

DATED: JAN 10, 1995;

SIGNED BY: RICHARD L. BANGART

Charles E. Danielson, M.D., M.P.H.
Director
Division of Public Health Services
6 Hazen Drive
Concord, NH 03301-6527

Dear Dr. Danielson:

This is to transmit the results of our review and evaluation of the New Hampshire radiation control program. This review, which concluded on August 19, 1994, was conducted in conjunction with the pilot Integrated Materials Performance Evaluation Program (IMPEP) in which common performance indicators were used to review NRC regional office and Agreement State programs. The review was conducted by a team of NRC reviewers led by Mr. Jack Hornor, Region IV, Agreement State Officer, Walnut Creek Field Office. This letter presents the results of the routine Agreement State review and should be considered as the findings of record for the review. The IMPEP pilot program review results will be presented in a separate document. Mr. Paul Lohaus, Deputy Director, Office of State Programs, Mr. William Kane, Deputy Regional Administrator, Region I, Mr. Craig Gordon, Region I State Agreements Officer, and the review team discussed the results of the review with Russell C. Jones, M.D., Acting Director, Division of Public Health Services and your staff on August 19, 1994.

As a result of our review of your program and the routine exchange of information between the NRC and the State, we believe that the New Hampshire program for regulating agreement materials is adequate to protect public health and safety. However, a finding that the program is compatible with the NRC's program is being withheld because the State has not adopted regulations equivalent to the following NRC regulations: "Emergency Planning Rule," 10 CFR Parts 30, 40 and 70 amendments (54 FR 14051) which was needed by April 7, 1993; "Standards for Protection Against Radiation," 10 CFR Part 20 amendment (56 FR 61352) which was needed by January 1, 1994; "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) which was needed by January 10, 1994; and "Notification of Incidents," 10 CFR Parts 30, 40 and 70 amendments (56 FR 64980) which was needed by October 15, 1994.

As you may be aware, New Hampshire's failure to maintain compatible regulations has been an ongoing problem. The NRC believes that regulations for the control of agreement material should be consistent throughout the regulatory community, and that the compatibility requirement is an important part of the Agreement State program. Therefore, we ask that you direct your attention to finding a method to accelerate the promulgation process. I would appreciate a response from you regarding this matter.

The review team found that New Hampshire statutes governing rulemaking and licensing are difficult to apply to complex, technical situations such as

controlling radioactive material. In our meeting with you, we discussed instances in which exemptions to these statutes had been granted to other State offices.

We were pleased to find that the overall quality of the radiation control program had improved significantly since the last review. The review team noted that the radiological health administrator and radioactive materials supervisor have made considerable progress in their efforts to provide the staff guidance and training necessary to establish an effective program.

Please note that the format of this letter differs from that used in our previous review letters. This letter summarizes the guideline provisions and submits our findings in all 30 program indicators as opposed to including only those indicators in which deficiencies were noted.

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

Enclosure 2 summarizes our review findings and recommendations for program indicators in which we believe improvements should be made. We request specific responses to these recommendations with your plans for corrective action. We ask that you respond within 30 days after you receive this letter; however, we recognize our delay in issuing this report. If you require more than 30 days, please advise us of the date we may expect your response.

Enclosure 3 summarizes our findings for indicators where the program satisfies the guideline provisions and there are no recommendations. A written response to the items in Enclosure 3 is not required.

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

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/encls: Diane Tefft
State Liaison Officer

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cc w/encls: Diane Tefft
State Liaison Officer

Distribution: See next page.

*See previous concurrence. **E-Mail.

OFC	WCFO	Region I	OSP:SPM	OSP:DD		
NME	JHornor	TMartin	KSchneider	PLohaus		
DTE	11/17/94*	11/30/94*	11/17/94*	11/20/94*		
OFC	NMSS:D	OGC	OSP:D	DEDS	EDO	
NME	RBernero	FCameron	RBangart	HLThompson	JMTaylor	
DTE	11/25/94*	12/1/94**	12/02/94*	12/07/94*	12/07/94*	

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Charles E. Danielson, M.D.

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TMartin, Region I
CGordon, RSAO, Region I
DChawaga, RSLO, Region I
JHornor, RSAO, RIV/WCFO
DCD (SPO1) PDR (Yes_X__ NO____)
New Hampshire File

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

The "Guidelines for NRC Review of Agreement State Radiation Control Programs" were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories. Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

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

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

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND RECOMMENDATIONS
FOR THE NEW HAMPSHIRE RADIATION CONTROL PROGRAM
FOR THE PERIOD JUNE 5, 1992, TO AUGUST 19, 1994

SCOPE OF REVIEW

The 22nd program review of the New Hampshire Agreement State program was held during the period of August 15-19, 1994, in Concord. The program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs. The State's program was reviewed against the 30 program indicators provided in the policy statement.

New Hampshire is one of three States that volunteered to participate in the pilot Integrated Materials Performance Evaluation Program (IMPEP) in which common performance indicators were used to evaluate both NRC regional offices and the Agreement State programs. This review of the radioactive materials portion of the State's program was conducted in conjunction with the IMPEP review. The IMPEP review report, addressing the common indicators, will be submitted separately.

The NRC review team leader was Jack Hornor, Region IV Agreement State Officer, Walnut Creek Field Office. Other team members were George Pangburn, Section Leader, and Scott Moore, Health Physicist, Office of Nuclear Material Safety and Safeguards.

The State was represented by Diane Tefft, Administrator, Bureau of Radiological Health, and Dennis O'Dowd, Supervisor, Radioactive Material Section.

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

A summary meeting to present the results of the review was held with Dr. Russell C. Jones, Acting Director, and Jack Stanton, Assistant Director, Division of Public Health Services, on August 19, 1994.

CONCLUSION

The program for control of agreement materials is adequate to protect the public health and safety. However, a finding of compatibility is being withheld because the State has not adopted regulations equivalent to the NRC amendments to 10 CFR Parts 30, 40 and 70, "Emergency Planning Rule;" 10 CFR Part 20 "Standards for Protection Against Radiation;" 10 CFR Part 34 amendment, "Requirements for Radiographic Equipment;" and "Notification of Incidents," 10 CFR Parts 30, 40 and 70 amendments (56 FR 64980).

