



State of Utah

DEPARTMENT OF ENVIRONMENTAL QUALITY DIVISION OF RADIATION CONTROL

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September 21, 1994

Paul H. Lohaus
Deputy Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Lohaus:

We have completed the review of the draft Intergrated Materials Performance Evaluation Program (IMPEP) report. We have divided our response into three attachments:

- Attachment A - Comments on the factual correctness of information indicated in the IMPEP report
- Attachment B - Response to recommendations indicated in the IMPEP report
- Attachment C - Response to ratings for the common performance indicators

The response does not include specific comments relating to the IMPEP process. As you are aware, I addressed many specific issues relating to the process at the Agreement States Mid-Year Managers Meeting in July. As a result of the report, several other issues relating to the process have been identified. These process issues will be addressed separately in response to the July 21, 1994 Federal Register Notice on "Adequacy and Compatibility for NRC and Agreement State Radiation Control Programs Necessary to Protect Public Health and Safety; Draft Statement of Policy" by the October 19, 1994 submission date. We wish to emphasize that many of the process issues will be critical in determining "where" the IMPEP program is going and we feel that the process comments from those states volunteering to participate in the pilot IMPEP process should be of the utmost importance, at least equal to the specific review comments.

We also wish to emphasize the importance of ensuring that Utah issues and concerns with the IMPEP report specific to our program are available for public review. If NRC receives a request for the Utah IMPEP report, we would expect that NRC would attach the Utah comments to the report. This is especially critical since at this time, NRC has chosen to assign a "marginally satisfactory" rating to our inspection program. We want all interested parties to have the availability of our disagreement in writing on this specific issue.

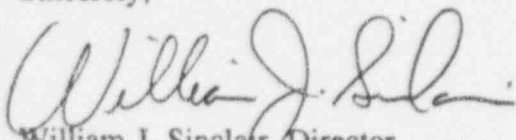
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We would expect this to be a normal process not only for Utah, but also for other Agreement States subject to the IMPEP process.

We also request copies of the IMPEP reports as they are finalized for the NRC Regions and Agreement States subject to this process. We appreciate the opportunity to travel to the Management Review Board Meeting on October 7, 1994 and will be available to respond to and answer any questions relating to Utah's program. If you have any questions, do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script, appearing to read "William J. Sinclair".

William J. Sinclair, Director
Division of Radiation Control

c: Dianne Nielson, Ph.D., Executive Director, UDEQ

ATTACHMENT A

Comments on the Factual Correctness of Information Indicated in the Integrated Materials Performance Evaluation Report

The following comments discuss the factual correctness of the information reported by the review team and summarized in the Integrated Materials Performance Evaluation Program (IMPEP) report.

1. Section 3.2, paragraph 2, second sentence--This statement is confusing. It appears that ", DRC" should be deleted between "Director" and "has."
2. Section 3.2, paragraph 5, fourth sentence--While it is true that cost of living increases for state employees have been essentially flat over the review period, some DRC employees have received additional merit step increases for successful and exceptional work performance. Therefore, some staff have received increases as great as 4.75% in a particular year.
3. Section 3.3, paragraph 3, third sentence--The DRC has used, for a number of years, its own Regulatory Guides for the following license types: portable gauges, fixed gauges, industrial radiography, medical and well logging. It would not be factually correct to infer that the State was only using NRC Regulatory Guides.
4. Section 3.4, paragraph 3, fourth sentence--The DRC inspector explained to the reviewer that the calibration firm was one of two firms in Utah. The inspector did not recall that another licensee had been approved for an instrument calibration service license on April 22, 1994. The licensee had not performed any instrument calibrations until June 15, 1994.
5. Section 3.5, paragraph 2--The information on radioactive material incidents for calendar year 1992 is not correct. The Annual Statistical Update for Utah, which was dated January 25, 1993 and submitted to the NRC Office of State Programs (OSP), contains the correct information. The information requested on page A.43 of the questionnaire for evaluation of agreement state radiation control program, is slightly different from the annual statistical update form prepared by OSP. This led to an error in the preparation of Appendix A, Evaluation of Agreement State Radiation Control Program, Part I, Program Guidelines and State Questionnaire Update.

For calendar year 1992, there were 15 incidents (5 involved Naturally Occurring Radioactive Material). The DRC conducted on-site investigations for four of the incidents and notified NRC about three incidents. None of the incidents were considered Abnormal Occurrences. It is correct to report that there were four incidents considered misadministrations in accordance with the 1987 revision to 10 CFR Part 35.

