the same time. Since the rule involves the transport of materials across state lines, the States are encouraged to adopt compatible regulations as soon as possible.
- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20 and 30 (61 FR 24669) that became effective on May 16, 1996, and which will become due on May 16, 1999.

The team notes that NRC staff is currently reviewing all Agreement State equivalent regulations to Part 20, Standards for Protection Against Radiation. These reviews are being conducted outside the IMPEP process and the States will be notified of the results.

During the examination of the State's procedures for promulgating regulations, the team noted that proposed rules or revisions to rules must be publicly announced 60 days prior to adoption, and a public hearing must be provided. The team examined the records of the last regulation package and found that the NRC was provided drafts of the proposed regulations early in the process and that the comments and suggestions made by the NRC staff were incorporated into the final regulations. It is the State's policy to send copies of final regulations to the NRC; however, it could not be verified that copies of the previous final regulations were sent to NRC. The review

team suggests that a file be maintained with the cover letters and ensuing correspondence of all draft or final regulations sent to the NRC.

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

4.2 Sealed Source and Device Evaluation Program

The review team did not review the State's sealed source and device (SS&D) program even though New Mexico currently has responsibility for this area. The review team discussed with the Secretary, New Mexico Environment Department, as to whether New Mexico has considered returning its authority for the Sealed Source and Device Evaluation Program. The Secretary stated that he would have the Governor send a letter to NRC turning back the SS&D evaluation authority. The State did not perform any SS&D evaluations during the period of the review.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although New Mexico has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in New Mexico. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance to be satisfactory for the indicator, Technical Quality of Licensing Actions; satisfactory with recommendations for improvements for the indicators, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Staffing and Training; and unsatisfactory for the indicator, Response to Incidents and Allegations. Based on implementation of new procedures for response to incidents, the MRB directed the team to revise the finding for the common performance indicator, Response to Incidents and Allegations, to a satisfactory with recommendations for improvements. The review team recommended that the New Mexico program be found adequate, but needs improvement, and compatible. Because of the significance of the concerns, the team also recommended that New Mexico be placed on probation and noted that heightened oversight is warranted. During the MRB meeting, three main issues were identified that New Mexico had to address in terms of programmatic improvements: (1) level of program staff and amount of resource support, (2) technical quality of staff and training needs, and (3) level of management support, involvement and oversight of New Mexico

Agreement program activities. The MRB found the New Mexico program adequate, but needs improvement, and compatible with the NRC's program. NRC management meet with upper management of the New Mexico program on December 4, 1997, before the MRB voted on the recommendation for probation status for the program.

The MRB reconvened to discuss probation for the New Mexico program. Based on the New Mexico actions to date, and the commitments by Secretary Weidler, the MRB did not conclude probation was now warranted. The MRB directed that the follow-up review be conducted within one year of the IMPEP review, that monthly conference calls take place with New Mexico staff, and that written progress reports be submitted every other month.

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

1. The review team recommends that the nuclear pharmacy inspection frequency be modified from 2 years to 1 year. (Section 3.1)
2. The review team recommends that initial inspections of licensees be performed within 6 months of license issuance or within 6 months of the licensee's receipt of material and commencement of operations, consistent with IMC 2800. (Section 3.1)
3. The review team recommends that the tracking system be revised to allow initial inspections to be readily identified to staff and management. (Section 3.1)
4. The review team recommends that the State increase the number of reciprocity inspections to better evaluate the health and safety implications of out-of-state companies working in New Mexico. (Section 3.1)
5. The review team recommends that the State maintain the RLRP staffing level to at least the level which existed throughout the review period. (Section 3.2)
6. The review team recommends that the State provide training to technical personnel in the areas of medical brachytherapy and irradiator technology. (Section 3.2)
7. The review team recommends that the State develop a formalized training program comparable to IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." (Section 3.2)
8. The review team suggests that documentation of license reviewers' actions be maintained in license files. (Section 3.3)
9. The review team recommends that the State inspectors attempt to observe licensee operations or demonstrations during all inspections. (Section 3.4)
10. The review team recommends that the State inspectors conduct independent measurements on all inspections. (Section 3.4)

11. The review team recommends that the State increase the rigor of reviewing technical health physics issues during inspections, and increase the breadth and scope of inspections. (Section 3.4)
12. The review team suggests that the State inspectors attempt to interview ancillary workers during inspections. (Section 3.4)
13. The review team recommends that the State inspectors attempt to conduct formal exit meetings with the senior licensee management on all inspections. (Section 3.4)
14. The review team recommends that the State develop a formal process for reviewing licensee responses to deficiency letters and closing open deficiencies. (Section 3.4)
15. The review team suggests that the State develop a formal process for inspectors and license reviewers to document and transmit pertinent information to each other for follow up. (Section 3.4)
16. The review team suggests that the State develop a process for ensuring that inspection files are complete, that all appropriate State documents are prepared and filed, and that licensee responses are received and filed. (Section 3.4)
17. The review team recommends that the State begin documenting all trips to licensees' or applicants' facilities when inspecting licensed activities, performing special inspections, or performing pre-licensing site visits during construction. (Section 3.4)
18. The review team recommends that the State management exercise more stringent supervisory review of inspection reports. (Section 3.4)
19. The review team suggests that the State complete its revision of the inspection report forms, insuring that each set of forms covers all key areas for the type of licensee being inspected, and that RLRP inspectors begin using the standardized form(s). (Section 3.4)
20. The review team recommends that the State make onsite, documented investigations of incidents, allegations, or misadministrations with potential health and safety effects (i.e., source disconnects, possible overexposures, lost sources, contamination, etc.). (Section 3.5)
21. The review team recommends that the State create an incident and allegation reporting form that would, at a minimum, identify the person taking the initial report, list the name and telephone number of the reporting party, provide the details of the incident or allegation as reported, record the State's conversation with the licensee or individual, describe corrective actions taken by the licensee, describe the investigation conducted by the State and the results, list citations or other regulatory actions, show the date the investigation was closed out and justification for closure, show date(s) incident was reported to the NRC or other agencies, and provide spaces for the signatures of the

- investigator and supervisor. A copy of the form should be maintained in the incident file and in the license file. (Section 3.5)
22. The review team recommends that the State establish a protocol for making independent investigations and evaluations of the licensee's actions. (Section 3.5)
 23. The review team recommends that the State initiate procedures to ensure incidents are followed up at the next inspection to verify that the licensee's corrective actions have been implemented. (Section 3.5)
 24. The review team suggests that when evaluating incidents, the State cite appropriate deficiencies when applicable. (Section 3.5)
 25. The review team recommends that the State: (a) set up a separate incident and allegation file system in the Santa Fe office, keeping all documents and records pertaining to an incident in one location, with the data cross-referenced to the license/inspection files there and in the Albuquerque office, and (b) establish a system to centrally log and track the progress of incidents and allegations. (Section 3.5)
 26. The review team recommends that the State develop and implement written procedures for responding to events involving radioactive material and conduct training sessions until all technical staff are fully trained and qualified in emergency response. (Section 3.5)
 27. The review team suggests that the State keep expanding the allegation procedures to include procedures for notifying the person making the allegation of the results of the investigation and including the allegation procedures in the event reporting form, tracking system, and emergency response procedures. (Section 3.5)
 28. The review team recommends that the State expedite promulgation of the compatibility-related regulations now overdue and those which are due within the next 12 months. (Section 4.1.2)
 29. The review team suggests that a file be maintained with the cover letters and ensuing correspondence of all draft or final regulations sent to the NRC. (Section 4.1.2)

LIST OF APPENDICES AND ATTACHMENTS

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Appendix C	New Mexico's Questionnaire Response
Appendix D	License File Reviews
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Attachment 2	NRC/New Mexico Management Meeting Minutes, December 4, 1997

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

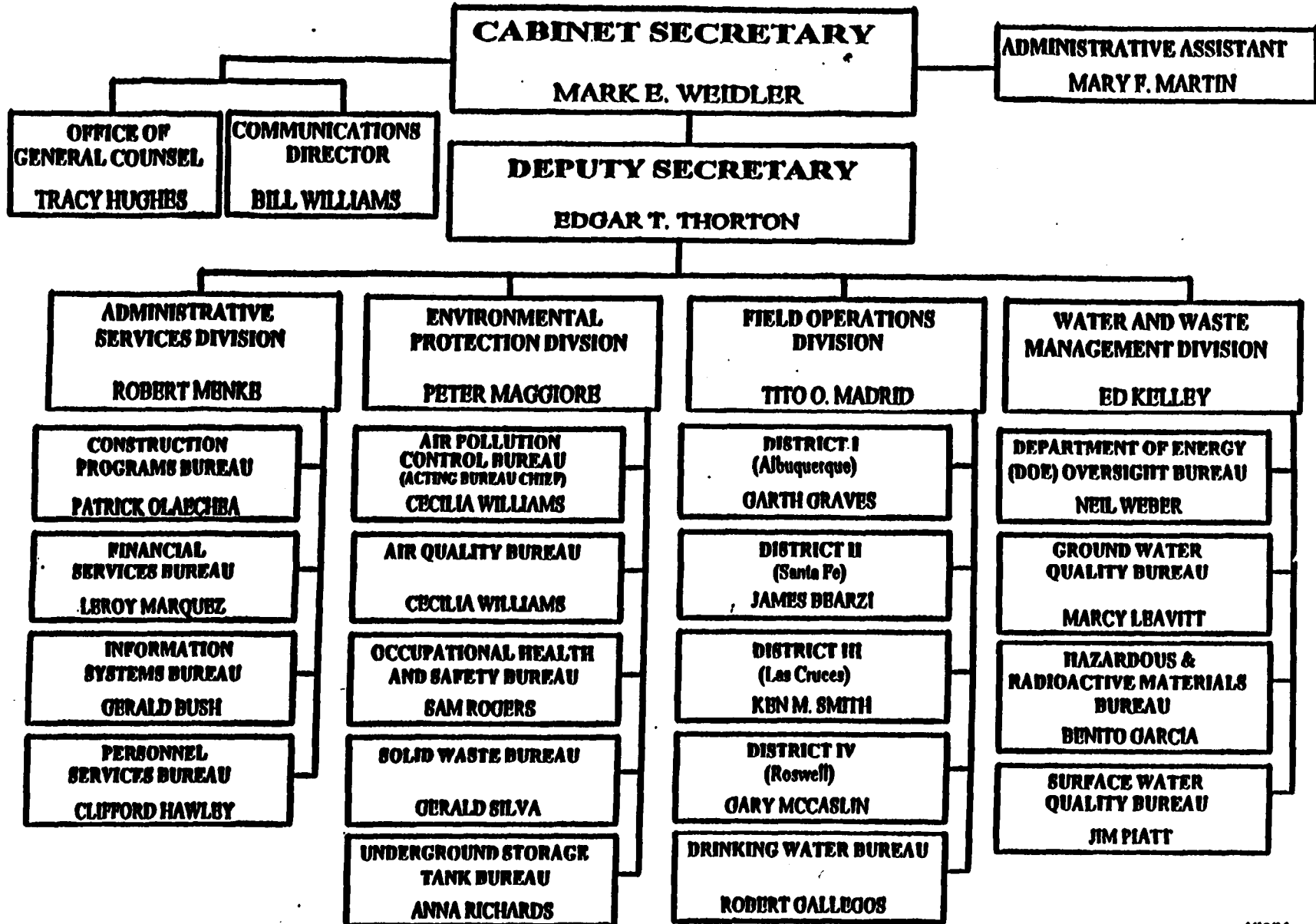
Name	Area of Responsibility
James Lynch, RIII	Team Leader Status of Materials Inspection Technical Staffing and Training
Terry Frazee, Washington	Technical Quality of Licensing Actions
Scott Moore, NMSS	Technical Quality of Inspections
Jack Honor, RIV, WCFO	Response to Incidents and Allegations Legislation and Regulations

APPENDIX B

NEW MEXICO
ENVIRONMENT DEPARTMENT
HAZARDOUS AND RADIOACTIVE MATERIALS BUREAU

ORGANIZATION CHARTS

NEW MEXICO ENVIRONMENT DEPARTMENT



**HAZARDOUS AND RADIOACTIVE
MATERIALS BUREAU**

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**ADMINISTRATION
AND SPECIAL
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**RESOURCE
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AND RECOVERY
ACT (RCRA)
INSPECTION/
ENFORCEMENT
PROGRAM**

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**RESOURCE
CONSERVATION
AND RECOVERY
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TECHNICAL
COMPLIANCE
PROGRAM**

**RON KERN
(505) 827-1558**

APPENDIX C

NEW MEXICO'S
IMPEP QUESTIONNAIRE RESPONSE

SEP 12 1997

Mr. Benito J. Garcia, Chief
Hazardous and Radioactive Materials Bureau
Water and Waste Management Division
Department of Environment
2044 Galisteo Road
P.O. Box 26110
Santa Fe, New Mexico 87502

Dear Mr. Garcia:

This acknowledges receipt of your August 28, 1997 request for an extension to October 10, 1997 of your response to my August 8, 1997 letter and draft IMPEP report. Although it will be difficult, receipt of your response by the extended date will still enable us to issue the final report in accordance with NRC's timeliness goals. After coordination with you, we have rescheduled the Management Review Board meeting to October 23, 1997, 2:00 p.m. to 4:00 p.m. If you have any questions, please contact me at (301) 415-3340 or James Lynch at (630) 829-9661.

Sincerely,

Original Signed By
RICHARD L. BANGART
Richard L. Bangart, Director
Office of State Programs

cc: Mark Weidler, Secretary, NMED
Ed Kelley, Ph.D., Director, WWMD
Bill Floyd, Program Manager, RLRS
Geoffrey Sloan, OGC, NMED

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New Mexico File

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*See previous concurrence.

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OFFICE	OSP	OSP:DD	OSP:D				
NAME	KNSchneider:gd	PHLohaus	RLBangart				
DATE	09/11/97*	09/11/97*	09/11/97				

OSP FILE CODE: SP-AG-19



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

WASHINGTON, D.C. 20555-0001

September 12, 1997

Mr. Benito J. Garcia, Chief
Hazardous and Radioactive Materials Bureau
Water and Waste Management Division
Department of Environment
2044 Galisteo Road
P.O. Box 26110
Santa Fe, New Mexico 87502

Dear Mr. Garcia:

This acknowledges receipt of your August 28, 1997 request for an extension to October 10, 1997 of your response to my August 8, 1997 letter and draft IMPEP report. Although it will be difficult, receipt of your response by the extended date will still enable us to issue the final report in accordance with NRC's timeliness goals. After coordination with you, we have rescheduled the Management Review Board meeting to October 23, 1997, 2:00 p.m. to 4:00 p.m. If you have any questions, please contact me at (301) 415-3340 or James Lynch at (630) 829-9661.

Sincerely,

Richard L. Bangart
Richard L. Bangart, Director
Office of State Programs

cc: Mark Weidler, Secretary, NMED
Ed Kelley, Ph.D., Director, WWMD
Bill Floyd, Program Manager, RLRS
Geoffrey Sloan, OGC, NMED



GARY E. JOHNSON
GOVERNOR

State of New Mexico
ENVIRONMENT DEPARTMENT
Hazardous & Radioactive Materials Bureau
2044 Galisteo
P.O. Box 26110
Santa Fe, New Mexico 87502
(505) 827-1557
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KLBZ
PHL
SLD
RKS
LSR



MARK E. WEIDLER
SECRETARY

EDGAR T. THORNTON, III
DEPUTY SECRETARY

August 28, 1997

Richard L. Bangart, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Bangart:

We are in receipt of your August 8, 1997 letter and attached draft IMPEP report which documents the results of the New Mexico Radiation Control Program review held in our offices July 14-18, 1997.

We request an extension of our response due date from September 11, 1997 to October 10, 1997 so that we may mount a complete response, and in order to work simultaneously on solutions to the IMPEP Review Team's recommendations and proposed conditions.

A meeting of the state Radiation Technical Advisory Council (RTAC) has been scheduled for September 24, 1997, and staff are preparing proposed amendments to the New Mexico Radiation Protection Regulations for consideration by the RTAC prior to forwarding to the Environmental Improvement Board for adoption. These amendments are required under the review team's compatibility findings and we would like to be able to resolve this before responding.

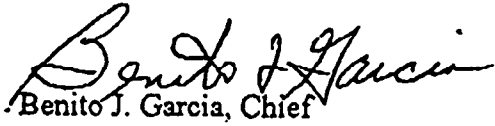
We likewise request an extension of your scheduled date for our appearance before the Management Review Board from September 25, 1997.

Due to the severity of the IMPEP Review Team's recommendation of program probation, which we take quite seriously, we trust you will respond positively to our requests and that we will be given adequate time to respond.

Mr. Bangart
August 28, 1997
Page 2

Please contact me at (505) 827-1557 should you require additional information.

Sincerely,



Benito J. Garcia, Chief

Hazardous and Radioactive Materials Bureau

cc: Mark Weidler, Secretary, NMED
Ed Kelley, Ph.D., Director, WWMD
Bill Floyd, Program Manager, RLRS
Geoffrey Sloan, OGG, NMED



GARY E. JOHNSON
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State of New Mexico
ENVIRONMENT DEPARTMENT
Harold Runnels Building
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MARK E. WEIDLER
SECRETARY

October 10, 1997

Mr. Richard Bangart, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: On-Site IMPEP Review - New Mexico, July 14-18, 1997
State Program Response to Draft Report

97 OCT 10 PM 2:36
OSP

Dear Mr. Bangart:

The New Mexico Radiation Control Program (RCP) thanks the IMPEP team for their preliminary findings for consideration to the Management Review Board (MRB). In addition to the information provided by Benito J. Garcia in his letter to Richard Bangart, dated July 28, 1997, below is our response keyed to the review team's findings, suggestions, and recommendations. Our focus is on findings requiring action by the State. We submit that we comprehend the new emphasis the review team believes our efforts should have. We can show that we are deliberately on that path. Probation is not warranted, especially in comparison to issues arising in cases of other state programs.

1. The review team recommends that the nuclear pharmacy inspection frequency be modified from 2 years to 1 year. (Section 3.1)

Response: As Attachment 1 indicates, the RCP has increased the inspection frequency for nuclear pharmacies to annually. The two-year inspection frequency being used previously was based on a frequency recommended in an out-dated copy of IMC 2800 which we believed to be current. The RCP has centralized the IMCs in a file which will be maintained by a technical staff person assigned by the RCP Program Manager.

2. The review team recommends that initial inspections of new licensees be performed within 6 months after license issuance or within six months after the licensee's receipt of material and commencement of operations, consistent with IMC 2800. (Section 3.1)

Response: The Bureau Chief, who signs newly issued, first-time licenses, now has a hard copy file for new licenses in his office and will track new license inspections on a six month basis. Also, the RCP Program Manager has established a tickler file and will prompt inspectors to inspections coming due during a two-month block at least a month in advance. The computer database used by

the RCP will likewise flag newly issued licenses which need to be inspected within the first six months. Additionally, a standard condition has been added to the RCP list of standard conditions to be inserted in newly-issued licenses instructing licensee to notify the RCP within ten days after receipt of licensed material.

3. The review team recommends that the tracking system be revised to allow initial inspections to be readily identified to staff and management. (Section 3.1)

Response: See Response No. 2, above. Also, the computer printouts of licensees showing inspections coming due will be generated by an assigned technical staff person during the last week of every month and a copy will be delivered to the Program Manager, the Bureau Chief, and all inspection staff. The Program Manager shall insure that the staff person responsible for the appropriate geographical area of the state completes any due or overdue inspection. The Bureau Chief will be responsible for notifying the Program Manager in writing of any initial inspections due for first time licensees still held on file at the end of the first six month period.

4. The review team recommends the number of reciprocity inspections be increased to better evaluate the health and safety implications of out-of-state companies working in New Mexico. (Section 3.1)

Response: When the 3-day notification is received of an out-of-state licensee's impending entry into the state, the RCP Program Manager will make a duplicate copy of the notification form and deliver it to the assigned inspector. Our goal is to make every reasonable attempt to conduct an unannounced inspection of at least 50% of the Priority 1 and Priority 2 reciprocal licensees. If unannounced inspections are not possible because directions for locating the licensee's activity are needed, documented phone calls will be made to obtain directions or to coordinate meeting up and accompany visits to the field site. If RCP staff workload, staff unavailability or other considerations do not allow for inspections of reciprocal licensees in field locations, the RCP Program Manager will write onto the notification form why an inspection was not conducted. A new master reciprocity inspection file has been created and will be maintained by the Program Manager in Santa Fe. Reciprocal license inspections will be coordinated with already pending routine inspections of state licensees to maximize use of in-state travel funding. Since the IMPEP review, three Priority 1 and 2 reciprocal licensees have been inspected at their temporary field sites in southeast New Mexico.

5. The review team recommends that the state maintain the RCP staffing level to at least the level which existed throughout the review period. (Section 3.2)

Response: As verbally committed by Secretary Weidler at the IMPEP team outbrief on July 18, 1997, the two Environmental Specialist positions vacated since the IMPEP review have been approved for hire and have been advertised for applicant interviews. The positions will be filled

following the interview process. Based on past experience, the new personnel will require extensive specialized training to be able to function independently as fully proficient staff. Prompt, appropriate training may need to be provided or supplemented through the NRC State Agreement Program (Attachment 2).

6. The review team recommends training for RCP personnel in the areas of medical brachytherapy and irradiator technology. (Section 3.2)

Response: The Program Manager has arranged with Dr. Tom Kirby, Medical Physicist at the University of New Mexico Cancer Treatment Center, for him to provide brachytherapy training to RCP staff on October 14, 1997, with refresher training thereafter annually (Attachment 3). There are currently brachytherapy programs at four hospitals in the state.

Paul Ripley, RSO at Ethicon EndoSurgery's 5 million curie Co-60 irradiator in Albuquerque, has approved RCP staff attendance at pool irradiator training to be offered by Nordion sometime in November, 1997. This training will be updated on an annual basis (Attachment 4). There are currently two pool irradiators in the state: the one at Ethicon and a 20,000 curie Co-60 model used for instructional and research purposes at the University of New Mexico School of Medicine.

7. The review team recommends that the RCP develop a formalized training program comparable to IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguard Program Area." (Section 3.2)

Response: The RCP Program Manager is developing an explicit formalized training program comparable to IMC 1246. The developed program will be submitted to the Bureau Chief by the Program Manager for review and approval. Current RCP funding does not support out-of-state training. Once again, the New Mexico RCP requests assistance from NRC for newly-hired staff. Justification for this assistance will be forthcoming in an official request to NRC. Regardless of the availability of formalized training assistance, the RCP will continue to expand in-house and on-the-job training and obtain training from the private sector and other state institutions.

8. The review team suggests that complete documentation of license reviewer's actions be entered and maintained in license files. (Section 3.2)

Response: The RCP Program Manager is developing standard operational procedures to assure that all calls, letters, and supplemental information generated during license review and amendment are documented in the license file (Attachment 5). The final SOPs will be provided to the Bureau Chief for review and approval. Since the IMPEP review, all files have been returned to the centralized Santa Fe RCP office. The importance of documentation for every action taken by staff

in response to licensees' requests has been discussed at RCP staff meetings. A telephone log sheet (Attachment 12) has been inserted at the front of every license folder for documenting conversations. All requests for additional material from licensees will henceforth be in writing. The RCP license review form (Attachment 5) has been modified to permit greater detail.

9. The review team recommends that the state inspectors make observations of licensee operations or demonstrations during all inspections. (Section 3.4)

Response: New inspection forms incorporate routine review of operations or observation of demonstrations (Attachment 6). The Program Manager and Bureau Chief have begun more frequent accompaniments of inspection staff and will continue to do so. One such accompaniment has been conducted by the Bureau Chief and one RCP inspector as a training exercise which included a radiographer field site operational inspection. The Program Manager has accompanied an inspector on another training inspection for a research and development laboratory licensee which included the observation of the use and disposal of material and the safety practices involved. The "Standard Operating Procedures Manual for License Inspections" has been revised (Attachment 7), and a copy has been delivered to each staff member. The importance of performance-based inspections has been discussed at RCP staff meetings and inspection forms have been finalized reflecting performance-based inspections. The importance of interviews with workers, independent measurements, status of previous violations, and the substance of discussions during exit interviews with management are reflected in the newly revised inspection report forms. With the relocation of all but one inspector to the central RCP office in Santa Fe, the Program Manager will now be able to discuss inspections face-to-face with inspectors and thereby will be able to ascertain what was found and what additional factors need to be addressed. The one non-central inspector will personally bring all inspection forms to the central office and discuss findings with the Program Manager as inspections are accomplished. The New Mexico RCP submits it should be noted that with the exception of one inspector, all inspection staff attended the U.S. NRC sponsored "Inspection Procedures Course" prior to the advent of performance-based inspection guidelines and not since. Before our first IMPEP review this July, RCP inspectors have never in the past been criticized for the type of inspections they were conducting.

10. The review team recommends that the state inspectors conduct independent measurements at all inspections. (Section 3.4)

Response: The importance of taking independent measurements on all inspections has been discussed at staff meetings since the IMPEP review. Inspection SOP documents have been changed to reflect the procedures for conducting independent measurements with portable survey instruments and for obtaining laboratory samples when it is deemed necessary as part of the inspection.