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The findings of the June 1992 review, which resulted in a decision to withhold adequacy and compatibility, were reported to the State in a letter to Dr. Patrick Meehan, Director, Division of Public Health Services, dated August 27, 1992. A follow-up review was conducted during the week ending

July 1, 1993, and the results transmitted to Dr. Meehan on February 9, 1994. At that time, the staff offered a finding of adequacy, but continued to withhold a finding of compatibility. The issues remaining unresolved following the July 1993 review are as follows:

1. Status and Compatibility of Regulations (Category I)

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

Comment from the July 1993 Follow-Up Review

The State has not adopted equivalent regulations to the NRC's "Decommissioning Rule," 10 CFR Parts 30, 40, and 70 amendments needed by July 27, 1991, and the "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70 amendments (54 FR 14051) needed by April 7, 1993. Both rules are items of compatibility.

Recommendation from the July 1993 Follow-Up Review

We recommend that the Bureau of Radiological Health (BRH) expedite the rulemaking process for the overdue regulations and continue in its efforts to adopt the other regulations needed for compatibility.

Current Status

The State's equivalent decommissioning rule was adopted and became effective on December 20, 1993. The equivalent rule for emergency planning is in draft form with an adoption target date of June 1995.

Since the 1993 review, three additional compatibility amendments have become overdue. "Standards for Protection Against Radiation," 10 CFR Part 20 amendment (56 FR 61352) was needed by January 1, 1994, "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) was needed by January 10, 1994, and "Notification of Incidents," 10 CFR Parts 30, 40 and 70 amendments (56 FR 64980) was needed by October 15, 1994. The State's equivalent rule to the 10 CFR Part 20 amendment was submitted for adoption on January 1, 1993, and is in the sixth round of responses to objections by the State Administrative Rules Committee. The equivalent rule for safety requirements for industrial radiographers is in draft form with an adoption target date of June 1995.

Maintaining compatible regulations continues to be a problem in New Hampshire and is discussed at length in our current recommendations.

2. Enforcement Procedures (Category I)

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

Comment from the July 1993 Follow-Up Review

Although the State had passed legislation authorizing the BRH to assess civil penalties and establish severity levels for enforcement actions, specific regulations must be adopted to implement this authority. At the time of the 1992 review, the State had not finalized their escalated enforcement procedures nor enacted the civil penalty rule, and we recommended the necessary rules be adopted. During the 1993 review, it was found the enforcement rule, policies, and procedures were not completed, but were to be finalized in 1994.

Recommendation from the July 1993 Follow-Up Review

We recommend that the State notify us when the enforcement rule, policies and procedures are adopted. In addition, the State should also notify us of any delays in the adoption process.

Current Status

The BRH has not yet produced a final version of their escalated enforcement procedures, nor have they submitted the regulations necessary to enact severity levels and civil penalties. This problem is addressed in our current recommendations.

3. Budget (Category II)

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

Comment from the July 1993 Follow-Up Review

The New Hampshire fees rule, which includes fee increases, received legal department approval and is in the final stages of adoption. The new fees will enable the department budget to cover the cost of new staff.

Recommendation from the July 1993 Follow-Up Review

We request that the State notify us when the fees rule is adopted.

Current Status

The fees rule became final on August 31, 1993, and funding now appears to be adequate to support program needs.

CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 23 of these indicators. Recommendations were made on the seven indicators discussed below. The remaining 23 indicators are discussed in Enclosure 3. A questionnaire containing the 30 indicators with specific questions pertaining to each indicator was sent to the State prior to the review.

The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, review of the State's written procedures and policies, discussions with program managers and staff members, review team observations, licensing and inspection casework file reviews. Specific assessments and recommendations are as follows:

1. Status and Compatibility of Regulations (Category I)

NRC Guidelines

The State must have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards, effluent limits, waste manifest rule and certain other parts), Part 61 (technical definitions and requirements, performance objectives, financial assurances) and those required by the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), as implemented by Part 40. The State should adopt regulations to maintain a high degree of

uniformity with NRC regulations. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable but no later than 3 years. The radiation control program (RCP) should have established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC. Opportunity should be provided for the public to comment on proposed regulation changes. (Required by UMTRCA for uranium mill regulation.) Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

Assessment

The New Hampshire regulations were compared with the latest chronology of NRC regulation amendments that are needed for compatibility. The State's regulations are compatible through the "Decommissioning Rule." As explained in the previous section, the State has not adopted rules equivalent to the following NRC rules: "Emergency Planning Rule," which was needed by April 7, 1993, "Standards for Protection Against Radiation," which was needed by January 1, 1994, "Safety Requirements for Radiographic Equipment," which was needed by January 10, 1994, and "Notification of Incidents," which was needed by October 15, 1994.

The New Hampshire program historically has been unable to promulgate regulations compatible with those of the NRC within the three-year timeframe. In an effort to determine the reasons for the ongoing problem and to explore possible solutions, the NRC team examined the State's rule prescribing the rulemaking procedures, reviewed action dates for rules currently in the promulgation process, reviewed the BRH's responses to the latest objections offered by the rules committee pertaining to the State's equivalent rule to the new Part 20, and held detailed interviews with management and staff of the Division of Public Health Services.

The team believes the primary reason for the delays can be traced to the State's rules dictating the rulemaking process. The "New Hampshire Rulemaking Manual" (Ls-A 2-93), published by the Division of Administrative Rules of the Office of Legislative Services, must be followed by any State agency writing rules. Thus, the same administrative rules designed for issuing driver's licenses, fishing licenses, etc., apply to the rules governing licenses issued for the use of radioactive materials. These rulemaking rules are so restrictive that they do not lend themselves well to complex, scientific licensing activities. For example:

- Each rule expires exactly six years after it is enacted and must be resubmitted in its entirety to remain in effect.
- Any guidance or directives, such as license conditions, regulatory guides, inspection priorities, fee schedules, and severity levels for enforcement actions, must be published in the form of rules. These rules also must be resubmitted every six years.
- Rules cannot include footnotes, appendices, or anything explanatory. Formulas must be written in such a manner that including a complex formula is not possible. Tables must be simple and numbered sequentially throughout the chapter (the entire radiation volume) which essentially requires that tables be renumbered at each additional rule change.

- The six-year sunset clause, in effect, prevents the certainty of long term control of radioactive materials and precludes the State from establishing permanent record-retention requirements.