6. Section 4.5, title--The title contains reference to "Category II." It is believed that this is intended to be part of the report to be issued in accordance with the current Agreement State review procedures.

ATTACHMENT B

Response to Recommendations Indicated in the Integrated Materials Performance Evaluation Report

The following information details the action or status by the Utah Division of Radiation Control on all recommendations listed in the draft Integrated Materials Performance Evaluation Program (IMPEP) report.

1. The team recommends DRC review their inspection priority list and make minor changes to some of the data. In a few cases, the wrong matching NRC program code was given, and in one case, the inspection priority was not clear.

Status:

Minor errors in the inspection priority list have been corrected. While the DRC does not use NRC program codes for tracking its licensees, the information is used to compare certain aspects of the Utah and NRC program. A listing of NRC program codes has facilitated this comparison. After the IMPEP review, inspection priorities previously under consideration for change were further considered and program changes were implemented. As a result of these changes, all license categories are now clearly indicated.

2. The team recommends that DRC inspect the three new licensees who had not been inspected as of the time of the review and, in general, should provide greater attention to assuring that new licensees are inspected within six months of license issuance.

Status:

Inspections were performed for the three new licensees prior to receipt of the review report. Actions have been taken to modify computer generated reports so that new licensees are clearly indicated and inspection dates are noted. This will facilitate communication to the inspection staff and tracking by DRC management.

3. The team recommends that DRC establish a limit of 30 days for issuance of enforcement letters (or letter of clear inspection), rather than use 30 days as a goal.

Status:

It must be noted that when the DRC (a small staff) becomes involved with incident response, allegation investigation, or escalated enforcement actions; the issuance of routine enforcement letters may be delayed beyond the goal. There may also be those circumstances where State programs, not related to Agreement State activities,

will be assigned a higher priority than the close out of routine enforcement actions. To minimize the possibility of exceeding the 30 day goal, inspectors have been instructed to track their work activities and to advise management of the probability of not meeting the goal so that priorities may be adjusted if necessary. It should be noted that the Utah inspections were accomplished within 3-14 days past the 30 day goal, resulting in an insignificant delay of communicating the inspection results to the impacted licensees. Maintaining a 30 day limit is inflexible and does not account for the complexity of inspections and associated inspection follow-up with larger licensees.

4. The review team recommends that DRC take the necessary steps to fund and fill the vacant Environmental Scientist III position within the materials program to assure that adequate levels of support are available for inspection of the materials program.

Status:

Constraints placed upon all Divisions within the Department of Environmental Quality by management make it unlikely that the vacancy will be funded and filled. As a contingency, the DRC intends to utilize the abilities of an individual currently working in the Environmental Monitoring/Low-Level Waste Section and individuals currently overseeing the control of x-ray machines. Actions will be taken to adjust staff attendance at NRC sponsored training courses to effectively implement this plan.

5. Although the regulations are cited in the cover letters to licensees, the review team recommends that medical license tie-down conditions reference State regulations.

Status:

Licensing staff have been instructed to reference State regulations in medical license tie-down conditions.

6. The review team recommends that license reviewers use checklists or equivalent computer documentation.

Status:

License reviewers have been instructed to revise checklists; developed by the DRC and the Conference of Radiation Control Program Directors, Inc. (CRCPD) E-15 Task Force on Procedures Manual - Radioactive materials; to best meet the current practices of the DRC.

7. The review team recommends that supervisory review and final dispatch records be kept in the license file. Although the information is available elsewhere, it would be

beneficial to retain all supporting documents in the file for future review.

Status:

Supervisory reviews will be recorded on the license routing sheet. The sheet will continue to track the status of licensing actions as well as peer review. Supervisory reviews will be performed on all actions involving a major licensee and every tenth licensing action tracked by the materials program supervisor. Major licensees are those licenses identified by the DRC in an answer to question 1 in Section V. A. of Appendix A, Evaluation of Agreement State Radiation Control Program, Part I, Program Guidelines and State Questionnaire Update, for the period from January 1, 1992 to December 31, 1993.

8. We recommend that DRC contact the calibration firm discussed in the assessment above and discuss the firm's calibration procedures, to eliminate any concern that the firm may not be performing calibrations correctly.

Status:

The DRC has three licensees authorized to perform calibrations of radiation detection and measurement instruments. Currently, two of the three licensees have been inspected. The third licensee is scheduled for inspection by October 31, 1994. This action is expected to alleviate any concern regarding the quality of an instrument calibration within the State of Utah.

