MDE

MARYLAND DEPARTMENT OF THE ENVIRONMENT
2500 Broening Highway • Baltimore Maryland 21224
(410) 631- 3000 • 1- 800 -633-6101 • http:// www. mde. state. md. us

Parris N. Glendening
Governor

Jane T. Nishida
Secretary

OCT 18 1999

Carl J. Paperiello, Deputy Executive Director for Operations
Materials, Research and State Programs
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

RE: Integrated Materials Performance Evaluation Program (IMPEP) Review of Maryland Agreement State Program during March 22-26, 1999

Dear Mr. Paperiello:

The United States Nuclear Regulatory Commission (USNRC) letter of July 6, 1999 to Maryland Department of the Environment Deputy Secretary, Arthur W. Ray, conveying the final report and findings of the Integrated Materials Performance Evaluation Program (IMPEP) review of Maryland's Radiation Program, has been referred to me for response. First, let me extend our appreciation to you and to the members of the IMPEP team for their comprehensive and thorough review of radioactive materials licensing and compliance activities in Maryland. We have reviewed the IMPEP team's final report of the March 22-26, 1999 MDE audit and are pleased that Maryland's Radiation Program was found to be both adequate to protect the public health and safety and compatible with NRC regulations.

One area in which the team noted a need for improvement is sealed source and device (SS&D) reviews. Maryland is committed to enhancing SS&D reviews to assure adequacy in areas of staffing, engineering review and overall technical sufficiency. Although Maryland is pleased with the end result of the IMPEP review, we would like to comment on the nature of the IMPEP audit of Maryland's SS&D program. Section 4.2.1 "Technical Quality of Product Evaluation Program", of the Maryland IMPEP report states that the review team identified "significant" deficiencies in Maryland SS&D sheets. Although we recognize the program's shortcomings and that there is a need to upgrade SS&D sheets, we do not believe that such issues constitute "significant" deficiencies. The record of such devices approved for distribution by Maryland reveals no radiation safety related difficulties, and this fact should be taken into account when characterizing elements of the SS&D program. There are more than 40 SS&D sheets currently in effect that Maryland has approved. The NRC IMPEP review is a performance – based evaluation and should consider factors such as the safety record of a state's program. In addition, while subjective judgment plays a role in the IMPEP review, it should be kept to a minimum. The critique of a state's program should be based on clearly articulated regulations or guidance. When a finding is based on an interpretation or performance on the part of the reviewer, it should be clearly stated as such. Under those circumstances, the characterization of the finding as a "deficiency" is inappropriate.

In addition to the SS&D issues, we intend to address the IMPEP team's recommendations in the area of licensing actions as well. The attached document entitled, Responses to 1999 IMPEP Recommendations constitutes Maryland's plan of action for both licensing and SS&D reviews.

We appreciate this opportunity to submit our responses to the IMPEP recommendation. Please contact me at (410) 631-3255 or Roland Fletcher at (410) 631-3300 if you have any questions.

Sincerely,

Ann Marie DeBiase

Ann Marie DeBiase, Acting Director
Air and Radiation Management Administration

AMD/RGF/jw

cc: Jane Nishida, Secretary, Maryland Department of the Environment
Arthur Ray, Deputy Secretary
Roland G. Fletcher, Program Manager III

Attachment: Responses to 1999 IMPEP Recommendations

RESPONSES TO 1999 IMPEP RECOMMENDATIONS

RECOMMENDATION 1

The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review.

RHP RESPONSE

The definition of person as given in Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) was revised by MDE's Waste Management Administration, in a manner acceptable to the NRC, and became effective June 28, 1999. A copy of the Maryland Register notice is attached.

RECOMMENDATION 2

The review team recommends that all inspection documentation be reviewed and signed by RHP management before the inspection correspondence is issued to the licensee.