The promulgation process makes rulemaking extremely labor intensive. Each rule (new or soon to expire under the sunset rule) is drafted by the BRH and submitted to the Division's legal coordinator. After the wording satisfies that office and the financial impact statement is prepared by the Legislative Budget Assistant, objections raised during a public hearing are resolved. Only after an amended financial impact statement is issued is the rule submitted as a proposal to the Joint Legislative Committee on Administrative Rules. The Committee then presents their objections which must be resolved before the rule is adopted. To illustrate the problem, after the initial filing, 18 rounds of comments, hearings and responses were required to adopt the decommissioning rule. So far, the legal coordinator has taken 11 months to process the initial review necessary to amend the equivalent regulations to the new Part 20.

The radiation control program is not the only agency in New Hampshire that must license complex, technical activities. In examining methods used by the State to control such activities, it was found that, when justified, agencies may be granted exemptions from the administrative rulemaking procedures. The Department of Transportation, for example, has been granted exceptions in order to regulate highway and bridge construction. In fact, precedent has been established within the Department of Health and Human Services, where the Division of Human Services has been granted an exemption from this procedure.

Recommendations

We recommend the Division take steps to accelerate the promulgation process. One mechanism that could be considered is proposing legislation to exempt the radiation control program from the administrative rulemaking procedures.

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

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992, and will need to be adopted by January 27, 1995.
- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) that became effective on July 31, 1993, and will need to be adopted by July 31, 1996.
- "Licensing Requirements for Land Disposal of Radioactive Waste," 10 CFR Part 61 amendment (58 FR 33886) that became effective on July 22, 1993, and will need to be adopted by July 22, 1996.
- "Decommissioning Recordkeeping, and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993, and will need to be adopted by October 25, 1996.
- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70, amendments (58 FR 68726) that became effective on January 28, 1994, and will need to be adopted by January 28, 1997.

2. Legal Assistance (Category II)

NRC Guidelines

Legal staff should be assigned to assist the RCP or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP, statutes, and regulations.

Assessment

Availability of legal assistance is a problem for the BRH. The small size of the radioactive materials program within the overall structure of State government makes it difficult to obtain attention from the Attorney General's Office on routine legal matters. Requests for legal assistance from the Attorney General are sent through the Legal Coordinator in the Division of Public Health. Because of the number of requests for legal review sent to this individual from the BRH, as well as other Offices within the Division, prompt legal assistance has been problematic. Cases in point include review of Part 20 equivalent regulations (approximately 11 months for legal review) as well as review of well-logging regulations (also 11 months for legal review).

Recommendation

The review team recommends that the Division of Public Health take appropriate steps to assure that the radiation control program has prompt legal assistance available when needed.

3. Inspection Frequency (Category I)

NRC Guidelines

The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations, e.g., major processors, broad licensees, and industrial radiographers should be inspected approximately annually -- smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency including for initial inspections should be no less than the NRC system.

Assessment

The review team compared the State's inspection frequencies with those of the NRC. The BRH licenses are placed into one of three inspection priorities: I (every year), II (every 2 years) and III (every 4 years). In general, the assignment of those priorities to the various classes of licenses results in inspection frequencies which are the same or more frequent than NRC's. However, the team noted two departures from this general observation.

NRC procedures require that new licenses in priorities I-V be inspected within 6 months of license issuance. BRH inspects new licenses at 4 months, 8 months or 12 months after license issuance for licenses in priorities I, II and III, respectively. Although this results in a shorter interval for those licenses in priority I; however, for a relatively small number of the State's license population, new licenses in priorities II and III, the initial inspection interval is longer than the NRC's.

Secondly, the State's inspection frequency for fixed site radiography as listed in their inspection procedures calls for inspections every 2 years,

whereas the NRC Inspection Manual Chapter 2800 requires that fixed site radiographers be inspected annually. BRH has only one fixed-site radiographer, however, and its inspection frequency as listed in the licensing data base is yearly.

Recommendations

- (a) The review team recommends that BRH revise its inspection priorities for initial inspections of new licenses to be no less frequent than the NRC's.
- (b) The review team recommends that BRH revise the inspection priority for fixed site radiographers to conform to their current practice of annual inspections.

4. Enforcement Procedures (Category I)

NRC Guidelines

Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended. Enforcement letters should be issued within 30 days following inspections and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated. Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent recurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses.

Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items. Written procedures should exist for handling escalated enforcement cases of varying degrees. Impounding of material should be in accordance with State administrative procedures. Opportunity for hearings should be provided to assure impartial administration of the RCP.

Assessment

The BRH uses the 1990 draft procedures, which are modeled after Appendix C of 10 CFR Part 2, to guide the enforcement process. However, as noted in the previous section, the Division must publish regulations to implement the authority to assess civil penalties and establish severity levels for enforcement actions.

Review of a sample of 13 inspection cases where notices of violation were issued to licensees indicated that most enforcement letters (10 of 13) were issued within 30 days of the inspection. In two cases, the letters were one and two months late, respectively. Review of a third case indicated that the enforcement letter for an inspection conducted on August 31, 1993, had not been issued as of the date of the review. This matter was discussed with the materials section supervisor who indicated that it would be issued promptly.

Enforcement letters were clear with respect to violations and uniformly cited the license condition or regulation being violated, as well as both the actions required and the timeframe for the licensee to respond. Licensee responses were promptly reviewed by the inspector, using a standard form that

is reviewed by the section supervisor, and promptly acknowledged in writing to the licensee.

Recommendation

BRH plans to submit a rule package to the legal coordinator in late 1994 which contains changes to its radioactive materials regulations to bring these into conformity with the revised Part 20 equivalent regulations. We recommend that BRH consider including the revised inspection and enforcement procedures, with the provisions for severity levels and civil penalties, as part of that package, rather than waiting to submit the rule separately.

5. Inspection Procedures (Category II)

NRC Guidelines

Inspection guides, consistent with current NRC guidance, should be used by inspectors to assure uniform and complete inspection practices and provide technical guidance in the inspection of licensed programs. NRC Guides may be used if properly supplemented by policy memoranda, agency interpretations, etc. Written inspection policies should be issued to establish a policy for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, interviewing workers and observing operations, assuring exit interviews with management, and issuing appropriate notification of violations of health and safety problems. Procedures should be established for maintaining licensees compliance histories. Oral briefing of supervisors or the senior inspector should be performed upon return from nonroutine inspections. For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Assessment

The review team determined through discussions with staff, review of New Hampshire's compliance manual, and a review of the inspection files that BRH has inspection procedures in place and that inspectors are following the guidance in those procedures. However, a review of the general procedures found that they do not cover some elements inherent to the inspection program, including exit interviews at the conclusion of an inspection and oral debriefings with the inspection supervisor following a non-routine inspection. In addition, the chapters of the compliance manual covering specific types of licensees need to be updated to conform with recent New Hampshire rule changes. Although the actual inspections did not demonstrate problems in these areas, the review team believes that the inspection procedures should be revised to include all essential elements of the inspection and updated to conform to recent State regulations.