11. The review team recommends that the state increase the rigor of reviewing technical health physics issues during inspections, and increase the breadth and scope of inspections. (Section 3.4)

Response: Inspection forms and Inspection Guidance Documents (Attachments 6 & 7) have been revised to broaden the scope of scheduled inspections. The revised forms and guidance documents have been and will continue to be discussed at staff meetings. The Program Manager will, by written memo, report to the Bureau Chief after each training session which forms and topics have been covered during the training sessions.

12. The review team suggests that the state inspectors attempt to interview ancillary workers during inspections. (Section 3.4)

Response: The Program Manager has emphasized the importance of ancillary worker interviews during inspection as per the SOP on General Provisions for Inspection Procedures (Attachment 7). The provisions of Subpart 10, Section 1005, of the New Mexico Radiation Protection Regulations, pertaining to consultation with workers during inspections have been discussed during staff meetings and included as an item for the monthly staff training meetings.

13. The review team recommends that the state inspectors attempt to conduct formal exit meetings with senior licensee management on all inspections. (Section 3.4)

Response: Inspection forms and inspection guidance documents have been changed to indicate that "the closeout conference should be held with the licensee's highest level of management available," and that "inspectors should always contact upper management upon entering a facility." The importance of following-up with upper management, even if unavailable at time of inspection, has been stressed at staff meetings.

14. The review team recommends that the state develop a formal process for reviewing and closing out for scheduled follow-up, all licensee responses to deficiency letters. (Section 3.4)

Response: The Program Manager has implemented a response tracking system using a period timed tickler file to be maintained by the Program Manager. The RCP Program Manager (initially) and the Bureau Chief will sign off on the adequacy of licensee response. Requests for additional information are always in writing, with copies of all correspondence to be placed in each licensee's folder. Failure to respond to letters of deficiency within the response period, is pursued by enforcement action as per the "Guidance and Policy for Escalated Enforcement Action" (Attachment 8). A form (Attachment 8-B) has been developed to track inspection follow-up activities.

15. The review team suggests that the state develop a formal process for inspectors and license reviewers to document and transmit pertinent information to each other for respective follow-up. (Section 3.4)

Response: Weekly staff meetings now include discussion of the previous week's activities. The Program Manager and inspectors can routinely discuss and timely identify information resulting from previous week's inspection efforts. Any need for remaining documentation needs will be satisfied in writing, and the Program Manager will reiterate what is needed by E-Mail to the inspector.

16. The review team suggests that the state develop a process for ensuring that inspection files are complete, that all appropriate state documents are prepared and filed, and that licensee responses are received and filed. (Section 3.4)

Response: Accordingly, each inspector is responsible for ensuring that all their inspection files are complete, that all check-list items are fully answered, and that responses to letters of violation are received. The adequacy of responses is reviewed and approved by both the Program Manager in writing. Letters in reply to licensee responses are signed by the Program Manager. The Program Manager reviews license files each time "circle of correspondence" is completed pertaining to licensing actions, inspections, and incidents.

17. The review team recommends that the state begin documenting all trips to licensees' and applicants' facilities when inspecting licensed activities, performing special inspections, and performing pre-licensing site visits during construction. (Section 3.4)

Response: The significance of documentation has been discussed at RCP staff meetings. All information gained through trips to licensed facilities will be documented in memoranda to file reviewed and approved by the RCP Program Manager.

18. The review team recommends that management exercise more stringent supervisory review of inspection reports. (Section 3.4)

Response: By relocating all but one of the RCP inspectors to the central office in Santa Fe, inspection reports will not accumulate in field offices without management review. The RCP Program Manager now reviews inspector field notes and inspection reports, and the Program Manager reviews licensee responses to violation notices. The Program Manager's written review and approval are entered into the licensee's file.

19. The review team suggests that the state complete its revision of the inspection report forms, ensuring that each set of forms covers all key areas for the type of licensee being inspected, and that RCP inspectors begin using the standardized form(s). (Section 3.4)

Response: New inspection report forms are in Attachment 6. Copies have been distributed to staff and are in use. Staff have been instructed on how inspection forms are to be completed, and the importance of completeness.

20. The review team recommends that the state make onsite, documented investigations of incidents, allegations, or misadministrations with potential health and safety effects (e.g., source disconnects, possible overexposures, lost sources, contamination). (Section 3.5)

Response: Revised guidance documents are in Attachments 9 & 10. Copies have been distributed to staff and are in use. Staff have been instructed on the contents of the incident response documents and incidents and allegations is an agenda item for monthly staff training meetings.

21. The review team recommends that the state create an incident and allegation reporting form that would, at a minimum, identify the person taking the initial report, list the name and telephone number of the reporting party, provide the details of the incident or allegation as reported, record the State's conversation with the licensee or individual, describe corrective actions taken by the licensee, describe the investigation conducted by the State and the results, list citations or other regulatory actions, show the date the investigation was closed out and justification for closure, show date(s) incident was reported to the NRC or other agencies, and provide spaces for the signatures of the investigator and supervisor. A copy of the form should be maintained in the incident file and in the license file. (Section 3.5)

Response: This suggestion is the summary and at the heart of the review team's findings and its overall recommendation that the RCP be given probationary status by the MRB. We believe that the state program provides excellent public health and safety protection. We acknowledge, however, that our concentration on file building and attention to the relatively new (at least new since our last NRC program review) implementation approach encouraged by IMPEP has been less than focused. Of course we have excuses, including a two-year long license renewal proceeding full of public controversy and our own on-going investigation and administrative hearing preparation. Nonetheless, we recognize the significant improvement our program implementation will realize by adjusting our approach. We are dedicated to it. We shall do it without probation. New incident and allegation report forms are in Attachment 11. Guidance document procedures have been developed for incident and for allegation investigations (Attachments 9 & 10). Copies have been distributed to staff and are in use. Finally, on September 16, 1997, Mr. Sam Pettijohn of the NRC trained New Mexico, Colorado, and Arizona Radiation Control Program Staff in use of new NMED software to track data internally and forward data to the NRC.

22. The review team recommends that the state establish a protocol for making independent investigations and evaluations of the licensee's actions. (Section 3.5)

Response: Attachment 7 contains the protocol to be followed for making independent investigations and evaluating the licensee's actions. The protocol has been distributed to staff and is in use.

23. The review team recommends that the state initiate procedures to ensure incidents are followed-up at the next inspection to verify that the licensee's corrective actions have been implemented. (Section 3.5)

Response: A separate section entitled "Incidents/Reports" has been incorporated into inspection forms which provides for listing information on types of incidents that occur after the last inspection, including notification reports and corrective actions. The importance of completing this section has been emphasized in staff meetings and inspection reviews by management. This will also be an agenda item at monthly staff training sessions.

24. The review team suggests that when evaluating incidents, the state include citations to appropriate regulatory authority (when applicable). (Section 3.5)

Response: In the past, the RCP has handled some deficiency notices verbally. The routine now requires Notice of Deficiency letters in all cases where a breakdown of procedures occurred or may have occurred to cause a reportable incident. Interviews with licensee management are conducted to discuss cause of incident, consequences and corrective actions taken.

25. The review team recommends that the state: (a) set up a separate incident and allegation file system in the Santa Fe office so that all documents and records pertaining to an incident are available in one location, with the data cross-referenced to license and inspection files centrally and in the Albuquerque office, and (b) establish a system to centrally log and track the progress of incidents and allegations. (Section 3.5)

Response: The incident and allegation files have been moved from the Albuquerque office to the Santa Fe office. A new Incident/Allegation Checklist has been developed, as well as a new Incident/Allegation Report Form (Attachment 11). The NMED database is now utilized to track all incidents and allegations and to forward the data to the NRC. A chronology file (hard copy) is also kept in the Santa Fe office, and a tickler file has been established to track the progress of incidents and allegations and prompt follow-up. The Program Manager is responsible for this tracking system.

26. The review team recommends that the state develop and implement written procedures for responding to events involving radioactive material and conduct training sessions until all staff are fully trained and qualified in emergency response. (Section 3.5)

Response: Written procedures are in place for responding to events involving radioactive material and staff has been instructed in their use. The RCP staff are not tasked with first responder duties but program staff have participated in various emergency response exercises, including the week-long DOE-sponsored "Digit Pace II" exercise in May 1997. Additional emergency response training is being sought.

27. The review team suggests that the state keep expanding the allegation procedures to include procedures for notifying the person making the allegation of the results of the investigation and including the allegation in the event reporting form, tracking system, and emergency response procedures. (Section 3.5)

Response: A new guidance document is in Attachment 10. Copies have been distributed and are in use by staff. Allegations will be tracked by the Program Manager and entered into the NMED database as if it were a reportable incident. Response deadlines and next inspection prompts are tracked.

28. The review team recommends that the state expedite promulgation of the compatibility-related regulations now overdue and those which are due within the next 12 months. (Section 4.1.2)

Response:

A. The RCP requested a meeting of the Radiation Technical Advisory Council (RTAC). The RTAC met on September 24, 1997 to entertain the RCP request to forward to the Environmental Improvement Board (EIB) the recommendation to promulgate NRC regulations needed from a compatibility standpoint. The RTAC took action on the two most critical compatibility regulations and withheld action on the others until a future meeting. The RCP will request a hearing from the EIB as soon as the RTAC formally submits the recommendation on the two compatibility regulations and will request another meeting of the RTAC to consider the remaining compatibility regulation requirements by the end of 1997. Subpart 3, Section 311. G.4.a. through d. (pages 3-32 through 3-33) of 20 NMAC 3.1 already contains the compatibility language for "Decommissioning Recordkeeping and License Termination; Documentation Additions" as adopted by the New Mexico EIB, April 3, 1995, effective May 3, 1995. The additional compatibility language from the Federal Register (61 FR 24669) was approved by the RTAC for inclusion under Subpart 3, Section 311.G (page 3-32) 20 NMAC 3.1 by the Environmental Improvement Board.

B. "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, and which became due on January 28, 1997 was also approved by the RTAC at the September 24, 1997 meeting for inclusion in Subpart 4, 20 NMAC 3.1 by the Environmental Improvement Board.

C. Work has begun on inserting language for the following additional amendments to the New Mexico Radiation Protection Regulations. Once the insertions have been made, the amended regulations will be taken before the RTAC for approval and recommendations prior to submittal to the Environmental Improvement Board. (These will be proposed for adoption no later than May 1998):

- (1) "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40 and 70 amendments;
- (2) "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments;
- (3) "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR parts 20 and 61 amendments;
- (4) "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments;
- (5) "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments;
- (6) "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments;
- (7) "Clarification for Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments;
- (8) "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment;
and
- (9) "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20 and 30 amendments.

29. The review team suggests that a file be maintained with the cover letters and ensuing correspondence of all draft or final regulations sent to the NRC. (Section 4.1.2)

Mr. Bangart
October 10, 1997
Page 11

Response: All regulation promulgation and NRC approval correspondence is now kept in discrete files for easy access.

In closing, we ask that the MRB take account of our struggles, recognize our improvements, and overrule the review team's recommendation for a period of probation. New Mexico's RCP will work diligently and in concert with the NRC to make any beneficial changes needed to improve the RCP.

Respectfully,

A handwritten signature in black ink, appearing to read 'Mark E. Weidner', written in a cursive style.

Mark E. Weidner, Secretary
New Mexico Environment Department

cc: ✓ Paul H. Lohaus, Office of State Programs, U.S. NRC
Jim Lynch, State Agreements Program, U.S. NRC, Region III

LIST OF ATTACHMENTS

- Attachment 1: -Schedule of Inspections
- Attachment 2: -Vacancy Advertisement--Personnel Announcements
Not Available As OF October 10, 1997
- Attachment 3: -Brachytherapy Course Outline
- Attachment 4: -Irradiator Safety Training
- Attachment 5: -Procedures For Licensing Actions/New Licenses
-Evaluation Form
- Attachment 6A: -General Inspection Report Form
-Instructions For Inspection And Preparation Of General Inspection Report
- Attachment 6B: -Medical Inspection Form
-Instructions For Medical Inspection Report
- Attachment 6C: -Density/Moisture Gauge Inspection Form
-Instructions For Portable Gauge Inspection Checklist
-Portable Gauge Inspection Checklist
-Portable Gauge Inspection By Mail
- Attachment 6D: -Industrial Radiography Inspection Form
-Instructions In Preparation For Industrial Radiography Inspection Report
-Industrial Radiography Field Site Inspection Report
- Attachment 7: -Inspection Procedures
- Attachment 8A: -Enforcement Procedures
- Attachment 8B: -Follow-up On Inspection Letter
- Attachment 9: -Standard Operating Procedure For Response To Incidents Involving
Radioactive Materials
-Incident Investigation Procedures
-Incident Reporting System/Abnormal Occurrence Criteria
- Attachment 10: -Allegation Response Guidance Document (being developed, to be
presented to MRB on October 23, 1997)
- Attachment 11: -Incident Report For Radioactive Material Licensees
- Attachment 12: -Telephone Log

ATTACHMENT 1
SCHEDULE OF INSPECTIONS

SCHEDULE OF INSPECTIONS

Priority	Type of License	Subsequent Inspection
1.	Broad License, Type B, Field Industrial Radiographers, Implant Industrial Radiographers, Radio- pharmacies, Gamma Irradiators. Well Logging Tagging Operations. (BM,IR, RP, GL, TA).	1 Year
2.	Broad License, Type B or C, Industrial with Multicurie Sources or Unsealed, except Gauge Licenses. Medical Institutional with Therapy, Generator or Airborne Sources. (BB, MI, GL, WL).	2 Years
2.	Academic Specific, Industrial Gauge Licenses, Industrial, Curie or Less Sealed Sources, Medical Institution, Medical Private Practice. Medical In-Vitro Only, Research & Development. (AC, DM, MD-PP, RD)	2 Years
3.	Industrial Calibration Services, Gas Chromatograph, Laboratory Analysis with Microcurie Sources. Storage Only. Depleted Uranium. Fixed Gauges, Bone Analyzer, Transportation Waste, Paint Analyzer, Eye- Applicator-Sr.90). (AN, GC, IX, GA, DU, SO, PA, MA, TW, BA)	3 Years

AC	Academic	GI	Gamma Irradiator	RD	Research & Development
AN	Lab. Analysis	GL	General License	RP	Radiopharmacy
BB	Broad Type B	IR	Indust. Radiography	SO	Storage Only
BM	Broad Medical	IX	Ion Exchange	TA	Tagging
CS	Calibration Service	IV	In-Vitro	TW	Transportation/Waste
DM	Density/Moisture Gauge	LA	Laundry	VT	Veterinarian
		MA	Bone M Analyzer	WL	Well Logging
DU	Depleted Uranium	MD	Medical Doctor-PP		
GA	Gauge	MI	Medical Institution		
GC	Gas Chromatography	PA	Paint Analyzer		

ATTACHMENT 2

**VACANCY ADVERTISEMENT--PERSONNEL ANNOUNCEMENTS
NOT AVAILABLE AS OF OCTOBER 10, 1997**



ATTACHMENT 3

BRACHYTHERAPY COURSE OUTLINE

FAX

Date: Friday, September 26, 1997

Time: 8:24:17 AM

3 Pages

To: Mr. Bill Floyd
Hazardous / Radioactive Materials Bureau

From: Thomas H. Kirby, Ph.D.
UNM CRTC Medical Physics

Fax: ,1,5058271544
Voice:

Fax: (505) 272-4973
Voice: (505) 272-4986

Comments:

Mr. Floyd,
Sorry for the delay. I have been working on this at home and did not have the latest outline at work. Although the sequence and topics are a little different than what you forwarded, the material is about the same. We can adapt it as needed. I will fax my resume in a few minutes.

Tom Kirby
Pager: 768-9422

Brachytherapy Overview for State Nuclear Material Inspectors
October 14, 1997

Course Director:

Thomas Kirby, Ph.D., Chief Physicist and Associate Professor
Cancer Research and Treatment Center
The University of New Mexico Health Sciences Center

1. **Schedule**
 - a. 09:00 - 09:30 Facility tour
 - b. 09:30 - 10:00 Introduction
 - c. 10:00 - 10:30 Applicable regulations
 - d. 10:30 - 11:00 Radioactive sources used in brachytherapy
 - e. 11:00 - 11:30 Handling and safety
 - f. 11:30 - 12:30 Lunch and discussion
 - g. 12:30 - 13:30 Low dose rate procedures
 - h. 13:30 - 14:30 High dose rate procedures
 - i. 14:30 - 15:00 Records and reporting procedures
 - j. 15:00 - 15:30 Wrap and discussion
2. **Introduction**
 - a. Definitions
 - b. Physical laws applicable to brachytherapy
 - c. Uses of brachytherapy in cancer treatments
 - d. Typical procedures
3. **Applicable regulations and training**
 - a. Federal: 10CFR Parts 20 and 35
 - b. State of New Mexico
 - c. University of New Mexico
 - d. Certification and training of Medical Physicists
4. **Radioactive sources used in brachytherapy**
 - a. Suppliers
 - b. Calibration and source strength specification
 - c. Types of sources and isotopes used
5. **Handling and safety of sources**
 - a. Source handling: distance, shielding and time
 - b. Shipping and receiving sources
 - c. Leak testing
 - d. Storage of permanent and temporary inventory
 - e. Record keeping
 - f. Transport from storage area to patient rooms
6. **Low dose rate procedures**
 - a. Gyn treatments: ^{137}Cs tubes, ^{192}Ir treatments
 - b. Volume implants
 - c. Endobronchial procedures

- d. Personnel protection
- e. Patient surveys and inventory control
- f. Restricted access
- g. Emergency procedures
- 7. High dose rate procedures
 - a. QA for source replacement
 - b. Monthly QA
 - c. Treatment QA
 - d. Procedures
 - e. Emergency procedures
- 8. Records and Reporting
 - a. Quarterly inventory and survey
 - b. Radioactive materials transfer record
 - c. Inventory control for patient treatments
 - d. Source strength records
 - e. Calibration and survey instrumentation records

SUMMARY OF QUALIFICATIONS

Thomas H. Kirby, Ph.D.

December, 1994

Academic positions:

Research Associate Professor at University of New Mexico Health Science Center
Assistant Professor at University of New Mexico Medical School (6 years)
Assistant Professor at Louisiana State University Medical School (2 years)
Instructor at Univ. Texas Houston Graduate School of Biomedical Sciences (6 years)

Education:

Ph.D. in 1980 (Biomedical Sciences) University of Texas at Houston
M.S. 1975 (Physics) Memphis State University
B.A. 1973 (Physics and Mathematics) Southern Illinois University

Teaching / educational productivity:

Instructor for 3 courses at UNM (RTT 350, 360, 370) 1 to 3 semester hours. 11 full academic courses at various levels from RTT school to graduate level (most of them multiple years) at different universities, including: Astronomy lab and lecture, General physics lectures and labs, RTT physics, Solid state physics, Dosimetry, Electromagnetic theory, Radiobiology. I developed the course curricula for most of these courses. All were regularly scheduled courses for academic credit, mostly 2 to 4 semester hours. The number of students varied from 4 to 30.

Scholarship / Research / Creative work

- 1) Author or co-author of 10 refereed published scientific articles
- 2) Invited speaker twice for national review courses
- 3) Author or co-author for 18 national presentations and abstracts
- 4) Author or co-author for 5 refereed technical reports
- 5) Two papers submitted for publication
- 6) Numerous other presentations and lectures for state or local organizations
- 7) Copies of several papers are included in the packet which are representative of my research interests in: imaging, methods used to review dosimetry of national clinical trials, and basic physical measurements related to radiation therapy.
- 8) Member of, or consultant for 4 national scientific task groups (1 current)
- 9) Member of 7 committees for national radiotherapy clinical trial groups
- 10) Principal or co-investigator for 3 research grants
- 11) Chairman of 1 national scientific task group (current)
- 12) American Board of Radiology certified in Therapeutic Radiological Physics
- 13) Reviewer for Medical Physics (peer reviewed scientific journal of AAPM)
- 14) Member of national scientific committee (currently in 2nd three year term)

Service and Administration

- 1) Chief physicist, UNM Cancer Research and Treatment Center (6 years). Responsibilities include development and implementation of new radiotherapy techniques, dosimetry and treatment planning, administration of physics section (8 employees), teaching, engineering, quality assurance, etc. The physics section has the general responsibility for treatment planning and quality assurance of radiation therapy treatments, machine maintenance, teaching RTT students, quality assurance and research and development, etc.
- 2) Physicist at M.D. Anderson Cancer Center, Houston (8 years). Duties included development and implementation of reviews for national clinical trials, teaching in graduate and RTT schools, supervision of graduate students.
- 3) Chief Physicist, Charity Hospital in New Orleans. Roughly the same duties as at UNM, but included supervision of RTT personnel.
- 4) Judge for New Mexico High School Supercomputing Challenge (last 5 years).
- 5) CQI coordinator for Radiation Oncology
- 6) Lecturer for Nuclear Engineering Department's high school teacher science symposia
- 7) Participated in several radiation treatments of animals for cancer in conjunction with area veterinarians.
- 8) Assisted in organizing national AAPM meeting (1982).
- 9) Served as scientific session chair at several national meetings.
- 10) Organized two national / international workshops.
- 11) UNM HSC RTT curriculum committee member
- 12) Advisor or member of 8 graduate student supervisory committees.
- 13) Assisted several other graduate / postdoctoral students from UNM and Los Alamos National Lab while at UNM.
- 14) Graduate student liaison for Univ. Texas Houston Department of Physics for several years. This faculty position served as initial contact for prospective graduate students.
- 15) Partial list of clinical radiotherapy techniques developed and implemented: total body photon irradiation for bone marrow transplants; total skin electron treatments for mycosis fungoides; stereotactic brain implants using radioactive seeds; I-125 eye plaque implants for ocular melanomas; high dose rate afterloader brachytherapy; determination of neutron components of high energy photon beams; calibration of neutron therapy beams; many other routine techniques and dosimetry procedures for radiation therapy.
- 16) Executed beta site tests for Computerized Medical Systems, Inc. radiation therapy treatment planning system.
- 17) Supervisor for Health Careers Opportunity Program high school students for the past 5 years. Average 2 high school students each summer who wish some exposure to the health care field.
- 18) Reviewed well over 100 radiotherapy departments for the NCI while at MDACC.
- 19) President, Computerized Medical Systems, Inc. users group.

Thomas H. Kirby, Ph.D.

CURRICULUM VITAE
April, 1995

Name: Thomas H. Kirby, Ph.D.

Present Title: Chief Physicist
University of New Mexico
Cancer Research and Treatment Center

Born: November 10, 1951
St. Louis, MO

Citizenship: U.S.A.

Social Security: 350-46-3740

Home Address: 5015 Larchmont, NE
Albuquerque, New Mexico 87111
(505) 271-0156

Office Address: Radiation Oncology Department
University of New Mexico
Cancer Research and Treatment Center
900 Camino de Salud, NE
Albuquerque, New Mexico 87131-5331
(505) 277-6141

Education: Ph.D. (1980) Biomedical Sciences
The University of Texas at Houston

M.S. (1975) Physics
Memphis State University

B.A. (1973) Physics and Mathematics
Southern Illinois University at Carbondale

Specialty Boards and Licenses:

Certified in Therapeutic Radiological Physics, American Board of Radiology
(1988).

State of New Mexico License in Radiation Safety and Radiation

Therapy Machine Calibration

Academic and Professional Appointments:

- 1989 - present: Chief, Physics Section, Radiation Oncology Department
University of New Mexico
Cancer Research and Treatment Center
- Assistant Professor
University of New Mexico School of Medicine
- 1986 - 1989: Assistant Physicist, Instructor
1983 - 1986: Assistant in Physics
Department of Radiation Physics
University of Texas M.D. Anderson Cancer Center at Houston
- 1986-1989: Associate Faculty Member
University of Texas Health Science Center at Houston
- 1981 - 1983: Staff Clinical Physicist & Consultant Physicist
West Jefferson General Hospital, Marrero, LA
- Chief Clinical Physicist
Charity Hospital of Louisiana, New Orleans, LA
- Assistant Professor
Louisiana State University Medical School, New Orleans, LA
- 1980 - 1981: Assistant in Physics
Department of Radiation Physics
University of Texas M.D. Anderson Cancer Center at Houston

National Scientific Committees:

- 1990 - present: American Association of Physics in Medicine (AAPM)
Radiation Therapy Committee (RTC)
- 1993 - present: AAPM RTC Task Group 54 (Linear Accelerator Primary / Scatter
Radiation), Chairman
- 1989 - 94: AAPM RTC Task Group 46 (Linear Accelerator Data)
- 1988 - 89: AAPM RTC Task Group 18 (Fast Neutron Dosimetry)
- 1983 - 86: AAPM RTC Task Group 29 (Total Body Irradiation Techniques),
Consultant
- 1983 - 89: AAPM RTC Task Group 31 (Quality Assurance)

National clinical trial groups:

- 1983 - 1986: Radiation Therapy and Physics Committee,
Brain Tumor Cooperative Group*
- 1980 - 1986: Radiotherapy Quality Control Subcommittee
Southeastern Cancer Study Group*
- 1987 - 1989: Radiation Therapy Oncology Group*
- 1986 - 1989: Member or alternate: Executive Committee, Radiation Therapy and
Physics Committee, Data Safety and Monitoring Committee
Collaborative Ocular Melanoma Study, National Eye Institute
- 1984 - 1989: Radiation Therapy Committee,
Radiation Therapy Quality Control Subcommittee,
Southwest Oncology Group*

*Funded by the National Cancer Institute for national clinical trials

- 1988 - 1989: South-North Center for Health Studies

Thomas H. Kirby, Ph.D.