RHP RESPONSE

As a result of NRC's recommendation, a goal has been established for inspectors to complete their reports within 10 days of the inspection date for non-complex licenses and to include a draft copy of the compliance letter, should one be needed, for review by the supervisor. For complex license inspections, a 30-day completion goal for inspection reports and compliance correspondence has been established, with appropriate sign off by the program manager.

RECOMMENDATION 3

The review team recommends that the State evaluate present and future staffing needs of the RHP and develop a strategy that will assure RHP's continued adequacy and compatibility.

RHP RESPONSE

Reassignment of positions within ARMA will result in an additional health physicist position being assigned to the licensing section. ARMA is also evaluating several options for obtaining engineering assistance in the review of SS&D applications.

RECOMMENDATION 4

The review team recommends that RHP management implement an action plan to reduce the number of backlogged licensing actions and set goals to improve the accuracy and overall technical quality of licenses.

RHP RESPONSE

RHP acknowledges the licensing backlog involving both renewal applications and routine amendment requests. The additional staff member mentioned above will target these areas. Additionally, a section supervisor will soon be designated giving the division chief a manager working in the licensing section to develop, evaluate and implement an action plan to reduce the backlogs and keep all future actions current. The plan will include goal setting to improve the technical quality and accuracy of licenses; biweekly meetings to address both IMPEP and other identified concerns and potential improvements; identification, evaluation and implementation of additional training; review and evaluation of monthly assignments of backlogged licensing actions; and the implementation of written license reviewer log books to facilitate the administrative overview of progress by the licensing section supervisor. We anticipate that this plan will be developed by October 15, 1999 and implemented by December 31, 1999.

RECOMMENDATION 5

The review team recommends that the State revise their allegation procedure to incorporate appropriate elements following NRC guidance documents.

RHP RESPONSE

RHP has reviewed NRC guidance documents regarding allegations. A new RHP allegation procedure has been drafted which addresses the IMPEP concerns and is consistent with the latest NRC guidance. The draft procedure is currently under review by the Maryland Office of the Attorney General to ensure compliance with Maryland statutory requirements. The AG's office anticipates completion of the review by September 24, 1999.

RECOMMENDATION 6

The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F for each registration certificate, and amend the registration certificates accordingly.

RHP RESPONSE

Sealed source and device certificates MD-1003-D-101-G and MD-1003-D-102-G are currently under review and will be modified in their entirety upon receipt and review of RHP requests for information from the manufacturer. The IMPEP audit concerns are being addressed in as indicated in the attached Response to Appendix F Comments.

RECOMMENDATION 7

The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrence review" in Management Directive 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device.

RHP RESPONSE

RHP will conduct a review of all of Maryland's SS&D sheets to identify potential missing information as defined by the prescriptive guidance in NRC's mandated document NUREG 1556 Volume #3 (July 1998). This review will be conducted with the goal of prioritizing those devices that may potentially have a higher safety risk. RHP's goal is to have all necessary modifications to Maryland sheets completed prior to NRC's one-year follow-up audit.

RECOMMENDATION 8

The 1996 IMPEP team recommended that an additional senior staff member be trained to perform the sealed source and device evaluations to supplement the program as it matures. The State had assigned an additional individual to the program who has completed one review to date and would also benefit from additional training and experience. The review team recommends that the State provide the staff additional training and experience in the review of sealed source and device applications and the drafting of registration certificates (including the guidance contained in NUREG 1556, Vol.3). This should include training and experience that will meet the qualification guidance found in Management Directive 5.6.

RHP RESPONSE See RHP Response to Recommendation # 3 and #4 above.

The individual filling this position will participate to the extent possible in the additional training of SS&D procedures through working directly with NRC's SS&D section at NRC Headquarters for a period of 2 weeks. MDE is also investigating the establishment of consulting service contracts with professional engineering firms or local universities to acquire mechanical engineering review of SS&D sheets. RHP staff is willing to group caucus with NRC Headquarters or other Agreement State SS&D staffs regarding the review of all past sheets for teaching purposes or provide said sheets for concurrence review.

