



STATE OF TENNESSEE  
**DEPARTMENT OF ENVIRONMENT AND CONSERVATION**  
DIVISION OF RADIOLOGICAL HEALTH  
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October 23, 2000

Mr. Paul H. Lohaus, Director  
Office of State and Tribal Programs  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555

Dear Mr. Lohaus:

I am responding to your letter dated September 22, 2000, to Mr. John Leonard. We have reviewed your letter and the attached draft IMPEP report which documents the preliminary findings from the review of the Tennessee Agreement State program conducted by your team during the week of August 21-25, 2000. Attached are our comments regarding the accuracy of the report.

It should be noted that the majority of the comments relate to Section 3.2 Technical Quality of Inspections and to Attachment C, Inspection Casework Reviews. In our discussions during and after the Review Team's visit to Tennessee, I expressed the concern that most of what we were hearing about this portion of the review was anecdotal. I stated that we were looking forward to seeing the casework so that we could try to understand the basis for the findings which were being formulated.

Having now had that opportunity, I must point out that we disagree with a large number of the specifics in this indicator. We feel that this finding places an inappropriate emphasis on doing inspections in accordance with NRC's SOPs, rather than those we currently use. Our SOPs have been in place for many years, and have not in the past come under such criticism. While they are no doubt due for an update, we believe that they are the standard against which technical quality should be judged. On that basis, we submit that the suggestions we have offered, if accepted, will improve the technical accuracy of the report.

00 OCT 24 PM 5:10

OSP

Thank you for the opportunity to provide these comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lawrence E. Nanney". The signature is written in dark ink and is positioned above the printed name.

Lawrence E. Nanney  
Director

## ATTACHMENT

### 3.1 Status of Materials Inspections

- Page 4, P. 1, L 1                      Remove “not” and add an “s” to require.
- Page 4, P. 1, L 2                      Sentence should begin with “Some of the reports....”
- Page 4, P. 2, L 5                      Sentence begins “Two reports....were missing...” The report dated May 2000 was not missing, it was being prepared by the principal inspector in that field office.
- Page 4, P. 2, L 8                      Sentence begins “The staff turnover...” Sentence should end at the semicolon. The Division does have a clear policy that requires all correspondence relating to all inspection findings be delivered to the Central Office for maintenance in the central files. The inspection reports were sent to the Central Office from the field offices for maintenance in the Central Office files per policy. The fact that the reports were not filed in the license files was not due to a lack of a clear policy.

### 3.2 Technical Quality of Inspections

- Page 4, P. 6, L 2                      Sentence should be changed to reflect that the inspectors were not interviewed for all 21 radioactive materials inspections conducted during the review period. The statement “...and interviewed inspectors for 21 radioactive materials inspections (for 17 licensees)....”implies that they were interviewed regarding each inspection. Had this actually occurred, many of the items which we believe were erroneously included in the casework findings, and to which we respond here, might not have been included in the first place.
- Page 5, P.1, L 6                      Sentence beginning “All notices of non-compliance...” should be deleted. Central Office Management only reviews inspection reports from Priority 1 licensees requiring financial assurance, licenses-for-delivery notices of non-compliance, and any inspections performed by Field Office Managers.
- Page 5, P. 3, L 6                      Sentence beginning “The review team...” The term “low quality” is subjective and pejorative and has no clear meaning in this context.

Page 5, P. 3, L 11

Sentence beginning “None of the inspection reports...” is factual, however, it is irrelevant. We have not yet adopted the concepts of performance-based inspections and routine inspector evaluation of safety significance and root cause of violations into our inspection SOPs. While this is in large part due to the fact that we have been extremely limited in our ability to get staff into both the Inspecting for Performance and the Root Cause Investigation courses, that too is irrelevant. It is relevant that, wherever these concepts are referenced in these review findings, we are being penalized for not following the NRC’s SOPs, while it has been portrayed that we are not following our own SOPs.

Page 5, P.5, L 5

Sentence beginning “In one instance...” The tour of the facility was during normal work hours, but after the last patient had been scanned.

Page 6,P.1, L 5

Sentence beginning “ In addition, under Section 098.05 of...”should read, “under Section 1000.08 ....”

Page 7, P.4, L 1

Sentence beginning “The Division Director retired...”and the following two sentences should be deleted. Replace the first three sentences with the following: “The Director of the Division retired in November 1999 and the Deputy Director was selected to succeed him in January 2000. The Technical Services manager was selected to be the new Deputy Director in July 2000. The Inspection and Enforcement manager was moved to a staff technical position in July 2000 and these two management positions are in the process of being filled.”