Workshop Coordinator:

Laboratory Director, "Practical Course of Physical Dosimetry in Radiotherapy for Latin American Physicists (in Spanish)", San Antonio, Texas, August 3-6, 1988.

"Radiation Therapy and Physics of Ocular Melanoma", Collaborative Ocular Melanoma Study Annual Meeting, Sun Valley, Idaho, 1987.

Editorial Boards:

Reviewer, Medical Physics

Honors and Awards:

Rosalie B. Hite Scholar, University of Texas GSBS, 1978 - 1980

President's Scholar, Southern Illinois University, 1969 - 1973

Society Memberships:

1977 - present:	American Association of Physicists in Medicine American Institute of Physics
1989 - present:	American Society for Therapeutic Radiation Oncology
1994 - present:	President, Computerized Medical Systems, Inc. Users Group
1988 - present:	American Homebrewers' Association
1978 - 1981:	Society of Photographic Scientists and Engineers

Grant Support

1987 - 1989:	CA10953, Co-Investigator, Radiological Physics Center (\$3M)
1992:	UNM Research Allocation Committee, Project #C-1041 Development of a Passive Thermometer Implant (\$1500)

Thomas H. Kirby, Ph.D.

1992:

US West Foundation: Heat Monitoring Project (\$2100)

Courses Taught:

- 1989 - present: Physics I & II, Quality Assurance
Radiation Therapy Technology Program
University of New Mexico School of Allied Health Sciences
- 1984 - 1988 Introduction to Radiation Physics,
Physics for Residents in Radiotherapy
Department of Radiation Therapy
University of Texas M.D. Anderson Cancer Center
- 1984 - 1988: Radiation Therapy Physics for Technologists
Radiation Therapy Technology Program
- 1982: Physics for Radiology Technicians
Radiobiology for Nuc. Med. Technologists
Louisiana State University Medical School
- 1980 - 1987: Atomic and Solid State Physics
University of Texas Graduate School of Biomedical Sciences
- 1976 - 1989: External Beam Dosimetry - Principles and Calibrations
External Beam, Interstitial and Intracavitary Dosimetry: Manual and
Computer Methods of Calculation
Dosimetry of High Energy Electron and X-ray Therapy Machines
Department of Radiation Physics
University of Texas M.D. Anderson Cancer Center
- 1973 - 75: General Astronomy Laboratory, Introductory Physics
Department of Physics, Memphis State University
- 1972 - 73: General Physics Laboratory
Department of Physics, Southern Illinois University

Student Supervisory Committees and Other Roles:

Randall Salyer, M.S., University of New Mexico, Nuclear Eng. M.S. Committee, 1995

Cynthia Malmer, M.S., University of New Mexico, Nuclear Engineering Summer Practicum
in Medical Physics, 1994.

R. Cole Robinson, M.S., University of Texas GSBS, 1987 - 1989, Chairman, "Energy

Response of LiF TLD-100 to High Energy Photons"

Student Supervisory Committees and Other Roles (cont'd):

Pei Fong Wong, M.S., Univ. of Texas GSBS, 1986 - 87, "Comparison of Electron Beam Depth-dose and Off-axis Profiles with Various Detectors in Water and Plastic"

Richard Umeh, M.S., 1986, University of Texas GSBS, "Determination of X-ray Beam Quality Changes of Linear Accelerator From Ionization Measurements in Phantom"

Charles Able, M.S., University of Texas GSBS, 1985 - 1987, "Evaluation of the MDAH Total Scalp Electron Irradiation Technique"

David Voehringer, Summer Student, 1988, "I-125 Dosimetry with Thin TLD Chips"

Ann M. Minter, Summer Student, 1985, "High Energy Photon Backscatter Factors"

Douglas A. Cates, Summer Student, 1984, "Total Body Photon Irradiation Dosimetry"

BIBLIOGRAPHY

A. Published Refereed Articles:

1. Zermeno A, Kirby TH, Cowart R, Marsh L: Laser Readout of Electrostatic Images, SPIE Appl. of Opt. Inst. in Med. VII, 173:81-87, 1979.
2. Zermeno A, Marsh L, Cowart R, Ong P, Kirby TH: Light Beam Readout of Electrostatic Images, XII Int. Conf. on Medical and Biol. Eng., Jerusalem, Israel, 1979.
3. Kirby TH, Zermeno A: Residual Potential in Amorphous Selenium Photoreceptors, SPIE Appl. of Opt. Inst. in Med. 8:61-64, 1980.
4. Gastorf RJ, Hanson WF, Berkley LW, Kirby TH, Chu C, Shalek RJ: A Comparison of High Energy Accelerator Depth Dose Data. Medical Physics, 10:881-885, 1983.
5. Kirby TH, Gastorf RJ, Hanson WF, Berkley LW, Gagnon WF, Hazle JD, Shalek RJ: Electron Beam Central Axis Depth-Dose Measurements, Medical Physics, 12:357-361, 1985.
6. Kirby TH, Hanson WF, Gastorf RJ, Connel C, Shalek RJ: Mailable TLD System

for Photon and Electron Beams, Int. J. Rad. Onc. Bio. Phys. 12:261-265, 1985.

A. Published Refereed Articles (cont'd):

7. Kirby TH, Hanson WF, Cates DA: Verification of Total Body Photon Irradiation Dosimetry Techniques. Medical Physics 15:364:369, 1988.
8. Kirby TH, Hanson WF, Johnston D: Uncertainty Analysis of Absorbed Dose Calculations from Thermoluminescence Dosimeters, Medical Physics 19:1427-1434, 1992.
9. Hazle J, Kirby TH and Hanson WF: Results of absorbed dose measurements for TG-21 protocol, Med Physics (accepted for publication), 1994.
10. Karlsson U, Kirby TH, Orrison W and Lionberger M: Ocular Globe Topography in Radiotherapy, Int. J. Rad. Onc. Bio. Phys. (accepted for publication), 1994.

B. Invited Talks:

"Thermoluminescence Dosimetry", Physics Department, Steven F. Austin Univ., 1988.

"Radiotherapy Beam Calibration Techniques", Medical Physics Review Course, AAPM Annual Meeting, Detroit, 1987.

"Medical Uses of Radiation", Workshop for High School Science Teachers, University of New Mexico Nuclear Engineering Department, Albuquerque, NM, 1992-94.

C. Abstracts and Talks Presented:

1. Kirby TH, Hanson WF: Comparison of Graphite and Nylon Thimble Farmer Chambers in the Superevoltage Region, AAPM meeting, Temple, TX, 1974.
2. Zermeno A, Marsh L, Cowart R, Ong P, Kirby TH: Light Beam Readout of Electrostatic Images, XII International Conference on Medical and Biological Engineering, Jerusalem, Israel, 1979.
3. Kirby TH, Zermeno A: Properties of the Duodiellectric Image Receptor, SPIE Applications of Optical Instrumentation in Medicine VIII Conference, Las Vegas, Nevada, 1980.

4. Kirby TH, Gastorf RJ, Hanson WF, Shalek RJ, Hazle JD: Electron Beam Central Axis Depth-Dose Measurements, Medical Physics 11:399, 1984.

C. Abstracts and Talks Presented (cont'd):

5. Kirby TH, Chu CH, Gastorf RJ, Hanson WF, Shalek RJ: Mailed TLD System for Monitoring Output of Electron Producing Machines, Med Physics 11:405, 1984.
6. Radiological Physics Center: Research Activities of the Radiological Physics Center, Scientific Exhibit. Proceedings of the Inter-American Meeting of Medical Physics, Chicago, IL, 1984.
7. Task Group 29, Radiation Therapy Committee of the American Association of Physicists in Medicine: Physical Aspects of Total and Half Body Photon Irradiation.
8. Kirby TH, Hanson WF, Cates DA: Total Body Irradiation Dosimetry. Medical Physics 12:523, 1985.
9. Smith SA, Hidalgo-Salvatierra O, Kirby TH: Energy Response and Fading Characteristics of Different Batches of LiF-TLD. Medical Physics 12:543, 1985.
10. Hazle JD, Hanson WF, Kirby TH, Gastorf RJ, Shalek RJ: Results of Absorbed Dose Measurements for Photon Beams Using the AAPM TG-21 Calibration Protocol. Medical Physics 12:518, 1985.
11. Kirby TH, Hanson WF, Gastorf RJ, Hazle JD, Aguirre JF, Kennedy PM, Wright BA: Experience of the Radiological Physics Center with the New AAPM Calibration Protocol. Medical Physics 13:597, 1986.
12. Hanson WF, Kirby TH, Kennedy PM, Hazle JD, Aguirre JF, Wright BA: Technical Reports from the Radiological Physics Center. Medical Physics 13:596, 1986.
13. Kalend AM, Reinstein LE, Kirby TH: Dependence of Wedge Factor Upon Measurement Depth. Medical Physics 14:490, 1987.
14. Robinson RC, Kirby TH: Energy of Response of LiF TLD-100 to High Energy Photon Beams. Phys. Med. Biol. 33 Supplement 1:7, 1988.
15. Hanson WF, Kennedy PM, Krefft GB, Aguirre JF, Kirby TH: Improvement in Dosimetry Practices Over 20 Years: A Historical Account From the RPC, 1989, ASTRO Meeting.

16. Kirby TH, Hanson WF, Johnston DA: Uncertainty Analysis of Absorbed Dose Calculations From Thermoluminescent Dosimeters, 1989 AAPM Meeting.
17. Karlsson UL, Kirby TH, Orrison W and Lionberger M: Localization Precision of the Ocular Lens for Radiotherapeutic Simulation, Radiological Society of North America, 1993 Annual meeting.
18. Orcutt FV, Karlsson UL, Kirby TH, Firoozbakhsh KK: The Shielding Effect of Spinal Implants During Therapeutic Radiation of the Spine, North American Spine Society Annual Meeting, San Diego CA, 1993.

D. Books and Chapters:

1. Kirby TH: The Effect of Neutron Radiation in Tissue, Thesis, MSU, 1975.
2. Kirby TH: Origin of Residual Potential in Amorphous Selenium Photoreceptors, Ph.D. Dissertation, University of Texas at Houston, 1980.

E. Technical Reports (peer reviewed):

1. Hanson WF, Shalek RJ, Kirby TH, Kennedy PM: Information That Should be Included in Every Patient's Radiotherapy Record (External Beam). Radiological Physics Center Technical Report 18, 1985.
2. Kirby TH, Minter AM, Hanson WF: Peakscatter Factors for High Energy Photon Beams. Radiological Physics Center Technical Report 19, 1986.
3. Kirby TH, Hanson WF, Wong PF: Estimate of the Minimum Radiation Dose Delivered to the Meninges From 10 MV X-Rays. Radiological Physics Center Technical Report 20, 1986.
4. Wright BA, Kirby TH, Hanson WF: Participation of the Radiological Physics Center in the NBS Ferrous Sulfate Dosimeter Electron Beam Monitoring Program. Radiological Physics Center Technical Report 21, 1986.
5. Kirby TH, Hanson WF, Gastorf RJ, Hazle JD, Aguirre JF, Kennedy PM, Wright BA: Experience of the Radiological Physics Center with the New AAPM Calibration Protocol. Radiological Physics Center Technical Report 22, 1986.

ATTACHMENT 4

IRRADIATOR SAFETY TRAINING





ETHICON ENDO-SURGERY

a Johnson & Johnson company

P.O. Box 26202
Albuquerque, New Mexico 87125

25 September 1997

To:

William Floyd
New Mexico Environment Department
Hazardous & Radioactive Materials Bureau
Radiation Licensing and Registration Section
FAX (505) 827-1544

From:

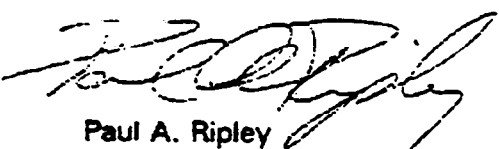
Paul Ripley
Radiation Safety Officer
License G1316-01

Subject: Summary of Training Subjects and Period of Training

Attached is one sheet listing the initial and periodic training requirements per 20 NMAC3.1 Section 1517.

This is what I am using for guidance on annual retraining.

Let me know if you need more.


Paul A. Ripley

ETHICON ENDO-SURGERY
 Albuquerque
 License GI316-01

Training Requirements

9/25/97
 2:10 PM

20 NMAC 3.1 Section 1517	Subject	Period (Weeks)
A.1	Fundamentals	To Operate
A.2	Regulations (SA 0401)	To Operate
A.3	Operation of Irradiator	To Operate
A.4	Procedures	To Operate
A.5	Accident Reports	To Operate
B	Operations Test	To Operate
C	On The Job Training	To Operate
D.1	Procedure Review	52
D.2	Regulation Review (SA 0401, 5.1.3)	52
D.3	Anomaty Review	52
D.4	Safety Performance Review	52
D.5	Equipment Performance Review	52
D.6	Emergency Drill	52
E	Performance Review	52

ATTACHMENT 5

PROCEDURES FOR LICENSING ACTIONS/NEW LICENSES

EVALUATION FORM



PROCEDURES FOR LICENSING ACTIONS

NEW LICENSES

New license applications go into loose-leaf RAM file folders.

PART I: NEW LICENSE APPLICATION REQUESTED

1. Print mailing label for person requesting license application.
2. Prepare LICENSE APPLICATION PACKET (Application form, instructions, NMED Form 045, and cover letter with information as to where copy of New Mexico Radiation Protection Regulations may be obtained).
3. Identify the LICENSE TYPE from application information (e.g., Well Logging, D/M Gauge, Medical, etc.).
4. Create TEMPORARY FILE. Include in this file a LICENSE APPLICATION REVIEW CHECKSHEET and a TRACKING SHEET as well as a copy of the cover letter [sent with the license packet to applicant].
5. Place TEMPORARY FILE in NEW LICENSE PENDING filing drawer. New license applicants do not have a deadline to submit an application. File ALPHABETICALLY.

PART II: NEW APPLICATION RECEIVED

1. Date stamp, log, and assign a docket number to NEW APPLICATION in accordance with standard procedures.
2. Retrieve TEMPORARY FILE from NEW LICENSE PENDING file drawer.
3. Mail a copy of a NEW APPLICATION RECEIVED LETTER to applicant. Place a copy of the NEW APPLICATION RECEIVED LETTER in the TEMPORARY FILE.
4. Place NEW LICENSE APPLICATION in TEMPORARY FILE. Put license review checksheet with APPLICATION.
5. Obtain price quote for printing public notice in legal notice section of newspaper of general circulation in area where

licensee will be located. Once purchase order is approved, send public notice to newspaper for publication.

6. Forward TEMPORARY FILE with NEW LICENSE APPLICATION to materials licensing supervisor or to designated license reviewer.

PART III: ISSUING NEW LICENSES

1. If DEFICIENCY LETTERS are written by TECHNICAL STAFF during the license review, support staff should process them within 5 days and TICKLE the file for the indicated amount of time.
2. When a response to a DEFICIENCY LETTER is received, support staff retrieves the TEMPORARY FILE from the TICKLE FILE drawer, places the document received in the TEMPORARY FILE, and forwards the file to the materials supervisor.
3. When the NEW APPLICATION review is complete, staff processes the license in draft using a DRAFT LICENSE as designated by technical staff.
4. Staff returns DRAFT LICENSE to RLRS Program Manager for final review.
5. Program Manager reviews draft license and submits to Bureau Chief for review.
6. Bureau Chief approves or disapproves draft & returns draft license for final typing, incorporating any recommended changes.
7. Bureau Chief signs license and keeps copy in tickle file for inspection within six months of date of issue.
8. After final reviews by technical and management staff, support staff makes copies of documents and mails license in accordance with MAILING Procedures. Support Staff completes data entry and files one copy of license in License file, and one copy in chronological file.

RENEWALS

PART I: RENEWALS COMING DUE

1. On the last Monday of each month, prepare mailing labels for licenses on the database report called UPCOMING RENEWAL LIST for the current month. This report lists all licenses expiring three (3) months from the date of the report.
2. Identify the LICENSE TYPE for each expiring license. Prepare LICENSE PACKETS, including application for renewals, instructions, and cover letter notifying license of impending expiration.
3. Mail RENEWAL PACKETS
4. Make TEMPORARY FILE with copy of cover letter for each licensee to whom a RENEWAL PACKET was mailed. Include in this file a LICENSE APPLICATION REVIEW CHECKSHEET and a TRACKING SHEET.
5. TICKLE for 60 days from the date the packets are mailed (this is one month before the license expires).
6. File temporary file under appropriate date in TICKLE FILE.
7. If the RENEWAL APPLICATION is not received by the TICKLE DATE, give the TEMPORARY FILE to the radioactive materials Program Manager for action.

PART II: RENEWAL APPLICATION RECEIVED

1. Date stamp, log, prepare TRACKING SHEET.
2. Retrieve TEMPORARY FILE from TICKLE FILE drawer.
3. Mail a copy of the TIMELY RENEWAL LETTER (signed by Program Manager) to licensee. Place a copy of the TIMELY RENEWAL LETTER in the TEMPORARY FILE.
4. Place LICENSE RENEWAL in TEMPORARY FILE.

5. Forward TEMPORARY FILE with RENEWAL APPLICATION to Program Manager or reviewer.

PART III: ISSUING RENEWAL LICENSES

1. If DEFICIENCY LETTERS are written by TECHNICAL STAFF during the license review, support staff should process them within 5 days and TICKLE the file for the indicated amount of time.
2. When a response to a DEFICIENCY LETTER is received, staff retrieves the TEMPORARY FILE from the TICKLE FILE drawer, places the document received in the TEMPORARY FILE, and forwards the file to the Program Manager.
3. When the RENEWAL APPLICATION review is complete, staff processes the license in draft using a DRAFT LICENSE as designated by Program Manager.
4. Staff returns DRAFT LICENSE to Program Manager for final review.
5. Staff completes processing, signs off on TRACKING SHEET, and forwards finished document to Program Manager for final review.
7. After final review by Program Manager, staff makes copies of documents and mails license in accordance with MAILING procedures. Staff completes data entry.

AMENDMENTS

PART I: ADMINISTRATIVE AMENDMENTS

NOTE: ADMINISTRATIVE AMENDMENTS are used for corrections to licenses or to make administrative changes to licenses, e.g., correct typographical errors.

1. When the ADMINISTRATIVE AMENDMENT OR CORRECTED COPY is complete, staff processes the license in draft using DRAFT LICENSE.
2. Staff returns DRAFT document to Program Manager for final review.

3. Staff prints final license and forwards finished document to Program Manager for final review.
4. After final review and signature by Program Manager, staff makes copies of documents and mails license in accordance with MAILING procedures. Two copies are made: One for license folder and one for chronological file.

PART II: LICENSEE-REQUESTED AMENDMENTS

1. Date stamp AMENDMENT REQUEST LETTER.
2. Place AMENDMENT REQUEST LETTER and TRACKING SHEET in TEMPORARY FILE FOLDER.
3. Forward TEMPORARY FILE with AMENDMENT REQUEST LETTER to Program Manager or reviewer.
4. If DEFICIENCY LETTERS are written by TECHNICAL STAFF during the AMENDMENT REQUEST review, support staff should process them within 5 days and TICKLE the file for the indicated amount of time.
5. When responses to a DEFICIENCY LETTER are received, support staff retrieves the TEMPORARY FILE from the TICKLE FILE, places the document received in the TEMPORARY FILE, and forwards the file to the Program Manager.
6. When the AMENDMENT REQUEST review is complete, support staff processes the AMENDMENT in draft using a DRAFT LICENSE.
7. Staff returns DRAFT LICENSE to Program Manager for final review.
8. Staff prints final license, signs off on TRACKING SHEET, and forwards finished document to Program Manager for final review.
9. After final review and signature by Program Manager, support staff makes copies of documents and mails AMENDMENT in accordance with MAILING procedures.

TERMINATIONS

1. Send Certificate of Disposition with Technical staff business card.
2. Create pending file with telecon document or letter requesting termination of license.
3. Tickle for 30 days.
4. Data entry for milestone tickle.

WORD PROCESSING

Support staff are expected to be able to use WordPerfect 6.0. The Agency provides training to use the word processing program.

The following STANDARD LETTERS are included in computer generated files:

- LICENSE APPLICATION REQUESTED LETTER
- NEW LICENSE APPLICATION RECEIVED LETTER
- AMENDMENT LETTER
- RENEWAL DUE LETTER
- TIMELY RENEWAL LETTER
- NOTICE OF NONCOMPLIANCE LETTER
- NO ITEMS OF NONCOMPLIANCE LETTER
- CLOSE LOOP INSPECTION LETTER

The following STANDARD DRAFT LICENSES are included:

- MEDICAL
- FIXED AND PORTABLE GAUGE
- INDUSTRIAL RADIOGRAPHY
- GAS CHROMATOGRAPH
- BROAD SCOPE
- INDUSTRIAL

LICENSE APPLICATION EVALUATION FORM

1. Applicant Name:
License Number:
Expiration Date:

2. Address: Actual Location:

Telephone #:

3. Contact: Contact:

4. Is the location listed identifiable from the description offered? (P.O. Box alone not acceptable) Yes No

5. Is the applicant a corporation? Yes No

If yes, is the corporation registered with the State Corporation Commission?
Yes No.

If No, request that registration be made prior to preceding with application review.

6. If applicant is not a corporation, has registration been made with Taxation & Revenue Dept.? Yes No

7. If the reviewer considers the application acceptable for review, has the reviewer issued a certified letter of acceptance to the applicant? Yes No

If yes, has the reviewer issued a Public Notice to the local paper nearest the proposed facility on a 60-day public comment period and possible hearing? Yes No.

Name of local paper:
Publication Date:
Application Date:

REVIEWERS EVALUATION COMMENTS:

(Adequacy must be evaluated by the reviewer. Reference Licensing Guides and 20NMAC 3.1 for all Applicants for Radioactive Materials License).

8. **Facility and Equipment:** The facility must be evaluated for proper radioactive material use and storage requested (design, shielding, etc.). Evaluation must include a consideration of health and environment impact from exposure and probable release of material to restricted and unrestricted areas: (See 20NMAC 3.1 - Subpart 3, Section 308 and licensing guidance specific to type of license , (e.g. Reg. Guide 10.8, "Use of Radioisotopes for Human Use") and Applicant's SOPs).

9. Evaluate the application and assume sufficient description is outlined for the isotopes and quantities to be used: (See Sealed Source and Device Catalog or Specific Regulatory Guidance for specific license type).

<u>Radioisotopes</u>	<u>Mass No.</u>	<u>Form (Chem/Phys.)</u>	<u>Model #</u>	<u>Quantity/Activity</u>
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10. Evaluate applicants description outlined for the uses to be made of each radioisotope and quantity:

14. Evaluate procedures for ordering and receiving radioactive material and procedures for safely opening packages containing radioactive materials. (See 20NMAC 3.1, Subpart 4, Section 432, or Subpart 7, Section 703 H).

15. Evaluate instrumentation used and survey procedures and frequencies by area, designated with action levels, and calibration frequencies by an NVLAP certified provider and certified by the State. (See 20NMAC 3.1, Subpart 4, Section 416, or Section 703B and 703 M, Survey Instrumentation and also Dose Calibrator Requirements, Subpart 703A).

16. Determine whether adequate dosimetry is being utilized. (NVLAP provider and frequency) and type of bioassay if required by license condition or application commitment. (See 20NMAC 3.1, Subpart 4 or, Section 707, Control of Aerosols and Gases).

17. Evaluate the possibility of radioactive waste production by the applicant and the ability to adequately store and dispose of such waste. (General Disposal requirements 20 NMAC 3.1, Section 433, "Waste Disposal General Requirements," and 435, "Disposal by Release into Sanitary Sewage", or "Disposal by Decay-in-Storage" and "Disposal by contracted Disposal Facility." See Standard Licensing Conditions, or other shielding requirements in 20NMAC 3.1.; (Section 703G., "Vial and Syringe Shields and Labels").
18. Evaluate the adequacy of the Radiation Protection Procedures, including General Rules For Safe Use of Radioactive Material and Emergency Plans, of the applicant's SOP Manual. (Radiation Protection Program, 20NMAC 3.1, Subpart 404 B. or 702.B). Keep doses as low as reasonable achievable (ALARA): The licensee shall at intervals not to exceed 12 months, review the radiation protection program content and implementation. RSO daily oversight. The following should be reviewed and evaluated:
- Fire Protection described in safety manual.
 - All placarding and labeling according to U.S. DOT regulations.
 - Good housekeeping commitments.
 - Effluent concentration limits in accordance with 20NMAC 3.1, Subpart 4:
 - A. Section 406, "Compliance with Requirements For Use Summation of External & Internal Doses.", or may be more restrictive;
 - B. Bioassay Program Yes No;
 - C. Section 417 as appropriate, Radiation Survey Program; Daily surveys and contamination daily smears, action levels in accordance with Appendix F, Table F-1, Reg. Guide 8.23;
 - D. Section 428 and 429, "Radiation Signs & Symbols," and "Exceptions to Posting Requirements";
 - E. Section 432, "Procedures for Receiving & Opening Packages," in accordance with U.S. DOT regulations,. In accordance with Section 325, "Preparation of RAM for Transport," exposure rate levels. See applicant's procedures.
 - Subpart 1, Section 108 & 441, "Records for Radiation Protection Provisions of Program," shall be kept until termination of license. Records of audits and reviews of program content and implementation maintain for 3 years after record is made. Other reporting procedures in specific areas were records and reports are required.