Although exit interviews are not covered in the procedures, the review team determined that materials inspectors were attempting to hold exit meetings at the conclusion of an inspection with the highest level of licensee management available. The review team also determined through interviews with the inspectors that oral debriefings are held informally with the section supervisor after the inspector returns from an inspection trip.

While reviewing the inspection reports, the review team found that several different versions of inspection forms (field notes) had been used over the review period. Although different inspection forms are appropriately used for different types of licensees, BRH also had several different sets of inspection forms for the same or similar type licensees. In addition, the

review team noted that some sets of inspection forms are missing sections that should have been inspected. For instance, a medical licensee inspection report had no indication on the inspection forms that the licensee's postings and leak tests were inspected. These areas were omitted from the inspection forms. Interviews with inspectors and the section supervisor revealed that BRH has been updating their inspection forms, which led to the different sets of inspection forms over the review period.

The team also examined the BRH's actions pertaining to conducting field inspections of radiographers and performing reciprocity inspections. The team found New Hampshire has only one industrial radiographer authorized for temporary job sites, and according to the staff, most of his work is done out-of-State. During review of the inspection files, it was noted that, although the inspector was unsuccessful in several attempts to conduct a field inspection, BRH made a reasonable effort to perform a field inspection of this licensee.

Recommendations

- (a) We recommend that BRH update the general procedures in the compliance manual to include such issues as exit meetings and oral debriefings with the inspection supervisor following non-routine inspections. We also recommend that BRH review and update, as necessary, the compliance manual chapters for each major category of licensee to conform to the New Hampshire regulations.
- (b) We recommend that BRH review, update, and standardize the inspection forms used for different categories of licensees.

6. Inspection Reports (Category II)

NRC Guidelines

Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of licensees' programs, and indicating the substance of discussions with licensee's management and licensee's response. Reports should uniformly and adequately document the results of inspections and identify areas of the licensee's program which should receive special attention at the next inspection. Reports should show the status of previous noncompliance and the independent physical measurements made by the inspector.

Assessment

Nine inspection reports were selected for the casework review, including reports by all four materials inspectors. The cases reviewed consisted of licenses in the following categories: teletherapy, specific medical (diagnostic and limited therapy), in-vitro laboratory, irradiator, industrial radiography (temporary job sites), survey instrument calibration, and portable gauges. The review team found that the inspection reports were generally well documented. Seven of the reports consisted of the inspectors' written comments on inspection forms. The remaining two reports were narrative, typed reports.

Documentation of independent measurements made by the inspectors was included in most of the reports. However, the review team found that in six of the nine cases reviewed, the report was missing information or only had partial information on the survey instrument used by the inspector to perform

independent and confirmatory measurements. Specifically, the model, serial number, and calibration date were missing in whole or in part on the six reports.

BRH regarded both narrative reports as describing routine inspections. Actually, one inspection of a portable gauge licensee was a special inspection in follow-up to a series of telephone calls associated with the licensee. The inspection closed some special issues, in addition to reviewing the licensee's routine radiation safety program. The other narrative report was for an initial inspection of New Hampshire's only large, dry-storage irradiator. Both narrative reports were intended to cover the full inspections, and in general, narrative reports are acceptable for these types of inspections. However, the review team noted that these two narrative reports did not include the full range of issues that would have been documented on the inspection forms. If narrative reports are to be used for routine inspections, the team recommends that the narrative report cover each of the items covered in the inspection forms. For special inspections, the narrative report need not be so comprehensive.

The review team observed that BRH has developed a form that is used by inspectors to evaluate licensee responses to notices of violations (NOVs). The inspector's review of the licensee's response, as evidenced by these forms, appears to be quite thorough. The review team noted that of the nine inspection cases reviewed, BRH requested further follow-up, beyond the initial NOV response, in two cases. This demonstrates that New Hampshire is effectively reviewing licensee responses to NOVs, and when the licensee's first response is not sufficient, BRH requests an additional response to resolve the outstanding issue.

Of the nine inspection reports reviewed, the section supervisor had signed off on seven reports, six in advance of dispatching the inspection results and one afterwards. Of the remaining two cases, the section supervisor was a co-signer on one of the reports, and in the last case, the report had not yet been issued. The review team noticed a healthy dialogue between the section supervisor and inspection staff, as evidenced by the section supervisor's handwritten notes on the inspection reports. The review team determined that the section supervisor is performing a thorough review of inspection reports.

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

Recommendations

- (a) We recommend that information on the inspector's radiation detection equipment (such as model, serial number, and calibration date) be included in each inspection report.
- (b) We recommend that narrative reports for routine inspections be more comprehensive. If the inspection is routine, the narrative report should cover, as a minimum, all of the subjects that would have been addressed in the inspection forms.

7. Confirmatory Measurements (Category II)

NRC Guidelines

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

- GM Survey Meter: 0-50 mr/hr
- Ion Chamber Survey Meter: up to several R/hr
- Neutron Survey Meter: Fast & Thermal
- Alpha Survey Meter: 0-100,000 c/m
- Air Samplers: Hi and Low Volume
- Lab Counters: Detect 0.001 μ Ci/wipe
- Velometers
- Smoke Tubes
- Lapel Air Samplers

Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities should not be used unless under a service contract. Exceptions for other State agencies, e.g., a State University, may be made. Agency instruments should be calibrated at intervals not greater than that required of licensees being inspected.

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

Assessment

The inspection reports were reviewed for documentation concerning confirmatory measurements and independent measurements. The review team determined that inspectors were performing sufficient independent measurements and, in most cases, documenting them in the inspection reports.

The review team discussed the equipment calibration procedures with the laboratory staff, and found that New Hampshire sends their radiation detection equipment to the State of South Carolina for calibration. The review team examined the documentation that South Carolina returns with the calibrated survey meters and found that the survey meters were being calibrated adequately. The review team also discussed the frequency of calibration with the laboratory scientist and determined that she has instituted a program to rotate the radiation detection equipment for calibration, so that instruments calibrated within the last quarter should always be available for the inspection staff. The review team also checked the latest inspection of New Hampshire's only temporary job site radiographer and found that the survey instrument used on that inspection had been calibrated within the quarter. This meets the guideline in the 1992 Policy Statement on Agreement State

Programs (57 FR 22495) that State instruments should be calibrated within the same time interval as required of the licensee being inspected.