Page 10, P. 7, L 2

Sentence beginning “However, in three out of...” can not be substantiated since there is no documentation in Appendix E as to what specific allegations the review team is referencing.

Page 12, Bullet 7

Add: “The Division incorporated 60 FR 28323 in all radiography licenses in January 1997.”

Page 13, Bullet 5

Add: “The Division incorporated this jurisdictional requirement in temporary jobsite licenses in April, 1996.”

## Appendix C, Inspection Casework Reviews

File No.: 1

At the time of the NRC review team visit the report was still in draft form and was in the process of management review when requested by the NRC review team. The report had not been fully reviewed but notes and omissions were noted on the draft report and was provided to the NRC review team with their full knowledge that it was an incomplete document. Several of the items noted in the review of this report reflect the draft status of the report. The information that is noted as not in the report was available in the inspector's notes and was included in the final document after management review.

Page C.2, File No. 5

a) Observations are not always possible in low-workload facilities. This is a small hospital with one technician performing 30 – 40 scans per month.

b) 1. The citation in the letter states: "Records for linearity tests which were to be conducted during the second quarter of 1999 were not available for review."

This is how we cite. If no records are available to prove tests were performed, then there is no proof tests were performed.

2. Requirement is for records to be maintained. If there is not a ring badge report then the licensee is still required to estimate dose and maintain a record. The ring badge record was not available.

3. The licensee's representatives were the nuclear medicine tech and the Director of Imaging Services. In a small hospital where use of radiation is limited, these individuals would certainly know if this type of training was taking place. The licensee's response clearly indicates that this training was not being performed.

c) Violation # 2 was not disputed by the licensee. They offered an explanation as to why there was no record from the processor.

d) The information on our internal inspection reports is sufficient to perform inspections in accordance with our SOP's. These forms and the method of completing these forms have been used for years (through other NRC reviews and one previous IMPEP review) without any substantial changes. The comment reflects the reviewer's opinions which we do not share.

Page C.2, File No. 6

a) Sentence beginning "Report indicated..." The inspection report did indicate that work had been performed in Alabama with two sources which were still in Alabama at the time of inspection. The licensee accepted the violation and stated they would make corrections.

Page C.3, File No. 7

Inspection date: 4/20/00

b) The inspector requested the RSO who was not present. They were provided with the acting RSO and an authorized user to conduct the inspection.

Inspection date: 8/5/99

b) In paragraph 28 of the inspection report, the records were noted as not being on file that resulted in the items of non-compliance 1 and 2.

c) The inspector requested the RSO who was not present. They were provided with the acting RSO and an authorized user to conduct the inspection.

Page C.3, File No. 8

The inspection dated 8/14/97 was performed by BAS (Barbara Shrader) not MW.

Page C.4, File No. 9

a) 1. The inspection report clearly identifies items that were untrackable by the licensee, B-25 boxes and drums. The licensee could not identify how long these packages had been on site or what they contained. This is an ongoing problem at this facility and has been the subject of numerous meetings with our office. The licensee is a very large facility with literally hundreds (if not thousands) of packages on site at any one time. The only feasible way to monitor the length of package storage is to require an auditable tracking system. The citation is accurate because there was no way for the licensee to demonstrate compliance.

2. How can an inspector be expected to total up hundreds of packages of material and figure out by observation how much radioactive material exists in an unpackaged state? Without a tracking system as discussed above activity on site is not auditable. Citation is valid.

3. It is not our policy to not cite for self-identification nor is it our policy to credit for self-identification and correcting as does the NRC.

4. The information the reviewer indicates is missing is not relevant. The licensee was required to but did not perform the bioassays.

5. The report goes into great detail about what the license requires (continuous sampling), what was being done (only 2 samples of each type for 10-12 burns, no sampling for the high temperature burn), why this was currently happening (reduction of HP staff and a change in procedures). The technical violation is clear – sampling of air effluent is not being performed during burn operations and the amount of radioactive material released by the facility cannot be determined.

7. “Seventh violation was for failure to demonstrate compliance with the public dose limits. The violation is not substantiated.” This is deemed incorrect in that the inspection report states on page 3, 5<sup>th</sup> paragraph, item #7, “The dose to the member of the public calculation was not available for 1999.”, and on page 6, item #27, “Dose to the Member of the Public...the 1999 dose calculation was not completed...no time estimates were received during the exit interview as to when this calculation would be available”. The review team’s report goes on to refer to the inspector’s report as follows: “The report includes the results of the annual TLD fence line monitoring. The highest recorded dose was 170 millirem in a year, with an occupancy factor of 1. A license condition allows 500 millirem in a year based on TLD results.” Although this is true, it is irrelevant in that the inspector did not cite against the 500 mR/year limit, rather against the SRPAR requirement to demonstrate compliance with the member of the public limit which is 100 millirem TEDE, not limited to an occupancy of 1. The 500 mR/yr limit is a separate requirement imposed by license condition which must also be met.