- Training as described for specific license types. (See 20NMAC3.1 and Applicant's SOPs for type of license requested).

19. For purposes of complying with the requirements of 20NMAC 3.1, Subpart 3, Section 311 F., "Decommissioning and Surety Plan for the Facility", is documentation requested attached. Send applicable letter of deficiency upon final evaluation or if this section does not apply to this applicant, answer N/A.

20. This application, after this review, is considered to be complete and adequate for license issuance. Yes No;

If Yes, License number assigned _____ ;

If No, Indicate what actions were taken:

Reviewed by _____

Date: _____

NMED/RLRS.REV. 10/97

MEMORANDUM

TO: New Mexico Radiation Material Licensee

FROM: William M. Floyd, Program Manager
Radiation Licensing & Registration Section

DATE: October 3, 1997

SUBJECT: Review Content of New/Amended License

Please carefully review content of enclosed New Mexico Radioactive Material License. Requested changes are indicated by bold lettering. Please report any errors or omissions to this section immediately. Licensees are to be thoroughly familiar with license content.

When requesting future license amendments, please include license name and amendment number to ensure that correct license is amended.

NOTE: Copies of the New Mexico Radiation Protection Regulations (20NMAC 3.1-May-3-1995) may be obtained from Santa Fe Printing, 1424 Second Street, Santa Fe, New Mexico, 87501, telephone number (505) 982-8111.

Should you have any questions, please call the office at (505) 827-1862.



APPLICATION FOR RADIOACTIVE MATERIAL LICENSE HUMAN USE

New Mexico Environment Department, Hazardous and Radioactive Material Bureau
525 Camino de los Marquez • P.O. Box 26110, Santa Fe, NM 87502-6110 • (505)827-4300
4131 Montgomery Blvd. NE, Albuquerque, NM 87109 • (505)841-9465

INSTRUCTIONS: Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed and signed. Retain one copy. Submit original to one of the above addresses. Upon approval of this application, the applicant will receive a Radioactive Material License.

1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIPCODE TELEPHONE NO.: () _____	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (if different from 1.a.) INCLUDE ZIPCODE
2. PERSON TO CONTACT REGARDING THIS APPLICATION TELEPHONE NO.: () _____	3. THIS IS AN APPLICATION FOR: (Circle appropriate item) a. NEW LICENSE b. AMENDMENT TO LICENSE NO. _____ c. RENEWAL OF LICENSE NO. _____
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete supplements A and B for each individual.)	5. RADIATION PROTECTION OFFICER (RPO) (Name of person designated as a radiation protection officer. If other than individual user, complete resume of training and experience as in Supplement A)

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE					
RADIOACTIVE MATERIAL LISTED IN:	CHECK ITEMS DESIRED	MAXIMUM POSSESSION LIMITS (millicuries)	ADDITIONAL ITEMS:	CHECK ITEMS DESIRED	MAXIMUM POSSESSION LIMITS (millicuries)
3-220 F FOR IN VITRO STUDIES		As Required	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
T 3, SCHEDULE C, GROUP I		As Required	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PART 3, SCHEDULE C, GROUP II		As Required	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS		
			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS		
			IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
			XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. For sealed sources include manufacturer and model or drawing number.			
ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the date of the guide.

.. MEDICAL ISOTOPE COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check one)
Names and Specialties Attached; and		Appendix G Rules Followed; or
Duties as in Appendix B; or (Check one)		Equivalent Rules Attached
Equivalent Duties Attached		
8. TRAINING AND EXPERIENCE		16. EMERGENCY PROCEDURES (Check one)
Supplements A & B Attached for Each Individual User; and		Appendix H Procedures Followed; or
Supplement A Attached for RSO		Equivalent Procedures Attached
9. INSTRUMENTATION (Check one)		17. AREA SURVEY PROCEDURES (Check one)
Appendix C Form Attached; or		Appendix I Procedures Followed; or
List by Name and Model Number		Equivalent Procedures Attached
10. CALIBRATION OF INSTRUMENTS		18. WASTE DISPOSAL (Check one)
Appendix D Procedures Followed for Survey Instruments; or (Check one)		Appendix J Form Attached; or
Equivalent Procedures Attached; and		Equivalent Information Attached
Appendix D Procedures Followed for Dose Calibrator; or (Check one)		19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check one)
Equivalent Procedures Attached		Appendix K Procedures Followed; or
FACILITIES AND EQUIPMENT		Equivalent Procedures Attached
Description and Diagram Attached		20. THERAPEUTIC USE OF SEALED SOURCES
12. PERSONNEL TRAINING PROGRAM		Detailed Information Attached; and
Description and Diagram Attached		Appendix L Procedures Followed; or (Check one)
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		Equivalent Procedures Attached
Detailed Information Attached		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon-133)
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS		Detailed Information Attached
Appendix F Procedures Followed; or (Check one)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
Equivalent Procedures Attached		Detailed Information Attached
		23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b.
		Detailed Information Attached

24. PERSONNEL DOSIMETRY (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
WHOLE BODY	FILM		
	TLD		
	OTHER (Specify)		
b. FINGER	FILM		
	TLD		
	OTHER (Specify)		
c. WRIST	FILM		
	TLD		
	OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL			b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR
Name of Hospital			
Mailing Address			c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS
City	State	Zip	

26. CERTIFICATE

(This item must be completed by the applicant)

a. The applicant and any official executing this certificate on behalf of the applicant named in Item 1.a. certify that this application is prepared in conformity with Part 3, New Mexico Radiation Protection Regulations and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

NAME (Type or print)

TITLE

DATE

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2.
---	----

3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

APPLICANT PHYSICIAN'S NAME AND ADDRESS			<p align="center">KEY TO COLUMN C</p> <p>Personal participation should consist of:</p> <ol style="list-style-type: none"> Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.
FULL NAME			
STREET ADDRESS			
CITY	STATE	ZIP	

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
BONE IMAGING			

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted on separate sheets) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
	REAGENT KITS		
OTHER			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:	6. PRECEPTOR'S SIGNATURE
NAME OF SUPERVISOR	
NAME OF INSTITUTION	7. PRECEPTOR'S NAME (Please type or print)
MAILING ADDRESS	
CITY	8. DATE
5. MATERIALS LICENSE NUMBER(S)	



GARY E. JOHNSON
GOVERNOR

State of New Mexico
ENVIRONMENT DEPARTMENT
Hazardous & Radioactive Materials Bureau
2044 Galisteo
P.O. Box 26110
Santa Fe, New Mexico 87502
(505) 827-1557
Fax (505) 827-1544



MARK E. WEIDLER
SECRETARY

EDGAR T. THORNTON, III
DEPUTY SECRETARY

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS: Complete Items 1-17 if this is an initial application. If application is for renewal of a license, complete only Items 1-7 and indicate new information or changes in the program as requested in Items 8-17.

(a) Name, street address, and phone number of applicant (Institution, Firm, Person, Department, etc.)	1.(b) Street address(es) and phone number at which radioactive material will be stored and used (PO Box numbers are not acceptable)
Person to contact regarding application (include phone #)	3. Previous License Numbers (if this is a renewal application, please so indicate and give current license number)
individual Users (name and title of individuals who will use or directly supervise use of radioactive material)	5. Radiation Safety Officer (attach resume of training and experience)

a) Element Mass No. (b) Form (Chem/Phys) (c) Max. Activity (d) Manufacturer & Model No. (sealed sources)

Use to be made of each item of radioactive material requested above (attach supplemental sheets if necessary)

Individual User(s) Training (attach resume). Complete the following information on the individual user(s) and their training in:

- (A) Nuclear physics, atomic structure, and interaction of radiation with matter
- (B) Radiation detection instrumentation, calibration, and standardization
- (C) Radiation protection, waste disposal, and survey and dosimetric procedures
- (D) Radiobiology, including effects of radiation on the human body

<u>Name, Title, Degree(s)</u>	<u>Where Trained</u>	<u>Length of academic Training in A, B, C, D</u>	<u>Length of on-the-job Training in A, B, C, D</u>
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Experience With Radiation (actual use of radioisotopes, attach resume)

<u>Name</u>	<u>Isotope</u>	<u>Maximum Activity</u>	<u>Place of Experience</u>	<u>Length of Experience</u>
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Radiation Detection Instruments (attach supplemental sheets if necessary)

<u>Model</u>	<u>Number available</u>	<u>Radiation detected</u>	<u>Sensitivity range mr/hr</u>	<u>Window thickness mg/cm²</u>	<u>Use of instrument (e.g. monitoring, surveying, measuring)</u>
--------------	-----------------------------	-------------------------------	------------------------------------	---	--

Method, frequency, and standard uses in calibration instruments listed in Item 10 (attach supplemental sheets if necessary)

12. Film badges, dosimeters, and bioassay procedures used (for film badges and TLD's, specify method of calibrating and processing, or name of supplier, specify frequency of exchange; attach supplemental sheets if necessary)

ITEMS 13-16 ARE TO BE ANSWERED ON SUPPLEMENTAL SHEETS

13. Facilities and Equipment. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. (Attach explanatory sketch of facility)
14. Radiation Protection Program. Describe the radiation protection program, including control measures. If application covers sealed sources, submit leak testing procedures where applicable; name, training, and experience of persons to perform leak test, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.
15. Waste Disposal. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.
16. (a) Survey Program. Describe the surveys to be made to determine if radiation hazards exist in a facility in which radioactive material is used or stored.
Records Management Program. Records keeping and reviewing records of surveys, material inventories, personnel exposures, etc.

CERTIFICATE

(This item must be completed by the applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1, certify that this application is prepared in conformity with the New Mexico Radiation Protection Regulations, Subpart 3—Licensing of Radioactive Materials, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name (Please Print)

Applicant Signature

Date

Certifying Official (Please Print)

Certifying Official Title

Certifying Official Signature

Date

ATTACHMENT 6A

GENERAL INSPECTION REPORT FORM

**INSTRUCTIONS FOR INSPECTION AND PREPARATION OF
GENERAL INSPECTION REPORT**

GENERAL LICENSE INSPECTION REPORT CHECKLIST



INSTRUCTIONS FOR INSPECTION AND
PREPARATION OF GENERAL INSPECTION REPORT

PART 1. INSPECTION BACKGROUND DATA

1. Complete all items; if this is an initial inspection indicate under last inspection date.
2. Check announced or unannounced.
3. With the exception of initial inspections all inspections should be unannounced.

PART 2. LICENSE DATA

1. Complete all items.

PART 3. PREVIOUS INSPECTION CORRECTIONS

1. Review the corrective action taken for all violations found during the last inspection. Either close out as satisfactory or list as a repeat finding on the current inspection.
2. Review acceptance of any recommendations made during the last inspection and close out if applicable.

PART 4. PERSONS CONTACTED

1. List all individuals contacted and their job titles.
2. For broad licensees, give the principal investigator and use authorization number or designation.

PART 5. MANAGEMENT

1. Describe the organization and attach an organization chart if applicable.
2. Describe the Radiation Safety Officer (RSO) position within the organization and the ability to carry out responsibilities such as filling vacancies and obtaining equipment and supplies as necessary.
3. Review minutes of the Committee meetings and verify actions required for safety are addressed. Did the committee perform safety audit responsibilities?
4. List name and title of Committee members.

PART 6. UNUSUAL OCCURRENCE OR INCIDENTS

1. Review any incidents reported and investigations since the last inspection.
2. Review corrective actions taken as the result of a Notice of Violation issued for a reportable incident.
3. In cases where overexposures have occurred, evaluate actions the licensee has taken to prevent recurrence.

PART 7. INVENTORY

1. Verify compliance with maximum allowable type and quantities isotopes authorized.
2. Verify frequency and accuracy of inventories taken by the licensee.
3. Verify that material is used in accordance with the application.
4. Uses of material.

PART 8. SEALED SOURCES

1. Verify that leak test are taken at required frequency.
2. Verify that records are accurate and complete.
3. Verify that qualified individual makes leak test swipe.
4. Verify that leak test samples are analyzed by qualified individual or authorized service.
5. Verify that safety mechanisms are tested (ie shutter) IAW license conditions or procedures.

PART 9. USE LOCATIONS

1. Identify temporary job sites authorized.
2. Identify storage areas.
3. Confirm that fire protection is provided.

PART 10. Training

1. Verify authorized users per license or license condition.
2. Review training records for users and ancillary personnel.
3. Discuss radiation safety principles with workers.
4. Review training provided for special uses such as transportation and waste packaging.
5. Review refresher training.

PART 11. POSTING

1. Verify that all posting requirements are being met.
2. Examine discarded containers. Are labels defaced when the container is discarded after use?

PART 12. EXTERNAL RADIATION MONITORING

1. Review all monitoring records from the last inspector forward.
2. Verify that all individuals who are required to have monitoring are assigned monitoring.
3. Evaluate type vs needs.
4. Evaluate the licensee's efforts towards reduction in dose (ALARA).

PART 13. INTERNAL DOSE EVALUATIONS

1. Confirm that bioassays have been done if indicated, and records maintained.
2. Determine equipment sensitivity and appropriateness of measurements.
3. Review records.
4. Review use of engineering controls.

PART 14. ENVIRONMENTAL

1. Evaluate all areas where releases to the environment may have occurred. Determine adequacy of the licensee's monitoring program. Review results.

PART 15. INSTRUMENTATION

1. Verify that the licensee has the proper type of instruments for their needs.
2. Verify that there is adequate instrumentation available for surveys.
3. Verify that calibrations are adequate and have been done in accordance with written procedures.

PART 16. PROCEDURES

1. Verify the licensee has copies of all procedure manuals and documents that were submitted with the license application. Review procedures for updates or changes not included in licensee file.
2. Review procedures covering receipt of licensed material.
3. Assure that procedures are followed by reviewing records of receipt and package surveys.
4. Assure that waste packaging and shipment procedures are followed and procedures are adequate by reviewing records of shipments.
5. Review transfer procedures and records of licensed material transfers that may have an impact on areas not under control of the licensee.
6. Verify that radiation protection standard operation procedures that were approved by the radiation control program have not been modified.
7. Verify that approved procedures are being followed.
8. Verify that emergency procedures are adequate for the needs of the licensee.

PART 17. RADIOACTIVE WASTE

1. Review waste storage and packaging procedures.
2. Verify that storage for decay procedures are not causing elevated radiation doses to waste processing workers.
3. Verify that all labels of empty containers and shields are defaced before items are released to sanitary landfills.

PART 18. Shipping and Packaging

1. Verify that all appropriate portions of U.S. Department of Transportation regulations Title 49 CFR 170-199 are complied with.
2. Verify that correct documentation on file.

PART 19. INSPECTOR'S MEASUREMENTS AND OBSERVATIONS

1. Make measurements in all areas called for, both wipes and direct radiation measurements.
2. Document results.
3. Attach a floor plan when radiation levels may have an impact on personnel exposures.
4. Complete the entire observation checklist.
5. Comment on discussions with radiation and ancillary workers. Are workers knowledgeable of precautions to take for various radiation hazards?

PART 20. INSPECTION FINDINGS

1. Supply a statement of facts for each item of non-compliance uncovered. Answer the questions; who, what, where, when, how, if possible for each item that may be contested. Follow the rules of evidence. Each item of non compliance must be tied to a specific regulator and/or license condition.

The licensee must be informed of all items of noncompliance uncovered either during the exit interview or following further consultation with the program management by the inspector in cases where the violations are not clear.

NMED/RLRS.REV. 9/97
K-GEN.PRO

GENERAL INSPECTION REPORT FORM

License Number _____
Expiration Date _____
Date of this Inspection _____
Inspection Priority _____
Previous Inspection Date _____

Type of Inspection Routine Announced Unannounced Initial Special

A. LICENSEE & ADDRESS

ACTUAL LOCATION

TELEPHONE _____

B. INDIVIDUALS INCLUDED IN MANAGEMENT INTERVIEW (109):

C. NAME OF RESPONSIBLE PERSON(Organizational chart):

D. SPECIAL LICENSE CONDITIONS (308):

E. Letter sent to Licensee on: _____

Inspector _____

Date of Report _____

Reviewer _____

Date of Review _____

1. FOLLOW-UP ON PREVIOUS INSPECTION FINDINGS:

2. SUMMARY OF LICENSED PROGRAM (Type of program):

3. INTERNAL AUDIT (Annual Safety Review & ALARA & SOP'S):

4. AUTHORIZED USERS: (Training Certification, Supervision of authorized users):

5. TRAINING/RETRAINING:

RSO Training/Experience

Responsibilities & Authority

Ancillary Personnel Training

Refresher Training

By whom/Certification

Written Exam Management Review

6. FACILITIES (Engineered Controls: Access Alarms & Controls, Transport Vehicles, etc):

7. SECURITY (425):

Access and Exit Controls _____
Fire Protection _____
Visible and Audible Warning Signals _____
Physical Security & Monitoring Upon Exit _____

8. EQUIPMENT (Survey Meters, See License Condition or Application):

Monitoring Instruments _____

Calibration Procedures _____ In-House _____ Vendor _____
Calibration Frequency _____
By Whom/Certification Posted _____

_____ Electronic Calibration. Frequency _____
_____ Operational Checks Performed _____
Records _____

9. PROCEDURES FOR RECEIVING AND OPENING PACKAGES (432):

10. INVENTORY LOG/RATE OF USE (317):

11. LEAK TESTS:

12. PERSONNEL DOSIMETRY:

Film Badge or TLD for each Individual

Processed by

Frequency

Exposure Records

Compliance with regulatory limits:

Exposure ALARA (<10% of minimum permissible)

Notification Reports Available to Employee

High Reading/Overexposures

Exposure History provided to Employees

Reports reviewed by

13. POCKET DOSIMETER:

Pocket Dosimeter provided by

Range 0-200 mR/hr.

Calibration Frequency

Exposure History Reviews

14. ENVIRONMENTAL &/OR AIR MONITORING PROGRAM:

(NOTE: ALI-Annual Limit on Intake Values Table 1, Column 1 & 2, Appendix B; DAC-Derived Air Concentration Values Table 1, Column 3, Appendix B)

15. RESPIRATORY PROGRAM (428): Yes No N/A

 Calculations
 Sampling/Analysis
 Records

16. SPECIAL PROCEDURES:

Are iodinations performed? Yes No N/A
IF YES, Isotopes/Quantities: I-125 I-131 Xe-133
Number of procedures per month (avg.) I-125 I-131 Xe-133
Type of monitoring Equipment _____

Performed by _____
Date _____ Results _____
Last charcoal filter change _____

17. BIOASSAYS (408) N/A

Isotopes: C-14 I-125 I-131 H-3 P-32
 License Conditions In-House Vendor
Frequency _____
Equipment/Instrumentation _____
Type of Test: Thyroid Urine Total Body Counting
Other _____
Action Levels _____

22. INCIDENTS OR OVEREXPOSURES:

Reports and Notification _____

23. OPERATIONS OBSERVED: (NOTE: Every attempt must be made to observe operations conducted in association with possession, use, and disposal of licensed material).

24. INFORMATION CONTINUATION FROM PREVIOUS PARAGRAPHS:

25. INDEPENDENT MEASUREMENTS(Results Compared to Licensee, NOTE: Attach analysis report sheet):

Bkgd	Instrument used	Model #	S/N	Cal.Date
Survey/wipe maps				

ATTACHMENT 6B

MEDICAL INSPECTION FORM

INSTRUCTIONS FOR MEDICAL INSPECTION REPORT



INSTRUCTIONS FOR MEDICAL INSPECTION REPORT

PART 1: INSPECTION BACKGROUND DATA

1. Check the appropriate box to indicate if the inspection was announced or unannounced.
2. Fill in the License Number, Inspection Agency, Expiration Date of the License, and the Inspection Date.
3. Did the licensee submit a timely renewal? N/A is used only with a new application.
4. Put in the amendment number when the license was last renewed in its entirety to the current amendment number.
5. Circle the priority of the licensee.
6. Put the date of the last amendment. If its been a year or more, you may wish to check with Licensing Section to determine whether subsequent amendments have been issued.
7. Check the appropriate supplement box(es) if the licensee is authorized for the group(s).
8. The Inspector's signature and the date the UIF was completed.
9. The Supervisor's signature and the date the inspection was approved. This date will depend on the agency's policy: upon completion of the inspection packet or approval of the NOV and cover letter.

PART 2: LICENSEE DATA

1. Fill in the licensee's name and address from the license.
2. If the inspection address is different from the license address, fill in. If it is the same, check the box.
3. Fill in the name and title of individual, administration, who was contacted at the last inspection. If it is a private practice, you may wish to put the business manager's name.

PART 3: LAST INSPECTION/CORRECTIVE ACTIONS

1. Fill in the date of the last inspection and the date of the letter which described the corrective action(s).
2. List the violation(s) noted at the last inspection. If it's too numerous, attach the NOV. If no items of noncompliance were found, write NONE in violations section.

3. List the recommendation(s) from the last inspection. If it's too numerous, attached the cover letter.

PART 4: PERSONS CONTACTED

1. List the names and titles of the persons contacted during the inspection:
 - a. The administrator and/or his assistant who is responsible for the radiology department - This could be the persons you contacted at the beginning of the inspection or the persons contacted by the radiology department.
 - b. The radiation safety officer and/or the chairman of the radiation safety committee and any other physicians that were contacted during the inspection.
 - c. The radiology manager and the chief nuclear medicine technologists.
 - d. The nursing supervisor if training is required of nurses.

PART 5: MANAGEMENT ORGANIZATION

1. If no changes had occurred in management structure, check the box. List the new management who will receive the inspection findings and the organizational chart of the facility.
2. Check if the RSO listed in License Condition #14 is still present.
3. If the Radiation Safety Committee is required:
 - a. Is the chairman as listed in License Condition #14 and is there a member of the administration on the committee?
 - b. Is the RSC meeting at their required frequency?
 - c. Does the minutes reflect the duties of RSC as described in Appendix B?
4. List the chairman, the radiation safety officer, and the administration member from the last inspection or license application. You may wish to make corrections during the inspection.
5. Comments section is for any additional information that is needed but could not be entered in PART 4 or 5 because of space limitation.

PART 6: UNUSUAL OCCURRENCE & INCIDENTS

1. If nothing was found in the inspection file or through interview of the staff, write the name of the senior person making that claim. Check the minutes of radiation safety committee to verify as well as exposure reports.
2. If incidents have occurred, has the facility implemented corrective actions to prevent a reoccurrence?

PART 7: POSTING

1. Is the licensee complying with NMRPR, Subpart 4?

PART 8: EMPLOYEE TRAINING

1. Use the remarks section to describe the training program for the technologist and ancillary staff as well as refresher/continuing education from the license applications.
2. Is the facility complying with commitments made in the license application? If no commitments were made, do you wish to make recommendations?
3. Circle Yes or No, if records were reviewed or if persons were interviewed.

PART 9: EXTERNAL PERSONNEL EXPOSURE

1. Write the name of the vendor from the license application or from the last inspection whichever is later. During the review of exposure records write down the account number, especially if it's a private practice.
2. The period reviewed should be from the last date that was reviewed during the last materials inspection. If the machine program has examined the exposure records after the last materials inspection, you may start from the last date of the machine program. Make a note in the comments section if you are not using the date that was reviewed during the last,materials inspection.
3. Is whole body and extremity monitoring being provided as required by NMRPR, Subpart 4? List badge type, film or TLD, and exchange frequency, monthly or quarterly. Spot check the percentage of late returns. If there is a large number, check the high risk category for complete record.
4. Are pocket dosimeters used? List the types and if they are being calibrated and leakage tested as required.
5. Are there any purported overexposures?

6. Does the facility have a complete and accurate exposure history?
7. Are the exposures ALARA?
8. All overexposure reports made to the Department?
9. Does the facility maintain records of prior doses?
10. Are reports provided to the employees?
11. Who reviews the exposure records?

PART 10: INTERNAL PERSONNEL EXPOSURE

1. If there is no bioassay requirement, check Not Applicable box and skip to Part II.
2. List License Condition(s) which require bioassays. If bioassay is required, is the method, frequency, and instrumentation as described in the License Condition(s)?
3. List the isotope(s) which require bioassay.
4. Was a dose assessment made on the positive bioassay?
5. Check the bioassay procedure(s) used.
6. Check the engineering controls in place to prevent uptake.
7. Was the negative pressure of the storage and use locations for Xe-127/133 checked?