The review team compared the list of equipment that BRH has with the list of instrumentation given in the guidelines. The review team determined that New Hampshire does not have or use a velometer, an instrument that measures air velocity. Such an instrument is needed for inspections of licensees that use airborne radioactive material to determine whether fume hoods are functioning correctly and whether areas of use are at negative pressure.

During the inspection accompaniment and in discussions with inspectors, the review team determined that inspectors do not use standard check source readings for response checks on their radiation detection instruments, although standard sources are available. During the accompaniment, the inspector said that he had checked the instrument for operability against a known "hot spot" on BRH's calibration source, and another inspector indicated that he knew of this practice. However, from a health physics perspective, it is preferable to compare the instrument's reading with a known reading from standard check source in a given geometry prior to each use.

Recommendations

- (a) We recommend that BRH acquire a velometer and use it, when appropriate, on inspections of licensees who have airborne radioactive material.
- (b) We recommend that BRH perform instrument response checks against known reference check sources on radiation detection equipment used on inspections.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

On Friday, August 19, 1994, Paul Lohaus, Deputy Director, Office of State Programs, William Kane, Deputy Regional Administrator, Region I, Craig Gordon, State Agreements Officer, Region I, and the review team met with Dr. Jones and his staff to present the results of the review.

The New Hampshire representatives were advised that, although the final determination of adequacy and compatibility of an Agreement State program would be made following NRC management review, the review team recommended a finding of adequacy and a withholding of the finding of compatibility because of the State's failure to maintain compatible regulations.

The State was informed that their program fully satisfies 23 of the 30 indicators, and our recommendations for the remaining seven indicators were presented and discussed. With the exceptions of the Status and Compatibility of Regulations and Legal Support indicators, the findings resulting in our recommendations were not considered to be significant.

The NRC representatives thanked the State for participating in the IMPEP pilot program. The common performance indicators concept and the IMPEP review process were explained, and the differences between the Office of State Programs and IMPEP reviews were discussed.

The State was commended for the improvements found in the program. Ms. Tefft and Mr. O'Dowd were recognized for their accomplishments.

The lack of satisfactory legal support was discussed, and the problem of maintaining compatible regulations was discussed at length. Dr. Jones was asked to find a solution to the ongoing compatibility problem.

Ms. Tefft pointed out that because of the labor involved in composing regulations, the BRH does not begin to draft regulations until the Suggested State Regulations (SSR) are available. Since these are frequently issued some time after the NRC regulation is published, this practice further delays the rulemaking process. She asked for the NRC's help in shortening the interval between the times the regulations are published and the SSRs are made available. The team recommended she use Title 10 changes to draft compatible State regulations in those cases where the SSR changes are not available in a timely manner.

In response to our comments, Dr. Jones acknowledged that the New Hampshire statutes governing rulemaking and licensing are difficult to apply to complex, technical situations such as licensing the use of radioactive material. He also questioned the need for the many new NRC regulations.

In conclusion, he thanked the NRC team and expressed his commitment to support the Agreement State program.

SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED
BY THE NEW HAMPSHIRE RADIATION CONTROL PROGRAM
FOR THE PERIOD JUNE 5, 1992, TO AUGUST 19, 1994

The assessments below are based upon information provided in the State's written response to the NRC questionnaire mailed to the State in advance of the review meeting, review of the State's written procedures and policies, comparison with previous review information, discussions with program managers and staff members, review team observations, licensing and compliance casework file reviews, and inspector accompaniments. The State fully satisfies the following indicators:

1. Legal Authority (Category I)

NRC Guidelines

Clear statutory authority should exist, designating a State radiation control agency and providing for promulgation of regulations, licensing, inspection and enforcement. States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA. States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulations for low-level radioactive waste management and disposal. The statutes should also provide regulatory program authority and provide for a system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur.

Assessment

The Division of Public Health Services is authorized as the State radiation control agency under New Hampshire Revised Statutes Annotated (RSA) 1990, Chapter 125. RSA 125-F:1 to F:25 covers radioactive material; RSA 125:77-b covers radioactive waste; and RSA 125-B covers emergency response. This is unchanged from the last review. The radiation control program (RCP) is administered by the Bureau of Radiological Health (BRH), and the BRH Administrator is the radiation control program director. However, the implementation of the procedures for regulations restricts the ability of the staff to write complex regulations. A recommendation for legislative exemption to a portion of these procedures was made in Enclosure 2 regarding the Status and Compatibility of Regulations.

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

NRC Guidelines

The RCP should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management. Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Assessment

The BRH is located within the Office of Environmental Health and Hazard Assessment which is part of the Division of Public Health Services (DPHS) in the New Hampshire Department of Health and Human Services. BRH is a small

program with only 99 licenses, but through the management chain, it has access to the Commissioner, Health and Human Services, who is appointed by and reports to the Governor.

3. Internal Organization of the RCP (Category II)

NRC Guidelines

The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy. Where regional offices or other government agencies are utilized, the lines of communication and administrative control between these offices and the central office (Program Director) should be clearly drawn to provide uniformity in licensing and inspection policies, procedures and supervision.

Assessment

The BRH is subdivided into five sections: Radioactive Materials, Radiation Machines, Radon, Radiochemistry and Emergency Response. Each section supervisor reports directly to the BRH administrator. Personnel in Radioactive Materials and Radiation Machines exchange duties on a monthly basis; i.e., a health physicist will do radioactive material licensing and inspection for a month, shift over to do x-ray registration and inspection for a month, and then return to radioactive materials. This assures that staff are up to date in these major program areas and minimizes the potential impact of any staff departures, which can be critical in such a small program.

4. Technical Advisory Committees (Category II)

NRC Guidelines

Technical Committees, Federal agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems. A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The committee should represent a wide spectrum of medical disciplines. The committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans. Procedures should be developed to avoid conflict of interest, even though committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

Assessment

The State has a Radiation Advisory Committee which meets quarterly. The Committee was created by statute (RSA 125-F:6) with members representing a broad cross-section of interests. The BRH administrator serves as Technical Secretary to the Committee and prepares agendas and minutes of their meetings. A review of the minutes for the past year indicated that the Committee discussed a wide range of topics, such as BRH's development of Part 20 equivalent regulations, the BRH budget for FY95 and New Hampshire's status regarding low-level radioactive waste management. The Committee also provided assistance in the evaluation of adequacy of training and experience for a proposed authorized user physician amendment request for a medical use license. In addition, members of the Committee serve as resource persons for BRH on technical matters within their individual areas of expertise.