With respect to the qualification guidance found in NRC Management Directive 5.6, we note that this guidance is currently under going review by an Agreement State/NRC working group. Therefore, we anticipate that the language in MD. 5.6 will be clarified so that the subjectivity, confusion, and ambiguity of the criteria are removed. Maryland intends to meet the training and experience guidance that results from the NRC-OAS project.

RECOMMENDATION 9

The MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report.

RHP RESPONSE

RHP's detailed response to IMPEP Review comments is contained in the Attached Response to Appendix F Comments.

RESPONSE TO APPENDIX F COMMENTS

MD-1003-D-101-G

A. The status of the deficiencies identified during the previous IMPEP is as follows:

1. **NRC:** The attachment marked as **CONFIDENTIAL** in 1996 is still marked **CONFIDENTIAL.**

   RHP: The **CONFIDENTIAL** label was inadvertently left on the attachment in the file after the manufacturer had approved the attachment for general certificate distribution. This sheet is currently being reviewed for modification in its entirety. The **CONFIDENTIAL** marking will be removed as part of that process. Given the facts, this finding is not a safety-related issue.

2. **NRC:** The Quality Assurance program was submitted by the registrant but the QA program is still not referenced in the registration certificate.

   RHP: Maryland will conduct an additional review of the manufacturer's current Quality Assurance/Quality Control (QA/QC) program against Regulatory Guide 6.9. The current QA/QC program will be referenced in the upcoming modification of the sheet. Given the facts, this finding is not a safety-related issue.

3. **NRC:** The issue that source exchanges should be performed by the manufacturer was not addressed.

   RHP: This issue will be closely reexamined and clarification will be made to the sheet, if necessary.

B. **NRC:** The description section of the registration certificate does not accurately describe the device. For example: (1) the registration certificate indicates a mylar cover and the application indicates a stainless steel cover; (2) the registration certificate indicates a source holder of aluminum and the application indicates acrylic; (3) the shutter material and workings are not adequately addressed; (4) the maximum air gap is not listed; and the "on" position indicators are not described.

   RHP: Each of these items will be reexamined and fully described in the new description section. Current device diagrams reveal that the cover of the shutter assembly is aluminized acrylic with the outer material of the assembly being stainless steel. Although not contained in the written description, the attached diagram clearly shows the air gap to be 0.5 inches and the location of the "shutter open" light.

C. **NRC:** The limited, hand drawn diagrams do not adequately show the critical safety components, materials of construction, methods of construction, or dimensions and tolerances of the device.

RHP: We agree that the hand drawn diagrams at issue were not adequate. The manufacturer has been put on notice to supply complete diagrams of all critical safety components with materials of construction, methods of construction and dimensions and tolerances. These diagrams will be evaluated during the modification process.

D. **NRC:** Some of the limitations found in the certificate do not follow the guidance "Limitations and Other Considerations of Use" found in NUREG-1556, VOL.3. For example: If sources need to be leak tested; where to wipe for the leak test should not be in the registration certificate; how the device should be transferred: installation and removal are not required by licensed personnel; and the retention of packaging materials should not be in the registration certificate.

RHP: The "Limitations and Other Considerations of Use" portion of this certificate will be reviewed against the NUREG-1556, VOL.3. Guidance. Maryland appreciates the specific and valuable comments made here. Since this level of expertise appears to be derived from direct, in-house NRC HQ SS&D training and operational procedures rather than the generic guidance Maryland was given to follow in Section 12.10 of NUREG-1556, VOL.3, there must be clarification on the criteria for evaluation.

E. **NRC:** The accessibility to the sources by the user, such as tamper resistant screws, is not described in the registration certificate.

RHP: This is a valid comment. It will be carefully reviewed during the sheet modification process.