The DRC submits that a service licensee can provide the best possible service only when the customer licensee clearly and effectively communicates its needs for an instrument calibration. If the customer licensee does not have an appropriate level of understanding regarding the use and calibration of survey instruments, then inaccurate or incomplete information may be relayed to the service licensee about the needed service. Under such circumstances, the service licensee may correctly calibrate the instrument, but with a source of radiation that is not appropriate for the customer's needs. It must be noted that "the licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured" [emphasis added, reference 10 CFR 20.1501 (b)]. The DRC believes this regulation places primary responsibility on the customer licensee for assuring proper calibration of instruments before the instrument is used to perform radiation safety surveys. This requirement must be met even when the survey instrument is calibrated by a calibration service licensee.

Therefore, the DRC contends that its response to the review team, regarding the method of addressing this problem, is still the preferred action. When taking this course of action, the DRC can assess the licensee's level of understanding regarding

the use of radiation survey instruments and can determine that adequate radiation surveys are performed by the licensee, thereby helping assure protection of the public.

9. In inspections that result in numerous violations, we recommend that DRC take enforcement action beyond a routine NOV. The enforcement action should specifically address the extent and severity of the violations, and any conclusion that DRC draws from the violations (e.g., that the extent of violations may be indicative of management breakdown, or that numerous minor violations may be indicative of declining licensee performance and a precursor to a more serious problem).

Status:

In cases where it is necessary, the DRC takes enforcement actions beyond the issuance of a Notice of Violation. A determination as to the particular sanction to be used involves the consideration of the severity level of the violation including its duration, the licensee's response to the violation and the licensee's past performance.

The DRC believes that "numerous violations" is a nebulous term. If the DRC were to establish a definition for this term, then its enforcement program could be considered overly prescriptive. The DRC believes that an effective enforcement program must provide for discretion to increase or reduce sanctions to provide appropriate regulatory messages to encourage improved performance. Establishing a "cook book" approach to any inspection where there are "numerous violations" is not in keeping with this philosophy.

The DRC submits that the decisions made by its staff were appropriate. There was a consideration of the licensee's past performance, the severity level of the problems, and the licensee's responses at the inspection close out meetings. Subsequent inspection of the cases in question showed that improved performance was evident. It can be concluded that for these cases the issuance of a Notice of Violation alone was sufficient to encourage improved licensee performance.

10. We recommend that DRC institute a formal requirement for inspectors to orally debrief their supervisor upon returning from an inspection that has any violations.

Status:

License inspectors were instructed to orally debrief their supervisor after returning from an inspection where there is an apparent violation. The debriefings will be noted on the license routing sheet. This action formalizes a practice which has been performed in an informal manner for quite some time. This recommendation was acted upon with the first inspection following the exit meeting with the review team. However, NRC Guidance suggests that an oral debriefing be performed for non-

routine inspections. It may not be a wise use of resources to orally debrief a supervisor that a moisture density gauge did not have a leak test performed within the prescribed time frame (which would constitute issuance of a NOV). Once again, some flexibility should be allowed in those cases where there is not a major safety or health concern yet a NOV is still appropriate.

11. When a licensee's response to an NOV is inadequate, we recommend that DRC require a further, satisfactory response from the licensee that provides an explanation of the licensee's corrective actions. If the licensee will not provide a satisfactory response, disputes the violation, or refuses to adequately address the violation, then DRC should take further action, as appropriate (to include DRC management contact with the licensee, confirmatory action letters, or orders).

Status:

The DRC will resolve an inadequate response from a licensee by seeking a satisfactory response that provides an explanation of the corrective actions. When the circumstances warrant, further action will be taken by the DRC.

The DRC does not have a practice, regarding inadequate licensee response to a Notice of Violation, of not sufficiently closing a violation. In both of the examples cited by the review team, the DRC determined that the licensee's response was adequate. The licensees' responses were found to include statements of their intention to comply with the Utah Radiation Control Rules. In determining proper closure to violations, consideration is given to general knowledge of the licensee and the licensee's response at inspection close out meetings. Therefore, both responses were determined to be satisfactory. The DRC contends that the decisions made by its staff were appropriate and the violations were brought to proper closure.