5. Contractual Assistance (Category II)

NRC Guidelines

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

Assessment

Not applicable.

6. Quality of Emergency Planning (Category I)

NRC Guidelines

The State RCP should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc. The plan should define the responsibilities and actions to be taken by State agencies. The plan should be specific as to persons responsible for initiating response actions, conducting operations and cleanup. Emergency communication procedures should be adequately established with appropriate local, county and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the plan while in draft form. The plan should be reviewed annually by Program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

Assessment

The Division published a revised emergency response plan, "DPHS Initiator Handbook," on June 15, 1994. In reviewing this document it was noted that the Handbook is designed to be used for response to incidents involving radioactive materials and at nuclear reactors. The radioactive materials section is sufficient to provide guidance for responding to incidents involving radioactive materials, including transportation incidents. Control copies and current call-down lists are distributed periodically to all appropriate persons or agencies. The State provides a 24-hour emergency number for anyone to use to report emergencies involving hazardous materials. BRH furnishes the communications center with a call list in the event a radiological emergency is suspected. This list, last updated on June 9, 1994, instructs the communications center to call down the list in order. The list begins with the BRH administrator and continues with the section supervisors, followed by the staff health physicists. It was determined through interviews that BRH personnel qualified as responders are given refresher training.

The materials section supervisor and an emergency planner demonstrated their ability to respond appropriately to radiation emergencies in a table-top scenario presented by the review team.

It was observed that adequate communications, survey and laboratory equipment are available within the Division to respond to emergencies.

7. Budget (Category II)

NRC Guidelines

Operating funds should be sufficient to support program needs such as staff travel necessary to conduct an effective compliance program, including routine inspections, follow-up or special inspections (including pre-licensing visits) and responses to incidents and other emergencies, instrumentation and other equipment to support the RCP, administrative costs in operating the program including rental charges, printing costs, laboratory services, computer and/or word processing support, preparation of correspondence, office equipment, hearing costs, etc. as appropriate. States regulating the disposal of low-level radioactive waste facilities should have adequate budgetary resources to allow for changes in funding needs during the low-level radioactive waste facility life cycle. After appropriations, the sources of program funding should be stable and protected from competition from or invasion by other State programs. Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

Assessment

Funding is sufficient to support the radioactive materials program. The total budget for this fiscal year for the BRH is \$959,982 and the radioactive materials program was allocated \$235,984 of this budget; this figure does not include the management and administrative aspects of the program. The radioactive materials program received \$35,000 from radioactive materials fees. The radioactive materials program (not including x-ray) is 14 percent funded by fees.

8. Laboratory Support (Category II)

NRC Guidelines

The RCP should have the laboratory support capability in-house, or readily available through established procedures, to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, etc., on a priority established by the RCP. In addition, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have access to laboratory support for radiological and non-radiological analyses associated with the licensing and regulation of low-level radioactive waste disposal, including soils testing, testing of environmental media, testing of engineering properties of waste packages and waste forms, and testing of other engineering materials used in the disposal of low-level radioactive waste. Access to laboratory support should be available on an "as needed" basis for nonradiological analyses to confirm licensees' and applicants' programs and conditions for nonradiological testing should be prescribed in plans or procedures.

Assessment

The BRH has its own laboratory which provides support to Radioactive Materials and three other sections. The laboratory recently added a full-time staff member to provide support to the radioactive materials program. The addition of this trained radiochemist has resulted in significant improvements in the radioactive materials program.

The radiochemistry laboratory is able to analyze environmental samples of many types, including air, milk, water, soil and vegetation samples. Inspectors'

wipe samples are also evaluated by the laboratory, and the new laboratory scientist has assisted radioactive materials inspectors in conducting surveys at licensees' facilities. Interviews with inspectors and with the laboratory scientist revealed that the laboratory is able to analyze inspectors' samples quickly, when needed. Inspection staff is satisfied with both the quality and speed of results from the laboratory. BRH indicated in response to the questionnaire that there have been no problems in obtaining timely and accurate results.

9. Administrative Procedures (Category II)

NRC Guidelines

The RCP should establish written internal procedures to assure that the staff performs its duties as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies, decommissioning and license termination, fee collection, contacts with communication media, conflict of interest policies for employees, exchange of information and other functions required of the program. Administrative procedures are in addition to the technical procedures utilized in licensing, and inspection and enforcement.

Assessment

The internal procedures were reviewed and discussed with the materials section supervisor. Specifically, the review team examined procedures for receipt and control of licensing requests; licensing data base entry; standard licensing letters; standard enforcement letters and control of fees. Inspection procedures and licensing procedures were reviewed separately and are addressed elsewhere in this report. As a result of our review, the procedures were determined to be adequate to assure that the staff performs the duties required and to provide uniformity and continuity in regulatory practices. BRH prepared a complete package of administrative and technical procedures for the review team. The package has been forwarded to the Region I State Agreements Officer for retention in his file.

10. Management (Category II)

NRC Guidelines

Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquiries, regulation revisions). RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services and fundings. Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, low-level radioactive waste disposal facilities, large scope-Type A Broad, and those which have the potential for significant releases to the environment) should receive second party review (supervisory, committee, consultant). Supervisory review of inspections, reports and enforcement actions should also be performed. For the implementation of very complex licensing actions, such as initial license review, license renewals and licensing actions associated with a low-level radioactive waste disposal facility, there should be an overall Project Manager responsible for the coordination and compilation of the diverse technical reviews necessary for the completion of the licensing action. The Project Manager should have training or experience in one or more of the main disciplines related to the

technical reviews which the Project Manager will be coordinating such as health physics, engineering, earth science or environmental science. When regional offices or other government agencies are utilized, program management should conduct periodic audits of these offices.