PART 11: NOBLE GAS/SANITARY SEWER RELEASES

1. Documentation that air concentration in controlled areas are within regulation limits, NMRPR, Subpart 4, Section 461, Appendix B.
2. Documentation that air concentration in uncontrolled areas are within regulation limits; NMRPR, Subpart 4, Section 461, Appendix B. Determination made by calculation or sampling analysis?
3. Documentation that water concentration in the sanitary sewer is within regulation limits; NMRPR, Subpart 4, Section 435, Appendix B. Note patient discharges into the sanitary sewer is exempted.
4. All accidental releases reported NMRPR, Subpart 4, Section 452?

PART 12: INSTRUMENT QUALITY ASSURANCE

1. List all model no. and serial no. of dose rate instruments compensated G-M, ion chambers, etc.
 - a. Instruments calibrated at required frequency?
 - b. Proper calibration procedures being followed and performed by an authorized vendor?
 - c. Instrument is capable of measuring the dose rate of therapy patient and/or Tc-99m generator?
 - d. Is it currently operable?
2. List all model no. and serial no. of contamination survey instruments; end-window G-M or pancake probe.
 - a. Instruments calibrated at the required frequency?
 - b. Is check source used to determine if detector is functioning?
 - c. Is it currently operable?
3. List all model no. and serial no. of dose calibrator(s).
 - a. Is the constancy of the dose calibrator checked each day the dose calibrator is used?
 - b. Is the linearity of the dose calibrator checked quarterly?
 - c. Is the dose calibrator calibrated annually?
 - d. Was the geometric variation of the dose calibrator performed at installation or after repair?
4. List all model no. and serial no. of gamma camera(s); fixed and mobile, that are used.
 - a. Is a uniformity flood performed each day the camera is used?
 - b. Is a spatial resolution performed weekly?
5. List model no. and serial no. of other counting system(s): thyroid uptake probe, well counter, etc.
 - a. Proper calibration procedures being followed?
 - b. Instrument(s) calibrated at required frequency?

PART 13: SEALED SOURCES

1. Does the licensee leak test required sealed sources at six month intervals?
2. Are leak test records complete and accurate; all required sealed sources must be leak tested unless there is a license condition exempting stored sealed sources.

3. Is the person taking wipe test of sealed sources authorized by the license?
4. Is the vendor, who is analyzing the wipe tests for leakage, authorized by the Department?
5. Is any positive leak test reported to the Department within five days of the test?
6. List all sealed sources located in Nuclear Medicine Department.

PART 14: PROCEDURAL REVIEW

1. All radioactive materials, standing and non-routine, ordered as per license condition?
2. Written protocols in place for off-duty delivery and security?
3. Package survey and opening per license condition and regulations?
4. Is licensee authorized for a generator and does it perform Mo-99 breakthrough on each eluate?
5. Did the licensee exceed possession limit?
6. Were all users authorized? In places that has only one authorized user, you must interview the user and the technologist and/or review nuclear medicine reports.
7. If locum tenens were used, does the licensee have documentation per license condition?
8. Is the nuclear medicine technologist certified or does the facility have a waiver?
9. Who determines the appropriateness of nuclear medicine procedures? Does he/she have written protocols available?
10. All use locations authorized?
11. All RAM controlled and secured by the licensee?
12. Use and User(s)
 - a. List all isotopes utilized by the licensee from the patient log.
 - b. List all groups authorized by the license with possession limit and if license fees are current.
 - c. List all authorized user(s) and the groups that they are authorized for in the license.
 - d. List all locum tenens used during the last three years and the groups that they were authorized for.

- e. List all authorized locations in the license.
 - f. List all Nuclear Medicine Technologists, Certified as well as trainees.
13. Are all necessary caution signs posted?
14. Was radiation monitoring done on each day isotopes were prepared and injected? List the period of record review.
15. Contamination survey performed each day of isotope use? List the period of record review.
16. Daily wipes for contamination surveys required and performed?
17. Survey of group 5 patients:
- a. Survey of patient at bedside, 1 meter, and doorway?
 - b. Nursing care notification posted on door and in patient's file?
 - c. Patient surveyed at discharge?
 - d. Room surveyed and decontaminated as required before release?
 - e. Use the remarks section to describe the training program for the nursing staff as well as refresher/continuing education from the license application.
 - f. Is the licensee complying with commitments made in the license application?
 - g. Circle Yes or No, if records were reviewed or if nurses were interviewed.
18. Disposal of radioactive materials:
- a. Does sanitary disposal by the licensee meet requirements of NMRPR, Subpart 4, Section 435?
 - b. Is the RAM decay storage area posted and does the radiation levels at uncontrolled areas meet NMRPR, Subpart 4?
 - c. How does the licensee insure that all radioactive labels are defaced?
 - d. Is the shipping records of generators complete and accurate?
 - e. Are the shipping records of other materials complete and accurate?
 - f. Does the transfer of any RAM meet U.S. DOT Regulations?
 - h. Does the facility dispose of radioactive animal per license commitments?
 - i. Does the licensee compact radioactive waste per license conditions?

PART 15: INSPECTOR'S MEASUREMENT & OBSERVATIONS

1. List model no., serial no., and calibration date of all instruments used to survey the licensee.

2. If the licensee has a floor plan, indicate radiation readings on the plan.
3. List the radiation range in the controlled and uncontrolled areas around the Nuclear Medicine Department.
4. Indicate if contamination evaluation or effluent sampling were performed.
5. Check those items observed and evaluated by the inspector.

PART 16: INSPECTION FINDINGS

1. List items of noncompliance.

PART 17: RECOMMENDATIONS

1. List all recommendations to the licensee.

PART 18: LICENSE REVIEWER ALERT

1. If yes, check the box and write a short description.

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MEDICAL INSPECTION FORM

License Number: _____
Expiration Date: _____
Last Inspection Date: _____
Inspection Priority: _____
Inspection Date: _____

Type of Inspection: Routine Announced Unannounced Initial Special

A. LICENSE NAME & ADDRESS

ACTUAL LOCATION

Telephone # _____

B. MANAGEMENT CONTACT/TITLE(ORGANIZATIONAL CHART (109):

C. RADIATION SAFETY OFFICER:

D. PROPRIETARY INFORMATION (307-F):

E. SPECIAL LICENSE CONDITIONS (308):

Inspector

Date of Report

Management Review

Date of Review

1. LAST INSPECTION: (VIOLATIONS/CORRECTIVE ACTIONS:

2. SCOPE OF LICENSED PROGRAM:

3. ADMINISTRATIVE REQUIREMENTS:

4. RADIATION SAFETY OFFICER (702B):

5. ALARA-STATEMENT & ANNUAL REVIEW (702A):

6. ALARA/AUTHORITY & RESPONSIBILITY/SUPERVISION (702):

7. MEDICAL RADIATION SAFETY COMMITTEE (702C):

(Note: Membership/Meeting Frequency/Minutes: Chair/RSO/Admin.)

8. AUTHORIZED USERS:

Locum Tenens

9. TRAINING/EXPERIENCE (712):

***(NOTE: ANCILLARY STAFF, MAINTENANCE, JANITORIAL, SECURITY)**

RSO Training

Physician Training

Nuclear Medicine Technician Certification

Employee Refresher and/or On Going Training

Nurse's Training

How Often

By Whom

Written Training Outline/Examination

Certification/Expiration Date

Records reviewed

Interviewed

10. GENERAL TECHNICAL REQUIREMENTS (703)

11. FACILITY:

12. POSTING:

Notice to Employees

License & Amendments

Current Copy of Regulations

Operating Procedures

Emergency Procedures

Nuclear Medicine Tech Certificates

13. CAUTION SIGNS:

Radioactive Materials Sign _____
 Radiation Area _____
 Airborne Radioactivity Area _____
 Container Labeling _____
 Radionuclide Labeling _____
 Vials/Syringe Labeling _____

14. SECURITY:

15. SEALED SOURCES (CALIBRATION SOURCES) (703 D.):

Sealed Sources	S/N	Cal. Date	Disposal Date
Co-57	_____	_____	_____
Cs-137	_____	_____	_____
Ba-133	_____	_____	_____
Co-60	_____	_____	_____
Ra-22	_____	_____	_____

16. LEAK TEST(415):

(NOTE: Person taking wipe test authorized by license condition or certified)

6 month intervals Date of leak tests _____

 Performed by _____ Certified/Expiration Date _____

17. SURVEYS:

(NOTE: Surveys each day of use with survey meter & wipes where prepared or administered and weekly where RAM are stored. & reported in DPM):

Survey Area Map _____ Injection Area _____ Hot Lab Floor _____ Tread mill _____
 Area(s) Action level _____
 Daily Radiation Monitoring _____
 Storage Area(s) Weekly Wipe Survey _____
 How are swipes analyzed _____ By whom _____
 Records _____

(NOTE: Contamination action levels-2000 cpm/100 cm sq., or see regulatory guides 8.23).

18. EQUIPMENT QUALITY ASSURANCE (703):

DOSE CALIBRATOR (703A.):

- Constancy-Daily
- Accuracy-Installation & Annually
- Linearity-Installation & Quarterly
- Geometrical Variation-Installation

(NOTE: For Procedures See Regulatory Guide 10.8.Appendix E).

Dose calibrator measurements(703C): _____

19. SURVEY INSTRUMENTS (703B):

(NOTE: Range-0.5 mR/hr-100 mR/hr & 1 mR/hr-1000 mR/hr):

- Backup
- Operational Check Source Performed
- Calibration Dates
- Calibration Frequency
- Certified Vendor Calibration Procedures:

Last Calibration dates

20. GAMMA CAMERA:

- Flood Fields Daily
- Bar Phantoms(Resolutions) Weekly

21. OTHER COUNTING SYSTEMS:

- Calibration Procedures
- Calibration Frequency

22. PROCEDURES REVIEW:

23. MOLYBDENUM 99 GENERATOR:

(NOTE: Mo 99 detection activity level 0.015 uCi/ml Mo-99 per mCi of Tc-99m before administered)

- Manufacturer
- Possession Limit/Activity
- Shielding

Exchange Frequency _____
 Molybdenum Breakthrough test _____
 Alumina Breakthrough test _____
 Disposal/Segregation: Decay-In-Storage _____

24. SUPPLIER RECEIVING(702H):

Inventory log Acquired from: _____
 Single dose Multiple doses _____
 Normal Delivery Time(s) _____
 Non-Routine Orders Security _____
 Accepted by _____
 Action Levels: Package survey-meter swipes _____
 Package Opening Procedures _____

25. EXTERNAL/INTERNAL PERSONNEL EXPOSURE:

PERSONNEL DOSIMETRY(415):

NVLAP Vendor Exchange Frequency _____
 Period Examined from to _____
 WB Ring Extremity _____
 Any exposure(s) exceeding limits _____

POCKET DOSIMETER:

Make/model # _____
 Calibration Frequency _____
 Exposure ALARA (10% of MPL) _____
 Record of Prior Dose Determination _____
 Reports reviewed by _____

26. INTERNAL PERSONNEL EXPOSURE:

27. BIOASSAY PROCEDURES:

Equipment or Instrumentation _____
 License Condition _____
 Frequency _____
 Isotope(s) I-123 I-131 Xe127/133 _____
 Method In-house vendor _____
 Thyroid Urine Whole Body Counting _____

Dose Assessment (Action Levels)

28. ENVIRONMENTAL CONTROLS:

Air Concentration, Controlled Area

Air Concentration, Uncontrolled Area

Engineered Controls:

Hood(s)

Charcoal Traps (NOTE: filter change dryrite should be blue not pink or white.)

Shielded Container

Negative Pressure:

Area Monitoring/Calculations

29. DISPOSAL:

Disposal log

Decay-In-Storage

Sanitary Sewer Disposal

Disposal of sources since last inspection

Deface RAM Labels

Shipping papers and package labels proper

Shipping Records

Any Shipment incidents

30. INCIDENTS/REPORTS:

Thefts or Losses

Overexposures Excessive contamination levels loss of time/facility

Equipment failure misadministration

Notification Reports

Corrective Actions

31. INSPECTOR'S OBSERVATIONS/COMMENTS:

Observation Checklist:

- | | | |
|---------------------------------|-----------------------------|------------------------------------|
| <u>1. Gamma Camera Tests</u> | <u>6. Syringe Shields</u> | <u>11. Package Opening-Surveys</u> |
| <u>2. Dose Calibrator Tests</u> | <u>7. Housekeeping</u> | <u>12. Storage Shields</u> |
| <u>3. Generators</u> | <u>8. Hoods</u> | <u>13. Refrigerator</u> |
| <u>4. Protective Clothes</u> | <u>9. Waste Containers</u> | <u>14. Employee Actions</u> |
| <u>5. Sample/Dose</u> | <u>10. Patient Bathroom</u> | <u>15. Area Monitoring</u> |
| | | <u>16. Other</u> |

(NOTE: KEY NUMBERS TO COMMENTS):

31. INSPECTORS COMMENTS:

32. INDEPENDENT INSPECTION SURVEYS:

Instrument Used:

<u>Model No.</u>	<u>S/N</u>	<u>Calibration. Date</u>
------------------	------------	--------------------------

33. INSPECTION FINDINGS:

34. RECOMMENDATIONS:

36. LICENSE REVIEWER ALERT YES _____ NO _____ IF YES, date sent _____

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ATTACHMENT 6C

DENSITY/MOISTURE GAUGE INSPECTION FORM

**INSTRUCTIONS FOR PORTABLE GAUGE INSPECTION
CHECKLIST**

PORTABLE GAUGE INSPECTION CHECKLIST

PORTABLE GAUGE INSPECTION BY MAIL



PORTABLE GAUGE INSPECTION CHECKLIST

1.INSPECTION BACKGROUND DATA () announced () unannounced

License Amendment No. _____

Inspection Date _____ Expires _____ Renewal []

2.LICENSEE DATA

Licensee _____

Address [] same as Lic. Item 2. _____

Insp. Locatn. [] same as above _____

Contact _____ Title _____

Phone No. _____

3.INSPECTOR _____ Date _____

Supervisor Approval

4.LAST INSPECTION - RESULTS AND CORRECTIVE ACTION _____
(Date of last inspection)

a. Noncompliance [] None Current Status

b. Recommendation [] None

5.PERSONS CONTACTED DURING INSPECTION

		Ent	Exit	Other
Mgt	a _____	[]	[]	[]
RSO	b _____	[]	[]	[]
Operator	c _____	[]	[]	[]
Ancillary	d _____	[]	[]	[]

6. MANAGEMENT/SAFETY ORGANIZATION same as last insp.

a. RSO's mgr _____	Title _____				
Same as 5.a <input type="checkbox"/>					
	IC	NO	RC	NA	NC
b. RSO as per License	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. ARSO as per License	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. UNUSUAL OCCURRENCES & INCIDENTS

a. None since last insp. per _____					
b. Theft or loss reported	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Notifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Presumptive Overexposure					
<input type="checkbox"/> yes <input type="checkbox"/> no See 11.f.					

8. NOTICES, INSTRUCTIONS, & REPORTS

a. Informational Posting					
(1) Copy of Regulation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) License and Amendments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) Operating (includ. emergency procdrs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) Notice to Employees	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Info Posting Notice Used		<input type="checkbox"/> yes	<input type="checkbox"/> no		

9. POSTING SIGNS AND LABELING

a. Area Posting					
(1) Radiation Area	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(1) Radioactive Material	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Container/Gauge Labeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Mfrs Label on Transport Case		<input type="checkbox"/> yes	<input type="checkbox"/> no		

10. TRAINING (Lic. Doc.)

a. Operators (obtain list or annotate in notes)					
(1) Records of training (certs.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) RSO statements of auth.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> List <input type="checkbox"/> Indiv. statements					

- b. RSO Procedural Knowledge
 - (1) Operating/Emergency procedures
 - (2) Shutter Cleaning
 - (3) Leak test collection
- c. Ancillary personnel

11. EXTERNAL RADIATION EXPOSURE MONITORING

- a. Vendor name _____ Acct. # _____
- b. Type of monitoring _____ frequency _____
- c. Period examined: From _____ to _____
 - (1) Range of annual exposure for ____ year, from ____ mrem to ____ mrem
- d. Number of workers in program _____
- e. In Accordance with Lic. Condition
 - (1) Dosimetry used yes no
 - (2) Compliance with reg. limit yes no
 - (3) Records maintained properly yes no
 - (4) Timely return to vendor yes no
- f. Report of Presumptive Overexposure _____

LOCATIONS OF STORAGE AND USE

IC NO RC NA NC

- a. Permanent Storage Locations
 - (1) Security
 - i) available/maintained
 - ii) adequate while recharging
 - (2) Fire Related Safety
 - (3) License Condition
 - i) location per item #10
 - ii) comply with drawing
 - iii) storage capacity for Possession limit
- b. Temporary Jobsites Documents (Lic. Cond.)
 - i) RSO auth. statement
 - ii) license
 - iii) manufac. instruc. manual/emerg. procedures
- c. In/Out Log

- d. Storage at Temporary Jobsites
- (1) Security
 - i) available/maintained
 - ii) adequate while recharging
- (2) Posting
- (3) Duration
- Minimum _____ days
- Maximum _____ days

13. INVENTORY

- a. Within possession limit # _____
 - b. Records of receipt, transfer, and disposal
 - c. Physical inventory (obtain serial numbers or attach list)
-
-

14. LEAK TESTS

- | | IC | NO | RC | NA | NC | | | | | | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-------|-------|-------|-------|-------|-------|-------|--|--|--|--|--|
| a. Leak/wipe test collected per required freq. (Lic. Cond.) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | |
| b. Records maintained (Lic. Cond.) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | |
| <table border="0" style="width: 100%;"> <thead> <tr> <th style="width: 33%;">Gauge</th> <th style="width: 33%;">Date of Test</th> <th style="width: 33%;">Vendor</th> </tr> </thead> <tbody> <tr> <td>_____</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> <td>_____</td> </tr> </tbody> </table> | Gauge | Date of Test | Vendor | _____ | _____ | _____ | _____ | _____ | _____ | _____ | _____ | _____ | | | | | |
| Gauge | Date of Test | Vendor | | | | | | | | | | | | | | | |
| _____ | _____ | _____ | | | | | | | | | | | | | | | |
| _____ | _____ | _____ | | | | | | | | | | | | | | | |
| _____ | _____ | _____ | | | | | | | | | | | | | | | |
| c. Persons collecting wipe tests, authorized | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | |
| d. Reports of positive results/corrective actions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | |

15. COMPLIANCE WITH OTHER/SPECIAL LICENSE CONDITION

- a. Maintenance
- b. Storage Only
- c.

16. TRANSPORTATION, PACKAGING & SHIPPING

- a. Method of Transport to Jobsites

- b. Security during Transport (49 CFR 177.842d) IC NO RC NA NC
 - (1) Open vehicle Closed vehicle
 - (2) Package braced, blocked or otherwise adequately secured in vehicle

- c. Packaging during Transport (DOT-7A, Type A 49 CFR 173.415)
 - (1) Uses mfr's case/package yes no
 - (2) Uses other case/package yes no
- d. Package Marking and Labeling
 - (1) Package legibly marked (49 CFR 172.300 thru 310)
 - (2) Package legibly labeled (49 CFR 172.403)
 - (RAD Yellow II, 2 sides of package)
- e. Shipping Papers Used (49 CFR 177.817e)
- f. Certifications (49 CFR 173.476 & 173.415a)
 - (1) RAM Test Certification available
 - (2) DOT-7A Packaging, Test Certification available
- g. Enroute Storage (describe)

INSPECTORS MEASUREMENTS & OBSERVATIONS

- a. Measurements

	Taken <input type="checkbox"/>	Not required <input type="checkbox"/>			
	Make	Model	Serial Number		
(1) Instruments used	_____				
(2) Calibration date	_____		Vendor	_____	
(3) Radiation levels in controlled areas	_____				
(4) Radiation levels in uncontrolled areas	_____				

b. Inspector Comments

	IC	NO	RC	NA	NC
18. DISCUSSION WITH OPERATOR					
a. Adequacy of Operator Knowledge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Operating/emergency procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii) Transportation/security	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii) Shutter cleaning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv) Leak/wipe test collection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v) Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b. Operator Comments

19. EXIT CONFERENCE WITH MANAGEMENT

20. TRAVEL DIRECTION TO LICENSEE

IC = In Compliance
NO = Not observed

RC = Recommendation
NC = Not Applicable

NC = Non-compliance

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INSTRUCTIONS FOR PORTABLE GAUGE INSPECTION CHECKLIST

1. LICENSEE AND PREVIOUS INSPECTOR STATUS

- A. Complete all items.
- B. Verify that previous violations have been corrected. Have the last inspectors recommendations been adopted?

2 PERSONS CONTACTED

- A. List the names and titles of individuals contacted.

3. MANAGEMENT/ORGANIZATION

- A. Attach an organization chart if available.
- B. Identify the RSO's positions within the company.
- C. If the company has various field locations list the managers of each.

4. UNUSUAL OCCURRENCES OR INCIDENTS

- A. Review any accidents that have been reported.
- B. Has there been a theft of a gauge reported?

5. POSTING OF INSTRUCTIONS

- A. Are all required documents posted?

6. AREA POSTING

- A. Observe all required posting of warning signs and labels.

7. TRAINING

- A. Review training records and complete certificates.
- B. Interview personnel to determine extent of knowledge of radiation survey.

8. EXTEND PERSONNEL MONITORING

- A. Review all monitoring records if monitoring is required by license conditions.
- B. Review storage location of badges when not in use.

9. STORAGE LOCATIONS

- A. Review all permanent storage locations authorized under the license.
- B. Are temporary storage locations used? If so, under what circumstances and for how long?

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10. **INVENTORY**

- A. List the make and model of all gauges possessed. Are all authorized by the License?
- 2. Determine the frequency inventories are taken by the RSO.

11. **LEAK TEST**

- A. Verify that all gauges are tested at the required frequency.
- B. Has the gauge been returned to the manufacturer for maintenance? Verify that a leak test is collected prior to placing it back in use.

12. **TRANSPORTATION, PACKAGING AND SECURITY**

- A. Verify all transportation requirements are met.
- B. Observe the security devices provided to prevent theft gauges while en-route to job sites.
- C. Review shipping paper work that the operator must carry while transporting the gauge to job sites.

13. **INSPECTORS MEASUREMENTS**

- A. Measure radiation levels at storage location to verify permissible dose rates to personnel adjacent to storage locker.
- B. Measure radiation levels at cab of the transport vehicle if the gauge is placed near the cab while in transport.

DENSITY MOISTURE GAUGE INSPECTION REPORT FORM

License Number _____
Expiration Date _____
Date of this Inspection _____
Inspection Priority _____
Previous Inspection Date _____

Type of Inspection Routine Announced Unannounced Initial Special

A. LICENSEE & ADDRESS

ACTUAL LOCATION

TELEPHONE _____

B. INDIVIDUALS INCLUDED IN MANAGEMENT INTERVIEW (109):

C. NAME OF RESPONSIBLE PERSON(Organizational chart):

D. SPECIAL LICENSE CONDITIONS (308):

E. Letter sent to Licensee on: _____

Inspector _____

Date of Report _____

Reviewer _____

Date of Review _____

1. FOLLOW-UP ON PREVIOUS INSPECTION FINDINGS:

2. SUMMARY OF LICENSED PROGRAM (Type of program):

3. INTERNAL AUDIT (Annual Safety Review & ALARA & SOP'S):

4. AUTHORIZED USERS: (Training Certification, Supervision of authorized users):

5. TRAINING/RETRAINING:

RSO Training/Experience

Responsibilities & Authority

Ancillary Personnel Training

Refresher Training

By whom/Certification

Written Exam

Management Review

6. FACILITIES (Engineered Controls: Access Alarms & Controls, Transport Vehicles, etc):

7. SECURITY (425):

Access and Exit Controls _____
Fire Protection _____
Visible and Audible Warning Signals _____
Physical Security & Monitoring Upon Exit _____

8. INVENTORY LOGS/ RATE OF USE (317):

9. LEAK TESTS:

10. PERSONNEL DOSIMETRY:

Film Badge or TLD for each Individual _____

Processed by _____
Frequency _____
Exposure Records _____
Compliance with regulatory limits: _____

Exposure ALARA (<10% of minimum permissible) _____

Notification Reports Available to Employee _____
High Reading/Overexposures _____

Exposure History provided to Employees _____
Reports reviewed by _____

11. POSTING & LABELING:

_____ NMED045 _____
_____ License and Operating Procedures: _____
_____ Regulations _____
_____ Emergency Procedures _____
_____ Any Notice of Violation _____
_____ Training Outline _____
_____ "CAUTION RADIATION AREA Signs" _____

Labeling on Device/Equipment _____

12. TRANSPORTATION (U.S. DOT 49 CFR 170-199):

13. DISPOSAL METHODS:

Storage Location _____

Transfer Records _____

14. INCIDENTS OR OVEREXPOSURES:

Reports and Notification _____

15. OPERATIONS OBSERVED: (NOTE: Every attempt must be made to observe operations conducted in association with possession, use, and disposal of licensed material).