12. We recommend that DRC develop a formal inspection procedure on documenting inspections.

Status:

The DRC makes use of NRC's Inspection Manual Chapter 2800 and Inspection Procedure 87100 for inspection guidance. A field form is used to guide an inspector through a good inspection for specific categories of materials licensees. The form serves as a report, which documents 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 management and licensee response. The DRC believes that its current practice adequately documents the findings of an inspection. Improvements in the field form are currently under review. Information prepared by the CRCPD E-15 Task Force on Procedures Manual has been consulted in this effort.

13. We recommend that DRC revise the inspection field notes to cover the inspection results in more detail, and especially to better document the inspector's observations of licensee operations and demonstrations.

Status:

Improvements to the field forms are currently under review. For additional information, see response to recommendation number 12.

14. We recommend that the inspection supervisor review all inspection reports (field notes) and sign off on the cover page before issuing the licensee a letter documenting the inspection.

Status:

This recommendation made by the review team is already the established process for the DRC, so a significant change is not necessary. For those occasions when the inspection supervisor is away on travel, the inspection staff have been instructed to have another qualified supervisor review the inspection report.

15. We recommend that DRC store the calibrator now located in the stairwell in a restricted area that will limit access by individuals, so that the dose rates for a member of the public will be less than 2 millirem in any one hour.

Status:

DRC management has obtained access to an appropriate location, one that may be maintained as a restricted area, within its offices.

16. The team would recommend that even if DRC does not immediately respond to every reported incident, those licensees where there is damage to devices containing radioactive material and equipment should be subjected to a special inspection to investigate circumstances and examine corrective action to prevent recurrence.

Status:

When a reported incident involves damage to devices containing radioactive material, a special inspection will be opened to investigate the circumstances and corrective actions.

17. We recommend that the Radiation Control Board consider establishing a written policy for conflict of interest consistent with other Division boards within DEQ. If appropriate, the policy should be coordinated with the Attorney General's Office.

Status:

A draft policy will be prepared in conjunction with the Utah Attorney General's Office for the Board's consideration at the December 1994 Board meeting. The Executive Secretary to the Radiation Control Board will present this recommendation to the Board as an action item.

18. We recommend that the State of Utah not delay implementation of regulations promulgated on a routine basis.

Status:

It is not the practice of the DRC to delay implementation of regulations promulgated on a routine basis. The DRC is aware that the Guidelines for NRC Review of Agreement State Radiation Control Programs specify that "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." While it is true that certain requirements in the Utah Radiation Control Rules were made effective more than three years after the effective date established by the NRC, the DRC did amend State regulations before the 3 year period elapsed for each regulation deemed a matter of compatibility.

The DRC is concerned that the guidance does not clearly address the distinction between amending State regulations and an apparent policy that the Commission expects Agreement States to **implement** compatibility requirements by the end of the 3 year period. The DRC recommends because of this concern, that more explicit guidance be published in the Federal Register.

Since there exists a Federal-State cooperative effort to formulate standards for protection against hazards of radiation which are coordinated and compatible, the DRC has furnished to NRC copies of draft regulations for early review and comment. One expectation of this exchange is that NRC review will help the DRC avoid promulgating regulations that are not compatible with those of NRC. For each of the rulemakings identified by the review team, timely comment by NRC on the Utah Radiation Control Rules could have averted the issue. We are disappointed that NRC does not currently conduct such reviews in a timely manner.

19. We recommend that procedures be developed and implemented for the selection of contractors to support the low-level radioactive waste regulatory program to avoid conflicts of interest with regard to those contractors working or supporting the licensee.

Status:

The procedures developed and implemented by other Divisions within the Department of Environmental Quality and procedures already specified by the State Division of Purchasing will be modified and adopted, as appropriate, by the DRC. In this specific instance, only one contractor was involved. Since the field of contractors were very limited, DRC staff had personal knowledge of potential conflicts of interest and knew that no such conflict existed.

20. To assure continuity and uniformity in regulatory practice, the review team recommends that the DRC take the necessary steps to complete its revision of their administrative procedures and provide copies to all employees.

Status:

Efforts are in progress to complete a revision of the procedures. It is anticipated that the effort can be completed in a suitable time.

21. We recommend that DRC calibrate all survey instrumentation at a frequency at or more frequent than that required for the licensee being inspected, or only use instruments on inspections that have been calibrated within the standards applicable to the licensee.

Status:

Inspection staff have been instructed to only use instruments on inspections that have been calibrated within the standards applicable to the licensee. The instrument calibration coordinator has been instructed to have an appropriate number of suitable instruments available to meet this program element.