Assessment

There is a high degree of informal interaction between staff and program management which is appropriate given the small size of the program. Interviews with the staff indicate that they frequently discuss ongoing work with the section supervisor and receive appropriate oral and written feedback on their work. Licensing actions are assigned by management taking into account the experience and training of the individual reviewers. Inspectors sign up for inspections scheduled to be done during that calendar quarter and are approved by the supervisor. The supervisor reviews all licensing cases and inspection enforcement actions; the review team confirmed documentation of such. In addition, the BRH administrator signs all completed licenses, thereby providing a second level of review. The section supervisor and BRH administrator meet frequently to discuss overall workload, status of cases, and aspects of specific cases, as warranted.

11. Office Equipment and Support Services (Category II)

NRC Guidelines

The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to larger (300-400 licenses) programs. Similar services should be available to regional offices, if utilized. States should have a license document management system that is capable of organizing the volume and diversity of materials associated with licensing and inspection of radioactive materials. Professional staff should not be used for fee collection and other clerical duties.

Assessment

Secretarial and clerical support for the BRH appear to be adequate. All technical staff have personal computers which are on a LAN (local area network). At the time of the review, the LAN was in the process of being upgraded. Licensing actions are controlled by a license management system which is capable of providing management with routine reports on the status of the licensing program. The materials section supervisor also plans to develop a computer data base to improve inspection tracking with implementation scheduled for mid-1995.

12. Public Information (Category II)

NRC Guidelines

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

Assessment

The BRH is required to comply with the State's Right-to-Know Act, as are all State agencies. Under implementing regulations contained in He-P 2002, agency records are available for public inspection and copying. Handwritten notes, draft material, proprietary, confidential and personal or medical information are exempt from public review.

13. Qualifications of Technical Staff (Category II)

NRC Guidelines

Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel including the director of the radiation protection program should be commensurate with the type of licenses issued and inspected by the State. For States regulating uranium mills and mill tailings, staff training and experience should also include hydrology, geology, and structural engineering. For programs which regulate the disposal of low-level radioactive waste in permanent facilities, staff training and experience should include civil or mechanical engineering, geology, hydrology, and other earth science, and environmental science. In both types of materials, staff training and experience guidelines apply to available contractors and resources in State agencies other than the RCP. Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Assessment

All technical staff have at least a Bachelor's degree in the physical or life sciences and have taken the NRC 5-week Applied Health Physics course. Position descriptions exist for all positions and are appropriate for the duties required.

14. Staffing Level (Category II)

Professional staffing level should be approximately 1-1.5 person-year per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel. For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years of effort, including consultants, are needed to process a new mill license (including in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978. States which regulate the disposal of low-level radioactive waste in permanent disposal facilities should allow a baseline RCP staff effort of 3-4 professional technical person-years (in addition to the two professionals for the basic RCP indicated in the first sentence of this indicator). However, in some cases, the level of site activity may be such that a lower level is adequate, particularly if contractor support is on call. In any event, staff resources should be adequate to conduct inspections on a routine basis during operations of the low-level radioactive waste facility, including inspection of incoming shipments and licensee site activities and to respond to emergencies associated with the site. During periods of peak activity additional staff or specialty consultants should be available on a timely basis.

Assessment

The BRH has four Level I health physicists who apply 0.35 FTE each to the radioactive materials program as well as one supervisor (Level II health physicist) who applies 0.9 FTE for a total of 2.3 FTE. Given the total license population of 99, BRH meets the criterion of 1-1.5 person-year per 100 licenses. The number of staff appears to be adequate to cover routine and most non-routine demands of the program.

15. Staff Supervision (Category II)

NRC Guidelines

Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel. Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy. Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Assessment

As noted above in the guideline on Management, the section supervisor assigns all licensing casework and reviews all outgoing licensing casework and inspection reports. Newer staff are limited to less complex license reviews and inspections which are within their training and experience. Interviews with technical staff and review of files confirmed that the section supervisor provides both formal and informal feedback to reviewers and inspectors to assure the quality of final products.

16. Training (Category II)

NRC Guidelines

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

Assessment

As noted above, all technical personnel have taken the NRC's 5-week Health Physics Course presented at the Oak Ridge National Laboratory. Staff are in various stages of completion of NRC core courses and have taken a variety of courses outside of the core courses including Radiological Emergency Response Operation training, Transportation, and Part 20 training. Review of the courses taken and discussions with staff and management demonstrated a strong management commitment to training and development of staff.

17. Staff Continuity (Category II)

NRC Guidelines

Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional

qualifications. Salaries should be comparable to similar employment in the geographical area. The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

Assessment

Staff turnover has been minimal during the review period; in fact the program has grown substantially since the last formal review. One individual in the radioactive materials program was promoted to a supervisory position outside the radioactive materials program and one individual in the emergency response section retired. The vacancy resulting from the promotion was filled and, in addition, two new health physicist positions were created and filled. The program was conducting interviews to fill the emergency response position at the time of the review and the position was expected to be filled in the August-September timeframe. Salaries for professional and managerial personnel are generally lower than those for similar employment opportunities in adjacent States, but this has not had an apparent effect on the BRH's ability to attract and retain personnel.

18. Technical Quality of Licensing Actions (Category I)

NRC Guidelines

The RCP should assure that essential elements of applications have been submitted to the agency, and which meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Additionally, in States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet State licensing requirements for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be adequately documented including safety evaluation reports, product certifications or similar documentation of the license review and approval process. Prelicensing visits should be made for complex and major licensing actions. Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions. The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

Assessment

New Hampshire issued 14 new licenses and 32 renewals in their entirety, and processed 24 terminations during the review period. In addition 142 amendments and 209 simple renewals were issued. Eight license files were selected for casework review including two new licenses, one amendment, three renewals in entirety and two license terminations. All license reviewers were included in the review. License types included one fixed gauge, two portable gauges, one sealed irradiator, three R&D labs, and one service license.

The licensing actions were reviewed for completeness, consistency, proper isotopes and quantities, qualifications of authorized users, adequate

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

The file reviews indicated the quality of the licenses was very good, and there were only a few isolated comments. All supporting documents were available. The deficiency letters were well-drafted and thorough. The license conditions were consistent with those used by the NRC. Unsatisfactory responses from the licensees were resolved and the results documented. It was noted BRH performs pre-licensing inspections and delivers new licenses in person if the reviewer feels it would be of benefit.

Because licenses in New Hampshire are only valid for 1 year, simple renewals are issued annually. Every 5 years, each license is renewed in its entirety, and the licensee must submit a new application and supporting documents.

19. Adequacy of Product Evaluations (Category I)

NRC Guidelines

RCP evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC, State, or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users. The RCP should review manufacturer's information on labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy. Approval documents for sealed source or device designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions. Approval documents for radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste for disposal should be complete and accurate as to the use, capabilities, limitations, and site specific restrictions associated with each product.