16. INFORMATION CONTINUATION FROM PREVIOUS PARAGRAPHS:

17. INDEPENDENT MEASUREMENTS(Results Compared to Licensee, NOTE: Attach analysis report sheet):

Bkgd	Instrument used	Model #	S/N	Cal.Date

18. INSPECTION SUMMARY:

19. EXIT INTERVIEW:

Senior Management

Date

License Reviewer Alert, memo sent?

If yes, Date sent _____

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PORTABLE GAUGE INSPECTION BY MAIL

1. Licensee Name _____
Address _____
City, State, ZIP _____
2. Radiation Safety Officer _____
Authority: who appoints and contact with management.
3. Describe any corporate or organizational changes in your company since the last inspection by this agency.

4. List below the PORTABLE RADIOACTIVE GAUGES you store and/or use:

<u>Manufacturer</u>	<u>Model Number</u>	<u>S/N</u>	<u>Radioactive Materials and amounts in millicuries</u>
---------------------	---------------------	------------	---

_____	_____	_____	_____
_____	_____	_____	_____

(Use supplemental pages if necessary to list additional units.)

5. Describe use of gauge: _____

6. Describe storage location of gauge(s). Submit drawings of storage area as Attachment 6.

7. List all the individuals who are authorized to use the portable gauges and who provided the training. (DO NOT SUBMIT COPIES OF THEIR TRAINING *CERTIFICATES)

<u>Authorized User</u>	<u>Trained by</u>	<u>Authorized User</u>	<u>Trained by</u>
------------------------	-------------------	------------------------	-------------------

(Use supplemental pages if necessary to list additional users.)

8. Radiation safety program management.
- The Radiation Safety Officer (RSO) takes care of radiation safety records, training and radiation safety tasks
 - RSO is the owner, a partner or manager
 - RSO was officially appointed by the owner, a partner or facility manager
9. Portable gauges must be stored in a secure area. Please check all that apply:
- Portable gauges are stored and not being used
- Portable gauges not being used
- will be returned to manufacturer
 - are stored and used at the address listed in Question 1 of this form
 - are stored at another permanent storage site listed on license
- Portable gauges are used in the field and stored at temporary sites
10. Portable gauges must be transported according to U.S. Department of Transportation Regulations. Please confirm:
- During transportation on public roads, the portable gauge is blocked and braced that it cannot change position during conditions normally incident to transportation (49 CFR Part 177.842(d).
 - Shipping papers accompany every shipment of radioactive material (49 CFR Part 177.817). Submit a copy of the shipping paper used to transport your gauge.
 - Emergency response information is included with shipping documents (49 CFR Part 172.602).
 - The emergency response telephone number is a 24-hour monitored, live line, not a beeper or other mechanical answering device (49 CFR Part 172.604).
 - A copy of the shipping document, the emergency procedures and the 24-hour emergency telephone number are kept in the driver's compartment within reach of the driver at all times during transport. [49 CFR Part 177.817 (e)]

11. Persons who use portable gauges should wear personnel dosimetry devices. Please check the type of dosimetry you wear and the exchange frequency:

- Film badge
- TLD badge
- Finger badge
- Exchange monthly
- Exchange quarterly
- Don't know*
- Other*

*Submit explanation.

12. Please check all the boxes that apply to maintenance you perform on your gauge.

- Routine device cleaning only; no source rod or shield block cleaning
- No maintenance, return to manufacturer for all maintenance
- Authorized for source rod or shield block cleaning by license condition
- During cleaning, put source rod in a "pig" to shield radiation
- Do source rod cleaning as described in manual
- Wear "finger badges" when doing do source rod cleaning
- Have special training to do source rod cleaning

13. Check the documents that are posted:

- Notice to Employees-NMED045.
- Vendor Certificate.
- Copy of the Radioactive Materials License, including attachments.
- Copy of NMRPR.
- Alternate Notice (this takes the place of the Radioactive Materials License including the application and any attachments, operating procedures and NMRPR).

14. Current copies of the following documents are transported with each gauge:

- The Radioactive Materials License
- Operating procedures
- The Validation Certificate
- Leak Test

15. Please confirm the following regarding leak testing:

- The RSO or designee does the leak test wipe
- Leak tests are done every 6 months in accordance with license condition
- Leak tests done on each sealed source for the past 3 years.

Isotope	Model #	S/N	Date of wipe	Analyzed by	Results
---------	---------	-----	--------------	-------------	---------

List below the vendor who does leak test analyses.

NAME _____
ADDRESS _____
CITY, STATE, ZIP _____
LICENSE NO. _____
CONTACT _____

CERTIFICATION

I certify that all items on this form are accurate and true.

SIGNATURE

PRINT NAME

TITLE OF CERTIFYING PERSON

DATE

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ATTACHMENT 6D

INDUSTRIAL RADIOGRAPHY INSPECTION FORM

**INSTRUCTIONS IN PREPARATION FOR INDUSTRIAL
RADIOGRAPHY INSPECTION REPORT**

INDUSTRIAL RADIOGRAPHY FIELD SITE INSPECTION REPORT



INSTRUCTIONS IN PREPARATION FOR
INDUSTRIAL RADIOGRAPHY INSPECTION

1. Inspection Background Data

- Complete all items at the conclusion of the inspection.
- Type of inspection - check all appropriate boxes.
- Indicate all persons contacted during the inspection.

2. Organization

- Describe the organization and comment on its radiation safety effectiveness.
- List all radiography and assistant radiography personnel. Indicate date of employment and technical certification if any, ie. level 3, etc.

3. Inspection History

- Provide a brief description of the licensee's recent compliance history. Include incidents investigated.
- Explain remaining items of noncompliance and why they have not been corrected.

4. Training

- Complete all items - review training provided for radiographers and their assistants. See NMRPR Subpart 5, Sections 515 & 527, Appendix A.

5. Internal Audits

- Verify audits done and by whom.
- Type of record - log/checklist, etc.

6. Maintenance of equipment

- Verify that all equipment has been maintained. Examine for flaws that should have been repaired such as labels, etc. Source crank mechanisms should be tested for smooth operation and wear of connector tip.

7. Posting

- Verify the licensee has supplied all necessary documents to field operating crews. Determine documents are posted for in-house operations.

8. Utilization Log

- Review an adequate number of utilization logs to complete all questions.
- Items should be checked if they are done - if not check N/A.

9. Inventories

- Are all sources accounted for quarterly?
- Indicate make and model of sources if different from those authorized by the license.
- Identify a select number of projectors and sources contained in them.

10. Facilities

- Describe only temporary storage locations (less than 30 days).
- Attach a plot plan if fixed facilities.
- Describe safety systems and their maintenance.
- Review storage areas including en route storage on vehicles.
- Field sites:

NOTE: A field site audit must be included in all radiography license inspections. At least one site should be visited to verify all operations are conducted according to the license and regulations. The field site inspection may be conducted prior to the complete inspection of the license and attached to the entire package when closed.

- Survey meters:
 - A. Verify records covering items 1-5.
 - B. Observe use and accuracy of meters during field site audits. Compare readings obtained with the inspector's meter's reading.
 - C. Determine if numbers of meters on hand are adequate for the size of the operation.

11. Personnel Monitoring.

- Complete review of all records.
- Supply the licensee with a statement that all records up to the latest reviewed had been looked at by the inspector.
- Verify monitoring equipment is worn during field site audits.

12. Leak Tests.

- Verify all sources have been leak tested at proper intervals and records are maintained.

13. Survey Records.

- Review and verify all survey records.
14. Posting & Labeling.
- Observe all necessary posting and labeling. Signs must clearly indicate radioactive material or radiation area at barricades of field sites.
15. Surveys.
- Measurements of dose rates at the surface of projectors should be made and if possible a comparison between the licensee's readings should be made.
 - The survey meter used by the inspector for measurements during any radiography inspection should be calibrated within 3 months.
16. Shipping/Receiving Procedures.
- Verify that all packages received have been surveyed.
 - Review shipping records to show that all spent sources had been properly packaged and surveyed.
17. Transportation.
- Verify all transportation requirements are met.
18. Incidents Procedures.
- Review any reports or incidents the licensee may have been involved with since the last inspection.

Comments/remarks:

Add any items not identified on the inspection form but may be pertinent to the licensee's ability to maintain a good radiation safety program.

Closing Conference/Exit Interview:

Describe the inspection findings to management and the Radiation Safety Officer. All violations must be explained to the licensee in advance prior to issuance of the Notice of Violation. If the inspector is uncertain about any items being actual violations, then the correct information can be communicated to the licensee after consultation with the supervisor. Recommendations should be made whenever an item of noncompliance is identified but there still needs to be improvement made in the safety program.

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RAM COMPLIANCE

Industrial Radiography

Field Site Inspection Report

[] Announced [] Unannounced Date _____

Licensee _____ License No. _____

Inspector(s) _____

Inspection Location _____

Radiography Personnel

Radiographer _____ Date Hired _____

Radiographer Assistant _____ Date Hired _____

Other(s) _____ Employer if not Licensee _____

Monitoring Equipment

Badge Supplier _____

Wear Period/Date Issued _____

Pocket Dosimeter S/N's _____ Calibration Date _____

Survey Meter Make, Model & S/N _____ Calibration Date _____

" " " " " _____ Calibration Date _____

Other Monitoring Device _____ Calibration Date _____

Radiography Projector/Equipment _____

Projector Make, Model, Serial # _____

Source/Activity, Serial # _____

Crank Assembly Condition _____ Good [] Fair [] Bad []

Source Tube Condition _____ Good [] Fair [] Bad []

Pigtail & Connector Tip Condition _____ Good [] Fair [] Bad []

Dark Room at Site _____ Yes [] No []

Projector Security Container _____ Yes [] No []

 B Container _____ Yes [] No []

Observations

Surveillance Maintained _____ Yes [] No []

Proper Connect/Disconnect _____ Yes [] No []

Correct Post Exposure Survey _____ Yes [] No []

Inspector/Licensee Survey Meter Comparison (Inspector _____ mR/hr)

(Licensee _____ mR/hr)

Documentation

Copy of the License _____ Yes [] No []

Latest Amendment Date _____

Radiographer Named on License _____ Yes [] No []

Operating & Emergency Procedures _____ Yes [] No []

 _____ Yes [] No []

Notice to Employees _____ Yes [] No []

Source Shipping Papers _____ Yes [] No []

Decay Chart/Leak Test _____ Yes [] No []

Other Documents _____ Yes [] No []

Vehicle Placarded _____ Yes [] No []

Findings

Items of Noncompliance

Findings

Items of Noncompliance

Corrective Action Taken

Job Allowed to Continue _____ Yes [] No []

Inspector's Impression

Inspection Plan Check _____ [] Office Audit Within 30 Days
[] Second Field Audit Planned
[] Hold for Next License Inspection
[] Other - Explain

Supervisors Review/Approval _____ Yes [] No []

Inspector Signature _____

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INDUSTRIAL RADIOGRAPHY INSPECTION FORM

License Number: _____
Expiration Date: _____
Last Inspection Date: _____
Inspection Priority: _____
Inspection Date: _____

Type of Inspection: Routine Announced Unannounced Initial Special

A. LICENSE NAME & ADDRESS

ACTUAL LOCATION

Telephone _____

B. MANAGEMENT CONTACT/TITLE (ORGANIZATIONAL CHART (109):

C. NAME OF RADIATION SAFETY OFFICER:

D. PROPRIETARY INFORMATION (307-F):

E. SPECIAL LICENSE CONDITION(308):

F. Letter sent to licensee on: _____

Inspector

Reviewer

Date of Report

Date of Review

1. FIELD SITE INSPECTION:

2. LAST INSPECTION: (VIOLATIONS/CORRECTIVE ACTIONS):

3. ALARA Program:

4. RECEIVING & SHIPPING :

Procedures for Shipping/Receiving:
Surveys When Received
Surveys When Shipped
Shippers Paperwork:
Records:

5. SURVEY INSTRUMENTS (Range 2-1000 mR/hr)(509):

- Manufacturer:
- Adequate Number Available
- Instruments Calibrated & Operable:
3 Month Interval Calibration:
Where Calibrated:
Records of Calibration:

- Safety Equipment (Collimators, Shields, Etc.):

6. LEAK TEST(510):

Wipes Performed by:
Method:

Six (6) Month Intervals:

Records Maintained:

7. QUARTERLY INVENTORIES/INTERNAL AUDITS(511):

Last Inventory

Model

S/N

Isotope/Ci

8. UTILIZATION LOG(512):

Device and Radiographer Identified:

Locations/Dates Identified:

Dosimeter Readings Recorded Daily

Dosimeter Recharged at the Start of Each Shift:

Physical Surveys Recorded

9. INSPECTION/MAINTENANCE OF DEVICES/CONTAINERS/CHANGER(513):

Equipment Check Prior to Use Each Day:

Equipment Check at 3-Month Intervals:

Records of Results

10. FACILITIES AND SECURITY(514):

Fixed facility as described in application

Surveillance or locked to prevent unauthorized entry:

Visible & audible signals to warn of presence of radiation

Direct Surveillance of High Radiation Area

Storage Area

Radiation Levels

Cameras/Containers Physically Secured:

Keys Controlled by:

11. POSTING(520):

NMED045
License and amendments
Written Operating and Emergency Procedures
Current Emergency Procedures
Current Copy of Regulations
Copies of Procedures furnished to all Radiographers and Assistance:
Instruction Appendix A, Subpart 5
Notification Procedures in case of accident
Procedures to minimize exposure during accidents
Any notice of violations orders issued
Posting of Vehicles; Storage Room or area; Devices & Storage Containers with "CAUTION RADIATION AREA signs.

12. RADIATION SURVEYS/RECORDS (521):

Frequency of Surveys
Temporary Field Surveys
Surveys after each exposure
Surveys prior to securing source container
Other surveys
Methods of survey (Radiation levels in unrestricted areas?)

13. PERSONAL MONITORING (517-523):

Film/TLD Supplier (NVLAP)
Frequency
Each Individual assigned Badge/Pocket Dosimeter/Ratemeter:
Annual Calibration Pocket Dosimeters:
Exposure Records Reviewed for the Period _____ to _____
Average Quarterly Exposure: _____
Reports Available for Review by Employees:
High Readings/Overexposures
Personnel provided exposure history

POCKET CHAMBERS Chamber (Range 0-200 mR/hr):

Pocket dosimeter provided by _____

Calibration Frequency _____

Dosimeter readings recorded _____

15. TRAINING/RETRAINING (515 & 527-Appendix A):

____ Radiographers named on license: _____

____ RSO _____

____ Training Experience _____

____ Responsibilities & Authority _____

____ Refresher Training _____

____ Approved Training Program: _____

____ Written Test: _____

____ Results Reviewed by Management: _____

16. TRANSPORTATION:

____ Type B Container _____

____ Vehicle Placarded _____

____ Registered User of Package _____

____ Shipping Paperwork _____

____ Approved NRC Camera Program _____

____ Transportation Index _____ mR/hr _____

Levels of Radiation exposure from Devices & Containers:

Exterior of device to source 10 Cm or less - 50mR/hr. or less

Exterior of device to source 20 Cm or more and all outer source container - 200 mR/hr. or

less _____

17. DISPOSAL:

_____ Disposal of sources since last inspection _____
_____ Authorized containers _____
_____ Shipping papers and package labels proper? _____
_____ Transfer records _____
_____ Any Shipment incidents _____

18. INCIDENTS/NOTIFICATION(452):

_____ Overexposures _____
_____ Loss of Control/Disconnect: _____
_____ Excessive Levels: _____
_____ Theft: _____
_____ Damage to Equipment: _____
_____ Incident Report/Investigation _____

19. INSPECTORS SURVEYS

20. INSPECTOR'S OBSERVATIONS/COMMENTS:

RAM COMPLIANCE

Industrial Radiography

Field Site Inspection Report

[] Announced [] Unannounced Date _____

Licensee _____ License No. _____

Inspector(s) _____

Inspection Location _____

Radiography Personnel

Radiographer _____ Date Hired _____

Radiographer Assistant _____ Date Hired _____

Other(s) _____ Employer if not Licensee _____

Monitoring Equipment

Badge Supplier

W/ Period/Date Issued _____

Pocket Dosimeter S/N's _____ Calibration Date _____

Survey Meter Make, Model & S/N _____ Calibration Date _____

" " " " " _____ Calibration Date _____

Other Monitoring Device _____ Calibration Date _____

Radiography Projector/Equipment _____

Projector Make, Model, Serial # _____

Source/Activity, Serial # _____

Rank Assembly Condition _____ Good [] Fair [] Bad []

Source Tube Condition _____ Good [] Fair [] Bad []

Wigtail & Connector Tip Condition _____ Good [] Fair [] Bad []

Dark Room at Site _____ Yes [] No []

Projector Security Container _____ Yes [] No []

B Container _____ Yes [] No []

Observations

Surveillance Maintained _____ Yes [] No []

Proper Connect/Disconnect _____ Yes [] No []

Correct Post Exposure Survey _____ Yes [] No []

Inspector/Licensee Survey Meter Comparison (Inspector _____ mR/hr)

(Licensee _____ mR/hr)

Documentation

Copy of the License _____ Yes [] No []

Latest Amendment Date _____

Radiographer Named on License _____ Yes [] No []

Operating & Emergency Procedures _____ Yes [] No []

Imaging _____ Yes [] No []

Notice to Employees _____ Yes [] No []

Source Shipping Papers _____ Yes [] No []

Decay Chart/Leak Test _____ Yes [] No []

Other Documents _____ Yes [] No []

Vehicle Placarded _____ Yes [] No []

Findings

Items of Noncompliance

Findings

Items of Noncompliance

Corrective Action Taken

Job Allowed to Continue _____ Yes [] No []

Inspectors Impression

Inspection Plan Check _____ Office Audit Within 30 Days
 Second Field Audit Planned
 Hold for Next License Inspection
 Other - Explain

Supervisors Review/Approval _____ Yes No

Inspector Signature _____

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ATTACHMENT 7
INSPECTION PROCEDURES



INSPECTION PROCEDURES

1.0 INSPECTION PROCEDURES - GENERAL STATEMENT - INTRODUCTION

Inspection procedures stress above all **observation of licensed operations**, review of authorizations, record review, identification of findings, recommendations, and management review (audit) by agency of inspectors/inspection results.

2.0 PURPOSE AND MISSION

State Radioactive Materials Inspection Programs insure the health and safety of the public and the environment from radiation hazards. To accomplish this mission, states conduct on-site reviews of licensed activities. Inspections

- o identify the factors needed to protect public health and safety;
- o use standardized, industry-wide methods and techniques to evaluate the uses of radioactive materials;
- o report regulatory findings to the public;
- o provide the licensee with a status report;
- o define necessary remedial actions; and
- o encourage the licensee to remediate problems promptly and efficiently.

Inspectors are to conduct on-site reviews of radioactive material users to measure the radiation hazard from the licensed operations; estimate personnel exposure from future use of radioactive material; assess compliance with regulations; and assure that licensees use good radiation protection practices throughout their operations.

The procedures discussed in this document can provide inter-state and NRC compatibility and nationwide enforcement uniformity. Licensees who do not follow rules and requirements while operating in one state cannot move to another state and re-establish the

same unsafe pattern of handling of licensed radioactive material.

3.0 DEFINITIONS

ALARA: An operating philosophy for keeping radiation exposures and effluent releases as low as reasonable achievable within acceptable cost.

Closeout or Termination Inspection: 1) verification that all RAM used or possessed by the licensee has been properly disposed of; 2) the facility is free from contamination; 3) records of all transfers or disposals are complete.

Dead File: Records which have been reviewed during an inspection which may be discarded or put in permanent storage. Such records include surveys, receipt, disposal, leak test, QC and QA, etc. Personnel dosimetry records should never be discarded.

Field Inspection: An inspection at a licensee's temporary job site.

Follow-up Inspection: An escalated enforcement action to verify the licensee's corrective actions have been taken and are effective.

Initial Inspection: The first inspection performed after a new license is issued. **This inspection must be performed within 6 months after RAM is received.** Phone contact should be made prior to scheduling the licensee's initial inspection to verify that licensed material has been received, but inspection itself must be unannounced. Do not inspect until radioactive materials are being used by the licensee. Include standard condition in newly issued licenses that license will be terminated in one year from date of issue if no licensable material has been received.

Interim Compliance Actions: A form completed by the licensee and returned to the Agency to verify compliance with rules and license conditions.

Notice of Violation: The formal written document issued to the licensee describing the inspection findings and citing violations of the State's Regulations or License Conditions.

Overdue Inspection: Any inspection date that exceeds the license priority due date. Example, a priority one licensee must be inspected once each year. If they are not inspected within 12 months of the last inspection they become overdue.

Prelicensing Inspection: Inspection at an applicant's facility to verify qualifications for license. Conducted only when the situation warrants a site visit.

Priority: The frequency of inspection for a given type of license.

RAM: Radioactive Material.

Reciprocity Inspection: A complete inspection of an out-of-state or NRC licensee's activities. Reciprocity inspections should be by their very nature field inspections.

Routine Inspection: A complete review of a licensee's activities for regulatory purposes.

Telephone Contact: The person who may be contacted prior to an inspection.

4.0 METHODS AND CRITERIA

Review of radiation safety inspection data results in proper evaluation of program adequacy. Inspectors should

- o be thoroughly familiar with regulatory requirements of the licensee;
- o have a complete knowledge of the particular license and all conditions placed on it by licensing staff;
- o plan to inspect each of the various requirements;
- o identify problem areas examined during the inspection;

- o determine which confirmatory measurements are necessary and the appropriate instrumentation to be used;
- o prepare an equipment list for everything that will be used during the inspection; and
- o be able to answer: who, what, when, where and why, when documenting items of noncompliance.

Preparation and planning are essential to an effective and efficient inspection. Review the license and referenced documents that describe the organization's radiation safety program. Review results of previous inspections and investigations. Prepare an outline that emphasizes possible problem areas such as responses to prior findings. Identify if promised corrective actions have been done.

The radiation safety survey may involve determination of radiation fields and concentrations both within and outside the radiation facility. The licensee should maintain records that will provide enough information about radiation levels to permit an adequate evaluation of their operations. **The inspector must make his own measurements to confirm licensee records.**

Review licensee records from several days that the licensee used radioactive material. Ask the licensee for all records for the dates selected which may include area surveys, leak tests, personnel monitoring results, meter calibration records, etc. Spot checking all required items for 20 dates since the last inspection presents a valid statistical picture of a licensee's compliance with requirements. The inspector may require the licensee to get a complete set of radiation measurements resulting from uses under review. These measurements will include radiation fields but may also include:

- o Wipe sampling for nuclide concentrations on surfaces in controlled and uncontrolled areas;
- o Air sampling in the breathing zone of operators to assess internal exposure to workers;
- o Bioassay and whole body counting to assess internal dose;

- o Process air sampling to measure nuclide concentrations to test engineering controls; and
- o Air sampling at discharge points to assess internal exposure of individuals in the surrounding community; (isokinetic sampling techniques must be used if discharges involve particulate radioactive materials.

The licensee's program for use of radioactive material should include provisions for collection, recording and evaluation of all environmental and process data described above. Review records to insure that the frequency and extent of observations are adequate within the scope of the licensed program.

A radioactive materials program review involves more than examination of licensee radiation records. Other records to review include:

- o Personnel radiation exposure records (film badge or TLD records for doses from external sources; bioassay records - urinalysis, thyroid counting and whole body counting - for doses from internal sources of radiation);
- o Investigation of incidents and near misses. These incidents include overexposures, excessive concentrations, or material losses which must be reported. Note if the licensee adequately investigated unusual occurrences to determine the cause and prescribed remedial actions to prevent recurrence;
- o Hazard evaluation and radiation safety surveys of proposed and ongoing uses;
- o Tests for leakage and contamination of sealed radioactive sources;
- o Proper radioactive material accounting methods, including records of receipt, transfer and disposal. The inspector should review records to show compliance with possession limits imposed by the license, and evaluate limits and conditions affecting disposal of radioactive waste imposed by radiation control regulations. Records of transfer should, in addition, be reviewed for license

authorization, not only with respect to the recipient's license but with respect to the license under review, as well; and

- o Records of medical procedures performed and doses administered. Review of these records bears on the question of efficacy as well as patient safety. Kinds of procedures performed and the doses administered to human subjects must be consistent with the authorizations specified in the license. Procedures performed pursuant to a Non-Routine authorization should conform with acceptable medical practices, although occasional use of an above-or below-usual range dose is permissible by request for exemption.

Assure that management procedures establish safe and effective use of radiation while furthering the goals of the organization. Agency reviews of programs should identify scientific merit. The question of merit most frequently arises in human use or field tracer studies.