ATTACHMENT C

Response to assignment of "marginally satisfactory" rating to the performance indicator of "Technical Quality of Inspections"

The Division of Radiation Control disagrees with the assignment of marginally satisfactory to the performance indicator of "Technical Quality of Inspections" based on the following reasons:

- A. It is not clear how the criteria for "inspections" as outlined in the IMPEP guidelines are divided or weighted. Upon review of the criteria for marginally satisfactory, we identified five major criteria with two of the criteria containing multiple factors. NRC indicated no concerns in three of the five criteria. In the two criteria containing the multiple factors, Utah was cited for three findings within each of the two major criteria. However, we feel that only one of the citations for each of these two criteria is valid. Listed below are the criteria as we have divided it with the findings listed by each of the criteria. Those findings in bold are findings that Utah disagrees and has stated the reasoning under the Recommendations comments section in this document.

NRC criteria

Findings

1. Some inspections do not address potentially important health and safety concerns

No findings

2. Indication of periodic problems with respect to completeness, adherence to procedures, management review, thoroughness, technical quality, and consistency

a) Licensee's survey meter was not properly calibrated by the licensee's firm

b) Formal debriefing of DRC management upon return from inspection trips, at a minimum when trips identify violations

c) Field notes do not sufficiently document the "depth" of the inspection

3. Findings in inspection reports and inspection files are, on occasion, not well-founded or documented and the review does not demonstrate an appropriate

d) Two of eight file reviews indicated an inadequate response

e) DRC has no procedures on

level of management review

on documenting the inspection forms such as MC 0610 "Inspection Reports"

f) Supervisor failed to sign cover page of field notes in 3 of 8 instances.

4. Accompaniment of inspectors by supervisors are performed non-systematically

No findings

5. Follow-up actions to inspection finding are not often timely

No findings

Dose calibrator stored inappropriately

B. One finding, the dose calibrator stored inappropriately, was placed within the "inspections" area findings even though the review team rated that it was not specifically related to the technical quality of inspections. We are puzzled why this is in the "inspection" area. This finding covered one third of a page in the "inspections" commentary. This may point out a problem with the indicators such that NRC has to make arbitrary decisions as to where to place findings. If this was counted against Utah in the inspection area, we feel it is inappropriate.

C. Therefore, Utah had three of five criteria with no findings, and had only one finding in the two criteria which considered multiple factors. Based on the information, we feel it difficult to conclude that the technical quality of inspections is marginally satisfactory. We would like to know if there is a "number" that qualifies as a failure in a criteria. In criteria 2 above, the factors of completeness, adherence to procedures, management review, thoroughness, technical quality, and consistency are listed. Under NRC's evaluation, we could state that DRC failed once on the factors of completeness (survey meter), adherence to procedures (management debriefing), and thoroughness (field notes). Considering the DRC arguments, we feel we only had one failure (field notes) out of six factors. Is even three of six (the NRC findings) enough to fail this multiple factor criteria?

D. How would DRC do on the satisfactory criteria?

1. Accompaniments of inspectors combined with an onsite review of a representative cross section of completed inspection files indicates inspection findings are usually well-founded and well-documented throughout

No findings

the assessment period.

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| 2. A review of inspector field notes or completed reports indicates that most inspections are complete and reviewed promptly by supervisors or management. | Finding b), c), e), f) |
| 3. Procedures are in place and normally used to help identify root causes and poor license performance. | Finding d) |
| 4. In most instances, followup inspections address previously identified open items and/or past violations. | No findings |
| 5. Inspection findings generally lead to appropriate and prompt regulatory action | Finding a) |
| 6. Supervisors accompany nearly all inspectors on an annual basis. | No findings |

Dose calibrator stored
inappropriately

As we evaluate this comparison, we find that DRC meets three of six criteria under the NRC evaluation. Considering the DRC arguments, five of six criteria would be met with only one criteria with multiple factors not being met (2 findings). This emphasizes the need for the NRC to thoroughly explain "why" a rating was assigned. As detailed above, DRC has made an effective argument for a satisfactory rating. The "why" we received a marginally satisfactory is not detailed to the point of how the criteria and factors were weighted one against another.

- E. Why does DRC care if overall the rating is still adequate and compatible? DRC is constantly under the microscope concerning performance especially in the area of inspections. By virtue of having a low-level waste site, there are high expectations that the inspection program is "excellent" in the least. Someone picking up the report could assume that the DRC program is only "marginally satisfactory" (e.g. C- or D grade) when in fact that is not the case in either the low-level or radioactive materials program.