Page C.5, File No. 11

a) 1. "Report states that record of inventory not available, not that it was not performed." Paragraph 20 (8)(d) of the inspection report states that quarterly physical inventories were not performed and were not documented. The citation is consistent with our procedures. The records were not available to indicate that the inventories had been performed. A record of the inventory is the only proof that it has occurred. Since the number of sources that the licensee can possess is variable (no single source to exceed xxx curies" for each of 3 different cameras) the licensee is required to keep records for any and all sources.

a) 2. The third violation in the inspection letter is worded "...requires in part that reports received from the TLD processor be kept for inspection by Division..." The citation reads: "TLD records were not available" and they were not all available. In addition exposure information from other types of dosimeter results were available.

a) 3. "The fourth violation was for failure to leak test sealed sources at six month intervals..." A licensee must have records of the initial leak test after receipt or of the manufacturer's leak test sent with the camera. Neither was available.

Page C.6, File No. 12

b) RSO was unavailable at the time of inspection but was involved in the response to the items noted.

Page C.6, File No. 13

a) 1. Paragraph 27 of the inspection report indicated the licensee's own area monitors showed a 700 mR/yr exposure in 1997 and 500 mR/yr for 1998 at the generator area and they had made no assessment which included this information and stack release data of iodine to determine compliance with the 100 mrem/yr limit. The statement "Empirically, it appears that no one likely would have exceeded the limit" by the reviewer ignores the data presented in the report of the licensee's own data in paragraph 27, our own independent survey data in paragraph 32 of the inspection report, and the fact that this is next to a glass wall which separates it from the uncontrolled area outside of the building.

a) 2. License condition 36 requires that the doors to the hot lab area (restricted) be maintained locked to prevent couriers' access and maintain contamination control. This

was the license condition violated and was cited as such. The doors were documented and observed as unlocked to the hot lab area and were noted in paragraph 22 in the inspection report. The citation was substantiated.

a) 3. Each violation of the failure to monitor was addressed immediately upon observing the failure to monitor. Since several drivers were coming and going during the inspection each incident was addressed as it occurred. This indicated a need for refresher training concerning this license requirement and that was noted to the RSO by making it a citation, addressing it at each incident observed and corrected, and during the closeout meeting as documented in the inspection report paragraph 19.

a) 4. The refrigerator and L-block were labeled with "Caution Radioactive Material" labels and were located in an unrestricted area (an area free of contamination and radioactive materials that the licensee had dedicated as such) of the facility as documented in their license. The labels should have been defaced or removed and documentation of the release survey showing no contamination be provided which they were not able to do. Our independent surveys noted in Paragraph 32 indicated no contamination in the office areas that included these items.

b) The response of the licensee dated 7/12/99 indicates not only the expansion of the restricted area but the relocation of waste and generator areas as a method to lower exposure rates to members of the public (in a letter dated May 17, 1999). The letter also indicates that this will put them into compliance with the regulations, correcting the cited violation, which was failure to ensure compliance with the limit.

Page C.7, File No. 14

a) "Cannot determine by inspection report if any interviews were conducted." The persons interviewed during this inspection were the Radiation Safety Officer, medical physicist, physicist, and oncology nurse as documented in the inspection report.

Page C.7, File No. 15

a) The RSO is the president and owner of the company.

Page C.8, File No. 16

a) 1. Leak tests were performed and reviewed but they were not being done on a six-month interval as noted in the

inspection report. The relevance of the reviewer's questions is unclear.

a) 2. The licensee committed to wearing personnel monitors in the initial application. License condition 23 of the license requires them to have badging. If they have badging, they are required by SRPAR to maintain the records. This is what was cited in the inspection report and letter.

a) 3. Licensees are required to maintain receipt and disposal records of the gauges they possess for review by the Division. The failure to maintain the records for review is a violation of license condition 20.

a) 4. The licensee indicated this person is an authorized user and the license requires in Condition 15.A. that they maintain a copy of the training certificate. This is a violation of the license.

b) Note that in paragraph 21 of the report the manager is Jay Richardson, Jr. This is a family business and the RSO Jay Richardson III is a member of management.