Evaluation of the potential for environmental radioactive material releases arising from uses under review involves, in addition to review of past and present performance already discussed, determinations of the following:

- o The Radiation Safety Officer. Are he and his staff adequately trained and experienced? Is there provision for use of a health physics consultant where training or experience is lacking? In more than a few cases the radiation safety officer will be entirely competent to administer a program but will lack the ability to make sound judgement on some more complicated technical problems. In these cases, the input of a consultant will be essential in making the difference between adequacy and unacceptability of office staff.
- o Users. Is prior training and experience, as determined by performance and questioning, adequate to enable users to safely undertake activities authorized by the license? Is there adequate provision for on-the-job training of new users? Is there adequate provision for retraining existing users in order to convey radiation safety

- program and/or regulation changes as they affect the program? Are ancillary workers informed as to basic radiation safety criteria (such as janitorial or clerical staff) for the type of material used by the licensee?
- In cases where users are specified by license conditions, does the program staffing conform to these conditions?
 - Engineering controls, ventilated enclosures, shielding, remote handling tools. Are ventilated enclosures adequate to prevent internal exposure? Are shielding and remote handling tools adequate to reduce external exposure to the lowest practicable levels within regulatory limits? Are exhausts from ventilated enclosures adequately treated to reduce emissions to the out-of-plant environs to the lowest practicable levels within regulatory limits?
 - Security Devices. Are interlocks and warning signals adequate to ensure strictly controlled and safe entry to high radiation or high airborne areas within the facility?
 - Do facilities conform to user commitments incorporated by reference in license conditions?
 - Posting. Are individuals adequately warned as to the presence of radioactive material, radiation fields and airborne concentrations? Are workers informed of their rights and obligations (Notice to Employees)? Does posting conform to license conditions and radiation control regulations?
 - Administrative procedures. Are these procedures adequate to define the duties and responsibilities of the Radiation Safety Officer with respect to such matters as records, surveys, leak tests, personnel monitoring including bioassay, investigation and reporting of incidents, and disposal of radioactive waste?
 - General radiation safety procedures. Are these procedures adequately developed for the instruction of users and other staff personnel?

- o Detailed operating and radiation safety procedures. Are these procedures adequate considering the uses which they describe and regulate?
- o Do existing procedures conform to procedures incorporated by reference as licensing conditions?

5.0 INSPECTION PRIORITIES

INSPECTION PRIORITY, from the definitions, means the interval between compliance inspections. Priority 1 means there is only one year between inspections; priority 2, two years, etc. The priority system addresses relative risk associated with a license. For example, a licensee with an inspection priority 1 has the greatest potential for hazards in health and safety. This priority requires the most frequent inspections because of the nature of the operations. On the other hand, an inspection priority 7 involves little potential hazard to health and safety and requires less frequent inspections.

Examples of priorities by license type: Note, this schedule is subject to change by programs based on safety emphasis.

Attachment I- See NMED INSPECTION PRIORITY TABLE:

6.0 INSPECTION PROTOCOLS

The word protocol means amenities, decorum, etiquette, conventions or customs contingent upon a subject. In the case of inspections of radioactive material licensees, protocols refer to the specific steps or procedures which are used to complete an inspection.

6.1 TYPES OF INSPECTIONS

1. Initial Inspections

Inspections of all specific licensees shall be conducted within six months after material is received and operations under the license have begun. Initial inspections of new licensees should be unannounced, but a phone call prior to a visit should be made to confirm that licensee has begun operations with licensable material.

2. Routine, Periodic Inspections

Inspections of licensees shall be conducted at intervals corresponding to their inspection priority. Priority 1 = each year; Priority 2 = each two years; Priority 3 = each three years; These should be unannounced unless prior notification of no more than 48 hours would enable more complex facilities to assemble documents to be reviewed by inspectors or to ascertain that licensees located in remote areas will have someone present to grant access to premises.

3. Follow-up Inspections

Follow-up inspections shall be conducted for cases involving willful or flagrant violations, repeated poor performance in an area of concern, or serious breakdown in management controls. Program compliance management shall determine whether a follow-up inspection should be conducted, based on the compliance score of the closed inspection code sheet. Each follow-up inspection shall be conducted within six months of the most recent inspection and should be unannounced.

4. Close-out Surveys

Upon notification that a license has expired or is being processed for termination, a close-out survey may be performed to ensure that licensed material has been properly disposed of and that affected areas of the licensed facility may be safely released for unrestricted use. Each survey, if supervisory personnel deems it necessary, shall be conducted as soon as possible after the notification is received.

5. Reciprocity Inspections

When a licensee that is licensed by another Agreement State or the NRC requests permission to work within the State permission may be granted provided: (1) the licensee does not work continuously for more than 180 days in a calendar year, and (2) the licensee notifies the State at least three days prior to entering so that an inspection may be conducted. An inspection of an out-of-state licensee is called a reciprocity inspection. The inspection report and correspondence to the licensee are handled the same as any other licensee inspection.

6.2 SCHEDULING INSPECTIONS

1. Obtain inspection due list.
2. Identify licenses within a geographical area to optimize travel.
3. Identify licenses most in need of inspection (prioritize).
4. Plan travel itinerary allowing for substitutions and have Program Manager, Bureau Chief and Financial Specialist approve overnight travel.
5. Announce visit in advance only if necessary.
6. Review licensed materials and prepare field notes (copy all necessary documents; do not take primary file into field).
7. Review previous inspections thoroughly and any incidents which may have occurred within the inspection interval.
8. Obtain necessary equipment.
9. Provide inspection schedule to management for emergencies.

6.3 INSPECTION TECHNIQUE

1. The inspector should have a complete knowledge of the license, and the State's Rules, Policies and Regulations.
2. **Always contact upper management upon entering a facility.**
3. The inspector should communicate effectively avoiding the use of leading questions or statements.
4. The inspector's appearance should reflect the Agency's idiom. Dress appropriately for the type of inspection.
5. When requesting records during an inspection, the

inspector should not assist with their location or procurement.

6. The inspector should be aware of licensee stalling tactics and maintain control of the inspection.
7. At the conclusion of the inspection, the inspector(s) should take time to themselves to evaluate all findings and identify possible areas of noncompliance. The inspector should feel confident that items of noncompliance are truly violations of regulations or conditions of the license. If in doubt, never call an item of noncompliance until certain. This should eliminate the possibility of rescinding a violation later, following a successful challenge by the licensee.
8. Inspection findings must be revealed and discussed with the licensee's management during the exit interview. Any other findings not identified during the exit should be communicated to the licensee by telephone prior to issuance of the Notice of Violation. **The closeout conference should be held with the licensee's highest level of management available.**

7.0 GUIDANCE

7.1 ALARA (AS LOW AS REASONABLY ACHIEVABLE)

A licensee engaged in license activities should, in addition to complying with regulatory requirements and license conditions, make reasonable efforts to maintain radiation exposures and releases of radioactive materials in effluents to unrestricted areas as low as reasonably achievable. Even though current occupational exposure limits provide a very low risk of injury, it is prudent to avoid unnecessary exposure to radiation. This can be accomplished by the implementation of good radiation planning, practice and commitment to policies that prevent departure from these practices.

The inspector can verify ALARA commitments by reviewing:

- o A written commitment by high level management to minimize worker exposure via the implementation of clearly defined

procedures and policies;

- o That licensee personnel are made aware of managements' commitment to keep occupational exposures ALARA;
- o That the radiation protection staff have been given authority to assure ALARA procedures and policies are carried out;
- o That workers are adequately trained, not only in the radiation safety procedures, but also in the ALARA philosophy;
- o That management and its designees perform periodic audits to find out how exposures and effluents releases might be lowered;
- o That modifications to procedures, equipment and facilities have been made to reduce exposures at reasonable cost where possible; and
- o The Quality Assurance (QA) and Quality Control (QC) programs where applicable (i.e. manufacturing, R and D, radiopharmacy, etc.).

7.2 GENERAL GUIDANCE FOR ALL INSPECTIONS

All inspections should include a mix of records and procedures review, observations, confirmatory measurements, and discussions with personnel involved in the "hands on" work.

Inspection of licensees should be done by observation of operation, interviewing of licensee personnel, and review of records. The record review should serve to verify both the observed operation and the information collected during the interviews.

General review of the licensee records, with special attention paid to problem identification, may be useful to identify areas deserving special attention during the inspection. The inspector should pay particular attention to evidence of trends that may lead to a breakdown in the licensee's safety program.

7.2.1 INTERVIEWS

Personnel interviews are extremely important.

1. All interviews with authorized users and ancillary workers must be documented, including job titles.
2. It's acceptable to ask workers to take a short examination to test their knowledge of radiation safety as it pertains to the type of operation being inspected.
3. Interviews can and should be held in private, away from the licensee's management and other workers that may intimidate the responses given.
4. Be certain to question janitorial staff regarding the labeling of radioactive material waste containers and areas to avoid during cleanup of labs.
5. Verify that receptionists understand the proper storage location for packages that contain radioactive materials that are either received or sent out by the facility.
6. Determine that supervision is provided for all license operations where unsupervised work is prohibited.
7. Personnel interviews are important! Ask the employees if they received the required training. Ask them questions about their training, job duties, and problems encountered to determine whether they are properly trained and capable of performing their duties safely and according to the operating procedures. Take the malcontent employee to coffee and listen to the problems of the radiation protection program as they perceive them.

7.2.2 RECORDS REVIEW

When reviewing records, the inspector should start with the last previous inspection and come forward in time. Occasionally records that go back beyond the last inspection must be reviewed to

verify that corrective action has been taken.

7.2.3 RECORDS RETENTION

The licensee is allowed to dead file all records that have been reviewed by the inspector. However, there may be legal time requirements for such records as personnel monitoring and bioassay exam reports.

7.2.4 OBSERVATIONS

The inspector can learn from direct observation whether the licensee is complying with regulations and licensing conditions, following his own written procedures and whether good radiation safety practices are utilized in the process. In some cases it may be necessary to stand back and assume you're a "fly on the wall", in order to adequately observe operations.

7.2.5 INDEPENDENT MEASUREMENTS

During most inspections, performing independent measurements is required. The need for radiation surveys, wipe surveys and tests of air, water, or soil will vary with the type of licensee. There are general rules concerning independent surveys by the inspector that must be followed such as:

- o Use of a survey meter of a type and range similar to the licensee's.

- o Use of a survey meter that is calibrated at the same time period as the licensee's. Example: For radiography inspections, always use a meter that has been calibrated within three months.

- o Meter calibrated against NIST standards and at two points per range.

- o Wipes of areas for contamination should cover 100 square centimeters.

- o Wipes should be evaluated by instruments that are sensitive to the isotopes in question. Differentiate between dose rate measurements and contamination measurements (mr/hr or dpm).
- o Verify survey instrument response with an appropriate check source.

7.3 INSTRUCTIONS FOR SPECIFIC LICENSE TYPES

RADIOGRAPHY

1. Should be unannounced.
2. A field inspection shall be made for 25% of the routine inspections of this type.
3. Observe operations incognito; use binoculars or observe without being observed during field site inspections.
4. Evaluate condition of radiography equipment, however, repair and replacement of old worn out equipment is the responsibility of the licensee.
5. Evaluate training and testing program.
6. Look for proper use of monitoring equipment.
7. Verify receipt and shipping procedures.
8. Assure adequate security of RAM.
9. Audits may need to be conducted during off hours (night time).

MANUFACTURING & DISTRIBUTION

1. Verify current client license authorization (make sure the licensee has all necessary client information to comply with transfer rules).

2. Review shipping procedures and records (make sure all shipping is in compliance with 49 CFR). Appendix Z has USDOT Limited Quantity form which may be useful.
3. Review processing/quality assurance methods (make sure all requirements for Sealed Source and Device registration or FDA have been completed).
4. Verify the final General Licensee in accordance with General License rules. Confirm if there will be a "drop shipment" to a middleman who must be specifically licensed.

BROAD LICENSES

1. Confirm RSC authorizations for users.
2. Assess risk potential among principal investigators based on type and quantity of RAM.
3. Depending on previous compliance history and recent risk assessment, observe a sample of Principal Investigators. (This may range from 15% to 100%, depending on licensee's status.

NUCLEAR PHARMACY

1. Begin inspection at 3 am (doses are prepared for distribution before 7 am).
2. Verify drivers' qualifications and proper training regarding USDOT regulations.
3. Verify supervision of ancillary workers using RAM.
4. Confirm that client information is accurate and current (make sure RAM is transferred only to authorized licensees).

WASTE BROKERS

1. Confirm that the resident time of waste does not exceed the licensed allowable time limit.

2. Verify the type of waste authorized (does licensee address mixed waste?).

MEDICAL INCLUDING DIAGNOSTIC, BRACHYTHERAPY AND TELETHERAPY

1. Confirm that doses are within well established limits.
2. Verify patient release criteria.
3. Verify that adequate personnel dosimetry and training is provided to nursing staff.
4. Verify physician and authorized user qualifications.
5. Confirm that scans are being read by an authorized user.
6. Confirm technologist licensure.
7. Verify camera QA in accordance with RDA recommendations.
8. Verify dose calibrator QA (cf. NCRP No. 95).

MOBILE MEDICAL VANS

1. If dose calibrator is transported, verify that accuracy and constancy are performed before each use.
2. Perform 25% site of use inspections.
3. Confirm that doses are verified prior to injection.
4. Confirm that facility surveys are performed upon exit from facility; confirm also that no residual contamination remains.
5. Confirm that there is license authorization for transport of dose calibrator and/or sealed sources.

SERVICE LICENSES (LEAK TEST, INSTRUMENT CALIBRATION, ETC.)

1. Verify that distribution and temporary job sites are authorized.

2. Confirm that leak test kit conforms to postal regulations.
3. Confirm that there is adequate instrument sensitivity regarding leak test analyses and NIST traceability of standards.

WELL LOGGING

1. Observe fishing operations if possible.
2. Verify requirement for casing of potable water zones.
3. Verify that tracer studies are performed in accordance with license conditions.
4. Site visitation permits may limit accessibility to well logging operations.

PORTABLE GAUGES (MOISTURE DENSITY GAUGES)

1. Verify authorized storage locations (check for home storage and vehicles).
2. Verify transportation and security procedures.
3. Verify that operator maintains security at all times.
4. Personnel monitoring; verify that authorized user list is current.

VETERINARY MEDICINE AND THERAPY

1. Verify patient release criteria and home instructions.
2. Verify technician qualifications and training.
3. Verify that there is license authorization (i.e. a license condition) to dispose of wastes down the sewer.
4. Veterinary medicine does not follow human use rules.

RESEARCH AND DEVELOPMENT

1. Verify that license status is only R & D and that there is no distribution.
2. Verify that animal use is conducted with adequate safeguards.

INDUSTRIAL LIXISCOPE

1. Verify that source exchange is authorized by license.

FIXED GAUGES

1. Verify location and labeling of gauges.
2. Perform inventory of all gauges including any Generally Licensed gauges.
3. Make sure the licensee has lockout procedures for maintenance.

GAS CHROMATOGRAPHS

1. If portable, verify that licensee uses proper shipping procedures.
2. Check venting of H-3 sources (Sc tritide).

8.0 INSTRUCTIONS FOR INSPECTION REPORTS

The basic intent of inspection reports is to provide a written record of inspections. The primary purposes of the written record are to: (1) provide a basis for compliance action and record the results of the inspection of the licensee; and, (2) provide information for management of the inspection program within the agency.

The minimum objectives of an inspection report are:

1. To eliminate unnecessary detail in inspection reports by

requiring documentation of only those facts necessary to form the basis for enforcement actions and to describe the scope and findings of inspections.

2. To achieve uniformity in inspection reports.

The minimum content of the report requires detailed summarized information gathered during the inspection limited to subjects which are applicable and have safety significance, plus those subjects for which non-compliance items were found. Where a subject was not inspected or was found to be not applicable, the inspector need only indicate this finding in the report.

For subjects of lesser significance, the inspector need provide only a summary of information and gathered including no more than that which may be necessary to support a conclusion of adequacy. It is not necessary to record all information obtained during the inspection. The inspector should use judgement and record essential facts that will give an overall view of the licensed program.

A reasonable effort should be made to attribute information to the proper source, such as statements by named individuals, excerpts or summaries from specific records, and observations by the inspector. If the source information is obvious, it need not be specified. References to inspection requirements in written inspection procedures should be made as necessary to facilitate reviewing the results of the inspection.

8.1 CONTENTS

The report is a concise record of factual, accurate information which is used to form the basis for compliance action, and describe the scope and findings of the inspection. At least it should include:

1. A description of licensed activities, including name, address, license number, priority, license type, inspection date, inspectors, instrumentation, and scope of inspection.

2. List licensee representatives and other individuals not employed by the licensee, who furnished information for the inspection. Limit the list to those at the technical and supervisory level and include the name and title of each individual. If convenient, indicate by an asterisk or other suitable note those individuals who participated in the exit interview.
3. Description of the organization to show responsible line of authority from operational level and radiation safety officer to management.
4. State actions on previous inspection findings. (Omit if not applicable or not inspected). To the extent that licensee action on the previously noted compliance items and unresolved items was examined, it should be described. Appropriate reference to the items is made followed by a description of the findings and a statement as to whether each item included remains open or is closed.
5. Functional or program areas inspected. This is the main body of the report containing paragraphs describing the inspection of functional or program areas. It is divided, where possible, into paragraphs with titles of the inspection procedures under which the inspection was performed. The titles of procedures may be shortened or expanded to provide an adequate description of the information reported.

Where the inspection was performed under one or two lengthy inspection procedures, the details should be divided into paragraphs by line items or groups of line items within the inspection procedures.

6. Exit interview. List the names and position titles of persons present at the exit interview with licensee management. The inspector should identify each subject discussed at the interview. It is not necessary to describe in detail the specific items discussed, a brief summarizing statement can be used. If the licensee's management has a position (agrees, disagrees, or comment) on compliance matters and unresolved items, this position

should be factually documented. Any contact after the exit interview regarding changes in management's position on an item should also be reported.

The depth of reporting for subjects inspected is related to the inspection findings as follows:

7. Noncompliance items and recommendations. It is necessary to provide full substantiating information for cited items of noncompliance and recommendations. For noncompliance items, the information required is a clear statement of the requirement - referenced, paraphrased or quoted - and a detailed description of the manner in which the licensee did not follow or meet the requirement. This description should be in sufficient detail to permit a knowledgeable reader to come to the same conclusion. The description of the item of noncompliance should include, as appropriate, the date(s) of the noncompliance, the means of identification (i.e., inspector observation, discussion, records, reports from licensee, etc.), the specific procedures, operation, or location involved, and the event or circumstances that occurred. If the requirement is conditional, the supporting information should describe the way in which the conditions are satisfied to make it clear that the requirement applies.
8. Acceptable areas. For subjects examined and found to be acceptable, the inspector should report, as a minimum: (1) what is inspected; (2) dates covered by the examination or review; (3) the acceptance criteria if other than regulations, license conditions or technical specifications; and, (4) the findings or conclusions of the inspector.

It is not necessary to report all information gathered to support a conclusion of adequacy. Normally, the depth of reporting should be related directly to the significance of the subject examined and the information obtained. For example, examination of licensee logs and operating records for a specified period of time can be reported as a listing of the records examined and the dates covered. Similarly, the result of a tour of the licensee's facility can be reported as a brief series of observations or highlights of

such observations. At the other end of the spectrum, follow-up of licensee reported events (e.g., incidents and overexposures) should be reported more fully, although it is not necessary to report all information obtained. Rather, the inspector should limit his reporting to the basis for concluding adequacy or keeping the item open. The objective is to report substantive information and minimize the reporting of information of lesser importance or interest.

8.2 REPORT GUIDANCE

Specific guidance regarding handling of reports is as follows:

1. Any finding leading to a conclusion that a noncompliance occurred shall always be handled as a noncompliance item except for minor licensee-identified noncompliances. Recommendations are made when deviations from acceptable or normal practice are noted and there is no regulatory basis for citation of noncompliance.
2. The following types of information should not be included in inspection reports:
 - (a) Opinions of a personal nature by the inspector;
 - (b) Identity of persons giving confidential information to the inspector and any part of the confidential information that would reveal the identify of such persons;
 - (c) Proprietary information.
3. Use of sketches (floor plans, equipment) and copies of licensee's forms and report should be used as attachments to the inspection report to provide clarity and to reduce the narrative portion of the report.
4. Inspection reports should be drafted as soon as possible following the inspection, typed and reviewed by area supervisor, reviewed by the supervisor and entered into the data tracking system.

5. The inspection report is an agency document and will ordinarily not be utilized elsewhere. It is acceptable to enter handwritten notations on the final typed report.

8.3 REPORT DISTRIBUTION

Following final review of the inspection report by the supervisor, the original is placed in the central license file in the licensing office and a copy is placed in the area office file.

8.4 REPORT FORMAT AND EXAMPLES.

In order to present a consistent and effective inspection report, the report outlines and examples presented should be reasonably adhered to. The report package should be filed in the following order, bottom to top:

- o Inspection report notes and check list on bottom.
- o Licensee's documents (plans, procedures, personnel monitoring reports, etc.).
- o Inspector's letter of inspection findings and Notice of Violation (NOV) [Notice of Noncompliance], if issued.
- o Licensee's response letter to inspection findings of NOV.
- o Final closing letter [close loop letter] to licensee from supervisor.
- o Inspection package tracking system.

9.0 INSPECTOR'S EQUIPMENT

9.1 RADIATION MONITORING EQUIPMENT

1. Survey Meter (cpm and mR/hr).
2. Detectors.
 - a. Energy compensated GM
 - b. Pancake probe.
 - c. Low energy NaI(Tl) probe (thin) and check source to

- confirm probe efficiency.
 - d. High energy NaI(Tl) probe (1x1) and check source to confirm probe efficiency.
 - e. Alpha scintillation probe and check source to confirm probe efficiency (optional).
 - f. Beta scintillation probe and check source to confirm probe efficiency (optional).
3. Check source NIST traceable (Cs 137)
 4. Audible alarm meter (optional).
 5. Personnel dosimetry (personal film badge or TLD NVLAP traceable for Categories I-VI)

9.2 SAFETY EQUIPMENT

1. Disposable gloves
2. Hard hat, safety shoes, earplugs, safety glasses
3. Disposable shoe covers

9.3 INSPECTION SUPPLIES

1. Inspection forms
2. Personnel dosimetry guide, prenatal guide, Notice to Workers, medical, portable gauge, IR, etc., guides
3. Consultant list, vendor list, etc.

9.4 MISCELLANEOUS HP SUPPLIES

1. CRM signs
2. Transportation labels (WI, YII, YIII)
3. Tape rule
4. CRM barrier tape
5. Burlap bags which can be filled with dirt for shielding

6. Indelible pens in black, red
7. Notepaper
8. Wipe test materials
9. Writing pens & pencils
10. Calculator
11. Tape recorder & tapes
12. Cellular phone

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ATTACHMENT 8A
ENFORCEMENT PROCEDURES



ENFORCEMENT PROCEDURES

1.0 ROUTINE ENFORCEMENT

- 1.1 Inspector prepares noncompliance letter. Bureau Chief reviews noncompliances and signs letter. Letter requires a 20-day response time.
- 1.2 Short form letter (no items of noncompliance) may be sent to licensee after the inspection indicating no items of noncompliance. These letters are to be signed by the RLRS Program Manager.
- 1.3 Each item of noncompliance is categorized according to severity level 1, 2, or 3. Severity level 3 noncompliances have a high probability of causing a health and safety problem; severity level 2 could cause a health and safety problem; and severity level 1 indicates an administrative noncompliance which has minor safety significance.

Repeat items of noncompliance must be stated in the noncompliance letter.

- 1.4 Notice of Noncompliance must be sent within 20 calendar days of the date of inspection closing.
- 1.5 Licensee response to noncompliance letter is required in 30 days.
- 1.6 Inspector follows up on licensee response. Supervisor may intervene if licensee response is unsatisfactory or inadequate.

If response is adequate, then:

- o Inspection is closed out with "close loop" letter after all items of noncompliance have satisfactorily been addressed.
- o An inspection report is completed as soon after the inspection as possible, and usually not longer than 30 days. Complicated or involved inspections may require a longer period to prepare and assemble all documents for the report.

If response is unsatisfactory, then:

- o Management level of this program becomes involved, and all correspondence should be signed by Program Manager and countersigned by the inspector.
- o Second letter with shorter required response time.

- o Phone calls are made as frequently as necessary to get the licensee's attention.

ROUTINE ENFORCEMENT (continued)

- o Follow-up visit may be made to spot check progress within 6 months of inspection.
- o Enforcement conference with licensee management at RLRS office should be offered as a last solution before going to escalated enforcement.
- o Shorten inspection frequency (raise priority temporarily).
- o Require periodic (weekly, monthly, quarterly) written reporting by licensee.
- o Administratively write additional restrictive license conditions into that specific license.
- o Administratively limit amount of isotopes that may be possessed.
- o Require specialized training programs and audits by licensee to be presented to State.

2.0 ESCALATED ENFORCEMENT/ADMINISTRATIVE PENALTIES.

2.1 74-3-11. Civil penalty; injunction.

A. If the director has good cause to believe that any person is violating a condition of a license issued by the agency, or administered by the agency pursuant to an agreement with the nuclear regulatory commission, or any regulation of the board, the person shall be given an opportunity to be heard at a hearing before the director. The director shall notify the person by certified mail of the date, time, place and subject of the hearing. If the director finds that the person is violating or threatens to violate a condition of the license or a regulation of the board, the director shall issue an order to cease and desist or revoke the license held by the person, whichever is appropriate.