Assessment

One sealed source and device (SS&D) registration certificate involving naturally occurring and accelerator-produced radioactive material (NARM) was issued by the State during the review period.

<u>Registration</u>	<u>Distributor</u>	<u>Radionuclide</u>	<u>Type of Use</u>
NH-0702-S-101-S	CIS-US, Inc.	Co-57	Rectangular Flood Source

The review team verified BRH evaluated the design and supporting data in accordance with guidance provided by the NRC. Engineering drawings, ANSI tests, radiation measurement results, and operating and emergency procedures were all in the file.

The materials section supervisor attended the 1991 NRC SS&D Workshop. During our discussion and document review, it was confirmed that he uses the guidance distributed at that meeting. In addition, he uses the following documents: the QA/QC manual edited by the NRC Office of Nuclear Material Safety and Safeguards (NMSS); NRC PGD 90-6 Rev 1; 10 CFR 21; NBS 126 (ANSI N542); NBS 129 (ANSI N538); NBS 116 (ANSI 540); NBS 136 (ANSI 432); NRC RG 10.10; NRC RG

10.11. It was also confirmed he follows the evaluation criteria provided in the All Agreement State Letter SP-94-082, dated 7/16/94.

BRH has no pending requests for SS&D evaluations.

20. Licensing Procedures (Category II)

NRC Guidelines

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should have program specific licensing guides, plans and procedures for license review and policy memoranda which relate to specific aspects of waste disposal. The program should include the preparation of safety evaluation reports, product certifications, or similar documentation of license review and approval process. License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions. The present compliance status of licensees should be considered in licensing actions. Under the NRC Exchange-of-Information program, evaluation sheets, service licenses, and licenses authorizing distribution to general licensees and persons exempt from licensing should be submitted to NRC on a timely basis. Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process. Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

Assessment:

BRH uses NRC regulatory guides and standard review forms supplemented by their own forms, guides, check sheets, and policy memoranda. In reviewing these documents, the team found that BRH has produced at least 18 new or revised procedures, regulatory guides, review forms, or similar documents. New Hampshire statutes require that license conditions and regulatory guides be published in the form of regulations. Because rule adoption is normally a lengthy process, licensing circumstances that are not covered by the standard conditions are handled either by internal policy or by requiring the licensee to furnish commitments that can be included in the tie-down condition.

The team noted that the new review forms and checklists are well written and provide appropriate guidance to license reviewers. The termination checklist, in particular, is excellent.

21. Status of Inspection Program (Category I)

NRC Guidelines

The State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. The inspection program in all States should provide for the inspection of licensee's waste generation activities under the State's jurisdiction. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should include provisions for pre-operational, operational, and post-operational facility inspections. The inspections should cover all program elements which are relevant at the time of the inspection and be performed independently of any resident inspector program. In addition, inspections should be conducted on a routine basis during the operation of the low-level radioactive waste facility, including inspection of

incoming shipments and licensee site activities. The RCP should maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available. There should be at least semiannual inspection planning for the number of inspections to be performed, assignments to senior versus junior staff, assignments to regions, identification of special needs and periodic status reports. When backlogs occur the program should develop and implement a plan to reduce the backlog. The plan should identify priorities for inspections and establish target dates and milestones for assessing progress.

Assessment

The materials section supervisor develops an inspection plan on a quarterly basis. The routine program of inspection according to BRH's frequencies requires approximately 39 inspections to be done each year. At the time of the review, there was no backlog of overdue inspections; only one inspection was overdue and it was scheduled to be inspected in September 1994.

With respect to initial inspections of new licenses, the review team looked into 13 new licenses issued during the review period and compared them against the criteria contained in the NRC Inspection Manual Chapter (IMC) 2800 which requires such inspections to be conducted within 6 months of license issuance. (As noted in Enclosure 2 in the guideline on Frequency of Inspection, the review team notes that BRH's criteria for inspection of new licenses are not as restrictive as those contained in IMC 2800.) Of those, 4 licenses were inspected more than 6 months after license issuance. The remainder were either inspected within 6 months of license issuance (7 licenses) or were determined to not have radioactive material (2 licenses).

22. Inspector's Performance and Capability (Category I)

NRC Guidelines

Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections. For the inspection of complex licensed activities such as permanent low-level radioactive waste disposal facilities, a multidisciplinary team approach is desirable to assure a complete compliance assessment. The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Assessment

Three of the four materials inspectors have been accompanied by their supervisor so far during 1994. Records indicate that in 1993 two of the inspectors were accompanied for audit purposes, and discussions with the staff indicated that new inspectors were accompanied for training purposes. The supervisor's goal is to accompany inspectors at least once during each year.

On August 16, 1994, Scott Moore, Office of Nuclear Material Safety and Safeguards, accompanied a BRH inspector during an inspection of GZA GeoEnvironmental, Inc. (316R), a portable gauge licensee.

The inspector was prepared for the inspection and conducted the inspection in a very thorough manner. The inspector demonstrated competence with inspection technique and health physics practices. He also demonstrated a good grasp of the safety issues involving the licensee, and he focused inspection effort on those areas. The inspection was executed well.

Interviews with the inspectors and the supervisor and review of the inspection files, demonstrated to the review team that BRH materials inspectors are qualified and technically competent to evaluate health and safety problems and to determine compliance with State regulations and requirements.

23. Responses to Incidents and Alleged Incidents (Category I)

NRC Guidelines

Inquiries should be promptly made to evaluate the need for on-site investigations. On-site investigations should be promptly made of incidents requiring reporting to the Agency in less than 30 days (10 CFR 20.403 types). For those incidents not requiring reporting to the Agency in less than 30 days, investigations should be made during the next scheduled inspection. On-site investigations should be promptly made of non-reportable incidents which may be of significant public interest and concern, e.g. transportation accidents. Investigations should include in-depth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). Investigation (or inspection) results should be documented and enforcement action taken when appropriate. State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures). Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency. The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Assessment

Fourteen incidents or allegations were reported to the State in the 22-month reporting period. The 1993 Annual Event Summary was sent to the NRC on April 28, 1994. There were no misadministrations involving therapy. In the five files selected for in-depth review, BRH had taken prompt, appropriate action. Investigations were thorough and well-documented. The section supervisor is in the process of revising the incident reporting forms and tracking system.