Page C.9, File No.17

a) 1. It is not incumbent on the inspector to go to the landfill and sample what has been sent there by the licensee to determine if they are within the concentration limits. It is also not incumbent on the inspector to take raw data and perform the necessary analysis to determine compliance. The license requires the licensee to show compliance and that is done through records. At the time of the inspection the records provided did not establish compliance for past shipments. The licensee agreed to our request and suspended the operation until a better understanding of the records could be ascertained. The licensee did not know nor were they able to show that they were in compliance on the day of the inspection.

a) 2. "Third violation was for failure to ...." The reviewer takes issue with the inspector's wiping technique and documentation of the area wiped for the survey without having any factual knowledge about the actual technique used. The reviewer notes that "...it is difficult to establish that the inspector's wiping technique **exactly approximated** (sic, emphasis added) 100 square centimeters." The reviewer goes on to suggest that the

inspector overwiped areas. The inspection report specifically points out "all swipes that were taken over an area of 100 sq. cm except for MVA 451 which was a Large Area Wipe". The swipes designated as taken over a 100 sq.cm area were in fact taken over a 100 sq. cm area (at least as close to 100 sq.cm as any health physicist can obtain with the 4 inch square "S" swipe technique which is an industry recognized standard) and were not gross swipes as the reviewer suggests. This comment represents nothing other than the reviewer's opinion, and is completely unsubstantiated.

a) 3. The basis of the 45-day limit is not something the inspection report would ever address. A careful review of the license would show that the 45 day limit has been discussed and negotiated over a long period of time. The inspector is to determine if all casks are within the 45 day limit and cite the facility if they are not.

a) 4. In Tennessee when we establish a clear limit of 5 pCi/gm, the limit is 5 pCi/gm. The licensee accepted that limit. Under our current SOPs, the inspectors determine compliance and cite if not in compliance.

a) 5. The amendment in question was for a procedure (including this monitor) to replace an existing procedure that the licensee could not make operate properly. The issues involving the stack monitoring at this facility have been ongoing for quite some time. While the inspector is not expected under current SOPs to comment on the safety impact, the safety impact of unmonitored stack releases should be implicitly clear. Being "hampered" to bring a facility into compliance is not accepted as an excuse for non-compliance. The remote alarm was committed to by the licensee in the amendment request and we expect commitments to be met.

a) 7. The report shows that the tests were over one month late and that the test failed when it was finally performed. The test was repeated on the next day and again failed. The facility did not get an acceptable test until almost 2 months later. All of this is in the inspector's report.

a) 8. The monitoring for these isotopes had not been performed. The citation is correct.

- a) 9. This comment is of no significance with respect to Tennessee SOPs, but the following responses are considered appropriate:

Citation # 11

These storage casks were transportation casks on loan to the licensee. The length of time authorized had been negotiated with the licensee by the licensing staff prior to the amendment. The licensee had not requested an extension and was still using the casks. Under our SOPs this is a violation of the license and was cited.

Citation #12

The citation was as follows:

12. SRPAR 1200-2-5-.113(1) requires, in part, that each container of radioactive materials shall bear a clearly visible label which shall bear the radiation caution symbol and the words "CAUTION – RADIOACTIVE MATERIAL" and include information that will permit individuals handling, or working in the vicinity of the container, to take precautions to avoid or minimize exposures (i.e. radiation level information).

Contrary to the above, containers of radioactive material in outside storage were not provided with adequate labeling in that containers were labeled with incorrect radiation level information which did not reflect the radiation levels associated with the current contents of the containers.

The safety significance should be obvious without elaboration.

Inspector Accompaniments

Page C.11, Accom. #2

The Radiation Safety Officer explained at the time of inspection that the source was used in February 2000 with no plans to use it the rest of the year.

Page C.11, Accom. #3

The Radiation Safety Officer, who is the radiographer on this license, was interviewed at the time of inspection.