B. The director may issue a cease and desist order, on an emergency basis, pending the hearing provided in Subsection A of this section, if he determines that immediate action is required to protect human health or safety. If a cease and desist order is issued on an emergency basis, the hearing before the director shall be held as soon as possible. The person who is the subject of a cease and desist order issued on an emergency basis may waive in writing the requirement of written notice of the hearing before the director in the interest of expediting that hearing.

C. The agency may seek injunctive relief against any violation or threatend violation of regulations, rules or orders adopted pursuant to the provisions of the Radiation Protection Act [74-3-1 to 74-3-16 NMSA 1978], and such relief shall be subject to the continuing jurisdiction and supervision of the district court and the court's powers of contempt. The action shall be filed in the district court for the county in which the violation occurred or will occur. The attorney general shall represent the agency.

D. In addition to the remedy provided above, the trial court may impose a civil penalty not to exceed five thousand dollars (\$5,000) for each day during which violation occurs.

E. Any person aggrieved by a final judgement of the district court under this section may appeal to the supreme court as in other civil actions.

ATTACHMENT 8B

FOLLOW-UP ON INSPECTION LETTER



FOLLOW-UP INSPECTON LETTER

Licensee _____ License Number _____

Inspector issuing letter of inspection: _____

Date Inspection letter was issued: _____

Date response due from licensee: _____

Response received by due date: _____ Yes _____ No

If yes, inspector should initial this form and "X" out the rest of the page.

If No, proceed to next step:

1st follow-up contact by inspector by telephone.

Summary: _____

2nd follow-up by registered letter. (Cite date and to whom letter was sent; copy to NMED legal) _____

3rd follow-up

Site visit by inspector to determine circumstances. (Cite date and summary of activities).

4th follow-up—Cease and Desist Order from the Secretary's office and subsequent escalated enforcement actions. (Cite actions taken.)

Summary: _____

Inspector: _____ Date: _____

Program Manager: _____ Date: _____

ATTACHMENT 9

**STANDARD OPERATING PROCEDURES FOR RESPONSE TO
INCIDENTS INVOLVING RADIOACTIVE MATERIALS**

INCIDENT INVESTIGATION PROCEDURES

**INCIDENT REPORTING SYSTEM/ABNORMAL OCCURRENCE
CRITERIA**



INCIDENT REPORTING SYSTEM

ABNORMAL OCCURRENCE CRITERIA

The following criteria shall be used for the determination of an abnormal occurrence.

Events involving a major reduction in the degree of protection of the public health or safety. Such an event would involve a moderate or more severe impact on the public health or safety and could include but need not be limited to:

1. Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Agency;
2. Major degradation of essential safety-related equipment; or
3. Major deficiencies in design, construction, use of, or management controls for licensed facilities or material.

Examples of the types of events that are evaluated in detail using these criteria are:

For All Licensees

1. Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rems or more of radiation or equivalent from internal sources.
2. An exposure to an individual in an unrestricted area such that the whole-body dose received exceeds 0.5 rem in one calendar year.
3. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 500 times the regulatory limit of Subpart 3, Schedule A, New Mexico Radiation Protection Regulations.
4. Radiation or contamination levels in excess of design values on packages, or loss of confinement of radioactive material such as (a) a radiation dose rate of 1,000 mrem per hour three feet from the surface of a package containing the radioactive material, or (b) release of radioactive material from a package in amounts greater than regulatory limits (Reference 10 CFR, Part 71.36(a)).
5. Any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.
6. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

7. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy which is judged to be significant relative to normally expected performance and which is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.
8. Any substantial breakdown of physical security or material control (i.e., access control, containment or accountability systems) that significantly weakened the protection against theft, diversion or sabotage.
9. A major deficiency in design, construction or operation having safety implications requiring immediate remedial action.
10. Serious deficiency in management or procedural controls in major areas.
11. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents), which create major safety concern.

INCIDENT REPORTS

PURPOSE

An incident report provides documentation of an event which may or may not involve radioactive materials or radiation from any source. It provides a method to later evaluate an event and its associated consequences.

DISCUSSION

The NRC has developed guidelines for the reporting of incidents involving radioactive materials. The information gathered is used in a national data base to evaluate trends and identify generic problems. They have divided reporting criteria into three categories:

1. Abnormal Occurrences--The most significant events. They require a written report for inclusion into the quarterly report submitted by the NRC to Congress. These events must be reported to the NRC by telephone as early as practicable.
2. Telephone Reports--These are incidents that require 24-hour notification of the State by a licensee or an event which receives significant media attention.
3. Other Reportable Incidents--Events that require reporting by a licensee to the State are covered in Subpart 4, Section 452, New Mexico Radiation Protection Regulations.

For Radiation Control, all incidents and potential incidents will be documented and entered into the record system. Hard copies of all reports will be kept by the Radiation Licensing and Registration Section in Santa Fe.

INCIDENT INVESTIGATION PROCEDURES

1. Upon receiving notification of a potential incident, complete the Incident Report, Attachment 11.
2. Document actions taken, people contacted, arrival and departure of emergency response personnel, and any other pertinent information.
3. Record any notifications made, being sure to include name, agency, date/time, and phone number. Verify reportability to NRC by checking requirements listed in Attachment 11.
4. If a press release is required OR any news media personnel are at the scene, notify Public Affairs. Attach copy of all releases, including summaries of interviews, to the report.
5. When other emergency response agencies respond or are called to respond, list all names, addresses, phone numbers and dates notified.
6. For transportation incidents, complete the transportation section.

For truck-related incidents, all of the required information should be on the manifest. In some cases, only an EPA No. will be listed for the carrier and the address, phone number, and contact person will not be available. Record the EPA number and the driver's name. Complete the remaining portion of the transportation section.

7. Give Incident/Allegation Report Forms to the Program Manager no later than the next working day.
8. The Program Manager will review the Incident/Allegation forms for completeness and reporting requirements.
9. The forms will be given to the designated person for assignment of a tracking number and data entry.
10. When the incident is closed, complete the close-out summary.
11. Date and sign forms and indicate if copies are required for the Incident chronological file.
12. The complete incident package is then given to the Program Manager for review and signature.
13. The package is returned to the designated person to complete data entry and filing.
14. Completed incident packages will be kept in a 3-ring binder for each particular licensee behind incident's tab. At the end of the year, the reports are then filed in the filing cabinet in the RLRS office in Santa Fe.

STANDARD OPERATING PROCEDURE (SOP)

FOR RESPONSE TO INCIDENTS INVOLVING RADIOACTIVE MATERIALS

I. GENERAL

- A. This SOP provides general guidance for responding to any incident, accident, or emergency in which radioactive materials or a machine source are involved, except for an accident involving reactors.
- B. The Radiation Licensing & Registration Section Program Manager has the primary responsibility for the coordination of all emergency responses. This central point of contact has been established to ensure a smoother, more unified response mechanism.
- C. The Director, and the HRMB Bureau Chief, will be advised of all incidents reported and response contemplated.

II. RESPONSE GUIDE

A. General

- 1. Whenever the Agency is apprised of an incident, accident or emergency, a response is required. This response may be in the nature of soliciting and providing information over the phone, scheduling an inspection at a later time, or it may involve an immediate on-site response. The RLRS Program Manager or the HRMB Bureau Chief will advise as to when an on-site response is necessary.
- 2. As guidance, an on-site response may be required in the following situations:
 - a. The Agency is requested to do so and the request does not entail a response beyond the equipment and training capabilities of program and staff;
 - b. If there is a source disconnect, lost source, overexposure or possibility of contamination.
 - c. If radioactive material other than gas, e.g., "a source," is lost, including a well-logging tool down-hole, or involved in an accident;
 - d. If there is an actual or potential hazard to public health and safety;
 - e. If the media should notify the Agency of any real or suspected incident;
 - f. If the Program Manager or Bureau Chief deem it necessary.

3. When receiving a notification of an incident, the person notified should complete an Radiological Incident/Allegation Report (Attachment 11) to obtain pertinent background information.
4. The Person notified of the incident should then verify telephone reports of incidents. This may be done by dialing the number given on the Radiological Incident Report, or in the case of a licensee, by checking the file to validate the information given.
5. During the response, normal office and inspection routines will be maintained unless the Program Manager orders otherwise.
6. If an on-site response is required, upon arrival at the scene, responders will:
 - a. Identify both the local/county official in charge and representatives of state agencies that may have responded. Most likely, at least for transportation incidents, a designated officer of the Department of Transportation will be on scene and will have assumed the role of Incident Commander.
 - b. Evaluate the situation.
 - c. Offer advice as necessary to protect public health and safety.
 - d. Advise the Program Manager of the evaluation as soon as possible. Contact with the RLRS office will be maintained throughout the response and the on-scene responders shall periodically update the RLRS regarding event developments.
 - e. Attempt to determine whether or not items of non-compliance led or contributed to the incident or accident after control has been established.
 - f. Maintain a record of actions taken.
7. Licensees are responsible for corrective actions. The licensee Radiation Safety Officer should remain with the responders until the situation is resolved.

III. VEHICLE USE

- A. The Agency designated emergency response vehicle should be used to respond to incidents for which use of a vehicle is deemed appropriate.

IV. REPORTING REQUIREMENTS

- A. 1. Reporting requirements for any incidents responded to are found in 20NMAC 3.1, Subpart 4, Section 452.
- 2. The Emergency Response Program Manager will publish periodically a roster of Emergency Response Duty Officers and will maintain an up-to-date Emergency Assistance Telephone Call List (Enclosure 3). Enclosure 3 will not be provided to anyone outside the Agency.

B. Press

- 1. The following guidelines apply:
 - a. Press releases will be provided by the Agency's PIO as deemed necessary by the Director. The completed Incident/Allegation Report form will provide the PIO with the basic information with which to prepare a preliminary release. Further information for media will be followed by subsequent releases as needed.
 - b. If a source is lost or unaccounted for, all appropriate media and local television stations, if necessary, will be accessed for the purpose of public safety as well as assistance in locating the lost source. Integrated media alert may also be used.
 - c. Responders on the scene may provide a short synopsis of what they found but should not engage in long discussions or speculation with media representatives. There will be one spokesperson (as previously designated) for the responders. Any information provided to the media should be provided in coordination with local, county and state officials at the scene. The State PIO should also be apprised of that information; press releases may then be issued by the RLRS.

Any questions, please do not hesitate to ask supervisors.

NMED/RLRS.REV. 10/97
N-INCID.PRO

ATTACHMENT 10

**ALLEGATION RESPONSE GUIDANCE DOCUMENT
(BEING DEVELOPED, TO BE PRESENTED TO MRB ON
OCTOBER 23, 1997)**



ATTACHMENT 11

INCIDENT REPORT FOR RADIOACTIVE MATERIAL LICENSEES





GARY E. JOHNSON
GOVERNOR

State of New Mexico
ENVIRONMENT DEPARTMENT
Hazardous & Radioactive Materials Bureau
2044 Galisteo
P.O. Box 26110
Santa Fe, New Mexico 87502
(505) 827-1557
Fax (505) 827-1544



MARK E. WEIDLER
SECRETARY

EDGAR T. THORNTON, III
DEPUTY SECRETARY

INCIDENT REPORT FOR RADIOACTIVE MATERIAL LICENSEES

LICENSEE NAME: _____	LICENSE NO.: _____
CITY: _____	PHONE NO.: _____
TYPE OF EVENT (check all that pertain): <input type="checkbox"/> Loss of Package Effectiveness or Contamination <input type="checkbox"/> Theft or Loss of Radioactive Material <input type="checkbox"/> Overexposure of Individual to Radiation <input type="checkbox"/> Overexposure of Individual to Radioactive Material <input type="checkbox"/> Excessive Levels of Radiation or Concentrations of Radioactive Material <input type="checkbox"/> Device Safety Failure <input type="checkbox"/> Leaking Source <input type="checkbox"/> Misadministration: _____ Diagnostic _____ Therapeutic <input type="checkbox"/> Transportation Incident <input type="checkbox"/> Other _____	
EVENT DATE: _____	DATE REPORTED TO STATE: _____
REPORTED BY: _____	REPORT RECEIVED BY: _____
OTHER LICENSEE INVOLVED (Name/License No.): _____	
RECIPROCITY LICENSEE? Y/N _____	AGREEMENT STATE: _____
LOCATION OF EVENT: _____	
ISOTOPE: _____	AMOUNT: _____

ATTACHMENT 12

TELEPHONE LOG



TELEPHONE LOG

DATE	LICENSE NAME & NUMBER	SUBJECT OF CONVERSATION	NAME & PHONE # OF PERSON SPOKEN TO	RLRS STAFF PLACING CALL

NMED/TELEPHON.LOG 10/97

NRC/NEW MEXICO MANAGEMENT MEETING MINUTES

On Thursday, December 4, 1997, Hugh L. Thompson, Deputy Executive Director for Regulatory Programs, NRC, and other NRC managers met with Secretary Mark Weidler, New Mexico Environment Department, and his management and supervisory staff to discuss performance concerns associated with the New Mexico Agreement State program. These concerns were identified as findings from the New Mexico Integrated Materials Performance Evaluation Program review, conducted July 14-18, 1997. The specific purpose of the meeting was to ensure that Secretary Weidler supported necessary actions by New Mexico to address program weaknesses and implement program improvements. Attachment 1 contains the agenda for the meeting. Attendees are shown by the Attachment 2 sign-up sheet.

Mr. Thompson explained the reason for the meeting and the NRC role to assure consistency among all Agreement State programs to achieve a "national" Atomic Energy Act materials regulatory program that is collectively implemented by NRC and the Agreement States to assure adequate protection of public health and safety. The "national" program features less dependency on the NRC by Agreement States. Secretary Weidler stated that probation for the New Mexico Agreement State program was not warranted based on initiatives already completed, as described in his October 10, 1997, letter to Richard L. Bangart; as described in William M. Floyd's December 3, 1997, letter to Members of the Management Review Board; and as described in discussions at the December 4, 1997, meeting. Secretary Weidler further noted that New Mexico's objective is to continue their Agreement State program, that he endorses the New Mexico program staff actions to implement necessary improvements, that he supports more active management oversight of the program by Mr. Garcia and Dr. Kelley, and that he will seek adequate funding for Agreement State program support (see below). A summary of the major discussion points and associated commitments follow.

Adequate Radiation Control Program (RCP) Funding

The FY 2000 budget submittal is the first opportunity to request additional RCP funding for training, travel, and other program needs. Planning for that budget request will begin in the summer of 1998. Secretary Weidler plans to obtain information from Mr. Garcia and Mr. Floyd about projected training costs and to either request those funds through the budgeting process (if in the amount of a few 10,000 dollars) or seek legislation to establish a fee base with at least some of the fees going directly to the Environment Department (if \$100,000 or greater). Currently, New Mexico has authority to establish fees, but the funds collected from fees would go the State general fund, not to the Environment Department. Secretary Weidler explained that to pass any new legislation, both support from Republican Governor Johnson and the Democratic legislature would be required. Secretary Weidler also explained the Governor's direction to minimize the costs of State of New Mexico government.

Commitment Summary: For FY 2000, Secretary Weidler will seek additional Agreement State program funding that is adequate to support necessary training and other program needs. A decision will be made in mid-year 1998 as to whether to seek additional funding through the budgeting process or seek legislation to establish licensee fees that could be used to directly fund the training needs of the Agreement State program.

Training Options

Even if funds are available, out-of-State travel is often difficult because of established State policy that discourages such travel. New Mexico will continue to explore training opportunities at Los Alamos National Laboratory and discussed whether it was possible that some NRC training courses could be presented within New Mexico, if the number of New Mexico and or regional students were sufficient to justify presentation in New Mexico. It also may be cost effective for New Mexico to contract with NRC to have courses presented in that State. NRC commented that some training courses are conducted in NRC Regional offices and at Agreement State office locations, when justified. New Mexico was advised to contact NRC's Office of State Programs if they were planning to develop such a request.

Commitment Summary: Secretary Weidler endorsed the commitment by Dr. Kelley and Mr. Garcia to identify and pursue options for training of New Mexico staff, including the use of training provided for Los Alamos National Laboratory staff, as appropriate.

Mr. Thompson endorsed the commitment by Mr. Bangart to provide Mr. Garcia an NRC contact to discuss NRC training and qualifications criteria used for Agreement State and NRC materials program staff.

On-The-Job Training

Mr. Garcia explained that in addition to formal classroom training and procedure revisions, on-the-job training was important to assure staff were using and implementing the additional knowledge and revised program procedures and to modify the regulatory "culture" of the New Mexico staff. He cited a recent example of an inspector accompaniment that he converted to an on-the-job training session for the staff member. Ms. Howell noted that New Mexico inspectors have the opportunity to accompany NRC inspectors when inspections of Federal NRC licensees are conducted in New Mexico, such as at VA hospitals. Two week's notice by NRC to New Mexico will allow sufficient time for New Mexico planning. Mr. Garcia noted that he and Dr. Kelley would be involved in RCP program management oversight in the future. Ms. Howell encouraged New Mexico to contact Region IV for guidance on any RCP issue that NRC could provide useful information.

Commitment Summary: Secretary Weidler endorsed the commitments by Dr. Kelley and Mr. Garcia to more actively involve themselves in management oversight and involvement in the New Mexico Agreement State program to ensure its success.

Mr. Thompson endorsed Ms. Howell's commitment to notify New Mexico two weeks in advance of planned NRC inspections to be conducted at NRC Federal facility licensees in New Mexico. Region IV will attempt to provide notification to New Mexico as soon as possible in the event that a special, unplanned, inspection occurs.

Staffing

Vacancy announcements for the two vacant RCP positions have been posted and 19 applications were received. Based on the review of resumes of 6 applicants, it appears that at least one candidate with a strong background has applied. Mr. Floyd will obtain and review resumes of the other candidates. The New Mexico RCP will have to work further with State Office of Personnel to resolve discrepancies in the initial qualification ratings of the applicants. Mr. Floyd further indicated that staff members normally assigned to the x-ray program were being used in the materials program because of the current staffing shortfall. Secretary Weidler indicated his support for continued staffing of the New Mexico RCP at its current level.

Commitment Summary: Secretary Weidler, together with Dr. Kelley, Mr. Garcia, and Mr. Floyd, committed to proceed with the hiring of two new staff members to fill existing vacancies.

Response to Events

Mr. Floyd indicated that the State had responded to three events since the MRB meeting on October 23, 1997. The written description of two events was included as part of his December 3, 1997, submittal to the Management Review Board. A third event response was being documented at the time of the meeting and will be sent to NRC when the document is final. Mr. Floyd indicated he is currently developing criteria that will be used by the RCP to aid in the determination of when a response to an event is appropriate. Once those criteria are developed, NRC will likely be requested to conduct a review.

Commitment Summary: Secretary Weidler endorsed the commitment by Mr. Floyd to provide NRC a copy of the third event response report discussed during the meeting and a copy of the criteria being developed to provide guidance for determining when a response to an event is necessary.

Mr. Thompson committed that NRC's Office of State Programs will review the event response reports prepared by the New Mexico staff and provide comments to New Mexico about the adequacy of the reports.

Next Steps

NRC indicated that the MRB would be reconvened in the near future to make the final decision on whether to recommend to the Commission that the New Mexico program be placed on probation. The schedule for the upcoming meeting will be coordinated with Mr. Garcia and he and his staff were invited to participate via conference call. Mr. Garcia stated that realistic feedback from NRC was useful to the New Mexico RCP. NRC representatives stated it was likely that an IMPEP follow-up review would likely be scheduled next summer.

The meeting adjourned at approximately 10:30 a.m., Rocky Mountain Standard Time.

Attachments:

As stated

NRC/NEW MEXICO MEETING AGENDA

DECEMBER 4, 1997

I. NRC AND NEW MEXICO AGREEMENT STATE PROGRAM RESPONSIBILITIES PURSUANT TO ATOMIC ENERGY ACT OF 1954, AS AMENDED

- **NRC discontinues regulatory authority upon assumption by New Mexico. New Mexico's radiation control program must be adequate to protect public health and safety and compatible with NRC's regulatory program**
- **NRC must periodically review Agreements and actions taken by the State under the Agreements to assure adequacy and compatibility.**
- **New Mexico committed in the 1974 Agreement to use best efforts to cooperate with the Commission and other Agreement States for protection against hazards of radiation and to assure the State's program will continue to be compatible.**
- **The Commission may suspend or terminate all or part of the Agreement if required to protect public health and safety.**

II. OVERVIEW OF INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP)

- **Required periodic program review conducted using a performance-oriented, team approach.**
- **IMPEP developed jointly by NRC and Agreement States. Agreement State representatives are members of the IMPEP review team and liaisons to the Management Review Board.**
- **Team report submitted to Management Review Board for approval on individual performance indicators, overall determination of the adequacy and compatibility of the Agreement State program, and the timing for the next IMPEP review.**
- **Except for emergency suspension necessary to protect public health and safety, Commission approval required for Agreement State program probation, suspension, or termination.**
- **Strong IMPEP program direction from NRC Headquarters assures consistent IMPEP implementation in NRC Regions and Agreement States.**

III. SUMMARY OF NEW MEXICO IMPEP REVIEW FINDINGS AND THE SIGNIFICANCE OF PROBATION FOR AN AGREEMENT STATE PROGRAM

- Team recommended overall finding of "adequate to protect public public health and safety but needs improvement" and "compatible with NRC's program."
- Non-common indicator Legislation and Regulations found satisfactory. Sealed source and Device Evaluation Program responsibility being returned to NRC by Governor of New Mexico.
- Of five common indicators, Technical Quality of Licensing found satisfactory; Status of Materials Inspection Program and Technical Staffing and Training found satisfactory with recommendations for improvement; Technical Quality of Inspections found satisfactory with recommendations for improvement after significant discussion about the possibility for a finding of unsatisfactory;
- Response to common indicator, Response to Incidents and Allegations found unsatisfactory by team, but MRB cknowledged that revised procedues appeared satisfactory. If properly implemented, a finding of satisfactory with recommendations for improvement is appropriate. No incidents at time of MRB to demonstrate implementation.
- Twenty-one recommendations and eight suggestions made by IMPEP team.
- NRC examined the need for program suspension before New Mexico committed to respond to significant events.
- MRB identified need for discussions with New Mexico before acting on team's probation recommendation.
- Probation ia a consideration when deficiencies in IMPEP performance indicators are of such safety significance that assurance of the program's ability to protect public health and safety may be degraded and NRC heightened oversight is required.
- Governor notified; State develops corrective action management plan; timeframe for implementation of improvements agreed upon; heightened oversight through reports, meetings, and/or conference calls.
- Notice in Federal Register; letter to all States; press release; notification to appropriate Congressional committees and members of the State's Congressional delegation.
- NRC considers need for program suspension or termination if program improvements not realized.

IV. KEY ISSUES RELATED TO A PROBATION DECISION

A. LEVEL OF PROGRAM STAFFING AND AMOUNT OF RESOURCE SUPPORT

- **Two current vacancies.**
- **Commitments to respond to significant events and conduct reciprocity inspections place further demands on staff.**
- **Apparent funding shortfall for necessary training and travel that could benefit the New Mexico Agreement State program, such as training for current and new employees and attendance at the Annual All Agreement States meeting.**
- **Is lack of licensee fees a contributor to resource limitations?**

B. STAFF TECHNICAL EXPERTISE AND TRAINING NEEDS

- **Training needs identified for irradiator technology, brachytherapy, dose modeling, inspection procedures, and inspection techniques.**
- **Written training and qualifications plan recommended to assure adequate training of staff.**
- **New procedure training.**
- **Improved effectiveness of supervisory inspector accompaniments.**

C. LEVEL OF MANAGEMENT SUPPORT, INVOLVEMENT, AND OVERSIGHT OF AGREEMENT STATE PROGRAM ACTIVITIES

- **Likely most critical determining factor on probation decision.**
- **Higher standards for program performance necessary.**
- **Commitment and plan to strengthen program needed from management above first supervisory level.**
- **Identification of program operational issues for which upper management should be informed/consulted, such as safety significant events, licensing/inspection backlog status, and status of staff training/qualifications.**
- **Needs: Resource Support, Program Goals and Corresponding Performance Measures, Assessment and Feedback.**

- **Legislation need for adequate program funding?**

V. FUTURE ACTIONS

- **MRB will reconvene to establish final MRB decision on finding for indicator. Response to Incidents and Allegations, and the question of program probation. New Mexico representatives will be requested to participate by conference call.**
- **If probation recommended, the Commission must approve.**
- **Periodic progress reports, periodic conference calls, and a followup review within six months to one year likely.**

VI. SUMMARY AND CLOSING

NRC / NMED meeting 10/4/92
MRB / State RCP issues

Benito Z. Garcia	NMED/HRMB	505 827-1557
Hugh L. Thompson, Jr	NRC/DEDD	301-415-1713
Richard L. BANGART	NRC/OSP	(301) 415-3340
Linda Howell	NRC/RTI	(817) 860 8213
Geoffrey Sloan	NMED	(505) 827-2993
Ed Kelley	NMED/WWMO	(505) 827-2855
Bill Floyd	NMED/RLRS	(505) 827-1862
Mark Weidner	NMED	827-2855