Page C.12, Accom. #5

a) This is incorrect. The inspector upon arrival at the facility went to the Administration office and was then directed to the RSO to conduct the inspection. (This was confirmed by the NRC reviewer to the inspector's supervisor at the time of the NRC review). No items of health and safety were noted by the inspector or by the NRC reviewer and the RSO decided not to include any higher management for the exit meeting.

b) This statement is incorrect. The inspector followed the inspection SOP which states on page 9 of the SOP in 1000.08 that selective direct observations of work in progress be conducted. The reviewer notes in the review of File 1 that he observed surveys being conducted by the inspector at which time pointed questions were asked of the workers concerning training and activities in which they were engaged. The reviewer indicated to the inspector's supervisor during the NRC review that observations, questions of workers and surveys were performed. In regard to the therapy dose administration not being observed, the inspector inquired about observing the procedure, the nuclear medicine technician asked that the patient's (an elderly female who was only partially clothed) right to privacy be respected, and the inspector concurred. The reviewer did not attempt to determine the reason for not observing the therapy dose. The inspector repeatedly asked the reviewer if he could clarify anything or answer any questions on the inspection activities. The reviewer did not comment at the time.

c) This is incorrect. The inspector spoke with several personnel during the inspection and during the performance of their duties. The inspector asked questions concerning the activities in which they were involved, about how surveys were performed, and if training was adequate, including Declared Pregnant Worker issues. The inspector also asked the technician who was performing the therapy procedure to walk through verbally the method and procedures he would follow to administer the dose and perform the exam.

## License Casework Review

Page D.3, File No. 11

Comment a) "Licensee letter dated 11/29/99 refers to telephone calls from reviewer 11/29/99 and 5/5/00 but no record of telephone calls in the file." This comment needs clarification in that a licensee letter dated 11/29/99 could not reference a telephone conversation that took place on 5/5/00. The situation is: Amendment 50 references letters dated 4/21/00, with attachments, and 5/8/00, with attachment. The letter dated 5/8/00 includes a copy of a letter dated 11/29/99 (which is referenced in Amendment 49) which references a phone call between the licensee and the staff reviewer on 11/29/99. The letter clearly states the discussion in the phone conversation; therefore, the acceptance of the letter by reference by the staff reviewer is the documentation of the phone call. The letter dated 5.8/00 references a phone call between license reviewer and the licensee documenting that a particular issue concerning the request of 4/21/00 (and the additional clarification of 5.8/00) was already taken care of (namely in Amendment 49 concerning financial assurance); the acceptance by the reviewer of the letter with this discussion and its subsequent reference in Amendment 50 is the documentation of the phone call.

## Appendix E, Incident Casework Reviews

File No. 1

a) We do not understand the sentence beginning "The reported levels of Am-241...." The laboratory results of the swipes in our file taken by our inspector indicate six out of the nine swipe samples indicated Am-241 with no detectable Bi-214 and Pb-214. The other three swipes (from floor areas) contained no detectable Am-241, but normal concentrations of Bi-214 and Pb-214. The Am-241 concentrations ranged from 5.3 pCi/wipe to 1753 pCi/wipe. The Pb-214 and Bi-214 ranged from 10.3 pCi/wipe to 13.3 pCi/wipe.

Page E.2, File No.4

a) "There was no written report by the inspector involved in this investigation." In fact, there were two copies of the same report in the file written by the inspector involved in this investigation.

b) "This event appears significant enough to have required an on-site response." However, the inspector documents in

the written report (which is a part of the file) that the stack analyses indicate no RAM release. In addition, the licensee's report dated 6/30/98 (also in the file), states that stack samples showed no release of radioactive material. Although the reviewer does not mention this, it should be noted that this incident was determined to not meet the incident reporting criteria as defined in SRPAR 1200-2-5-.141.

c) In the reviewer's comments under item d), there are quotations around a statement from the licensee's report as follows: "three hours of decon in P-4 – water, sludge and filter media". However, the actual statement in the file reads: "Decon Operations and Health Physics Began a clean-up of Parcel 4 Storage Area-Retrieving Filter Media, water & sludges.-clean-up took about 3 hours". It was not interpreted that this "clean-up" was exclusively radioactive decontamination, but rather simply a clean-up of the mess that was present, some decontamination and some non-radioactive clean-up. The inspector was notified the day after the event occurred. At that time the recovery operation was complete. Sufficient information was submitted by the licensee to close this event. A site visit was not deemed necessary.

Page E.3, File No. 6

a) "There was no written report by the inspector involved." There were two reports from two individuals involved in this incident in the file.

Page E.5, File No. 12

The type of investigation should be changed from "phone" to "site visit" as recorded in the file. The enforcement document in the file states that inspections were conducted by staff on 3/2/99 and 3/3/99.

Page E.6, File No. 14

Site of incident should be changed from "Not recorded" to "President's Island – Ergon" as recorded on the front sheet of the incident report.

#### Appendix F, Sealed Source & Device Casework Reviews

File No. 5

The telephone conversation clarifying certain details of the device was documented. No further letter documentation was considered necessary.