F. **NRC:** The issue of locking the device in the open or closed position was not addressed by the applicant.

RHP: The device shutter operability is a function of the supplied air pressure. If there is insufficient pressure the shutter remains closed. The need for a locking device will be reexamined during the sheet modification process. Given the facts, this finding is not a safety-related issue.

G. **NRC:** Labeling on this device is made of plastic and the application states that the label will be attached to the source assembly. It is not clear if the label is on the inside of the device on the source assembly or on the outside of the device, how the words on the label are applied (e.g., engraved, etched, painted only), or where the label will be attached.

RHP: The manufacturer's submittal states that the label is applied on the top of the device. The labeling mechanism of the device will be reexamined and the labeling section of the certificate will be reworded and clarified to encompass all relevant aspects. Given the facts, this finding is not a safety-related issue.

H. **NRC:** Likely accident conditions are not addressed and no dose estimate was provided for cleaning the device.

RHP: Some likely accident scenarios were examined in 1996. All likely accident scenarios and dose estimates for routine and non-routine scenarios will be examined during the upcoming modification of this sheet.

I. **NRC:** In lieu of prototype testing, an engineering analysis was performed by the applicant, but it was not submitted and reviewed by the staff. In addition, the registration certificate states that the applicant "will closely observe performance," yet there is no description of how this observation will be performed and if the statement is enforceable.

RHP: This is a valid observation that will be carefully examined during the upcoming modification of this sheet.

J. **NRC:** The source listed on the registration certificate (IPL model BFI-90) is not registered on a separate sheet and there was no technical review performed on the source as part of this registration certificate. This could be an unapproved source.

RHP: The source manufacturer confirms that the above source (BFI-90) is a California registered sealed source. However, it appears that BFI-90 is a catalog designation with the actual source model designation, as defined on CA406S118S, being PHI-90 GFS Series. Any confusion regarding the model designation of the source will be clarified prior to the upcoming modification of the Maryland sheet.

K. **NRC:** The conditions of normal use are incomplete (e.g., "dry environment, does not address vibration or corrosive atmospheres).

RHP: Corrosive atmospheres and vibration limits will be evaluated during the upcoming modification of this sheet.

L. **NRC:** A quality control (QC) program was submitted after issuance of the certificate, but the certificate was not amended to include or reference the document. The QC program is complete, but there is a conflict of interest with the President, CEO, QA Manager, and head of production all being the same individual and only a limited number of people in the company.

RHP: The QC program will be reexamined in accordance with current guidance. As noted in the response to A.2, the QC program will be included in the modified sheet. With respect to the comment regarding conflict of interest, the fact that one individual holds several different titles is unavoidable in a company of this size. Given the facts, this finding is not a safety-related issue.

M. **NRC:** The surface dose rate is 1.8 rad/hr (beta) and 17 mrad/hr at 24 inches. These dose rates are higher than the typical generally licensed device.

RHP: Information submitted by the manufacturer regarding beta dose rates will be reexamined for sufficiency in accordance with American National Standards Institute (ANSI)

N538. The question of general licensing for this device will also be reevaluated. Of note is the fact that only two of these devices are currently in the public domain.

N. **NRC:** The certificate was amended shortly after issuance to correct "non-substantial errors," yet there is no mention of this in the certificate file. The RHP reviewers could not explain the changes.

RHP: This SS&D sheet was initially issued on January 16, 1996. A date error on the signature page resulted in the issuance of an amendment in its entirety on July 11, 1996. Given the facts, this finding is not a safety-related issue.

O. **NRC**: The primary RHP reviewer stated that some deficiencies were discussed with the applicant over the telephone, but there were no telephone records in either the certificate file or the license file.

RHP: All pertinent discussions with any applicant regarding aspects of the review process will be documented and maintained in the SS&D registration file.

MD-1003-D-102-G

A. **NRC:** No deficiency letters were found in the file. No documentation of telephone conversations discussing deficiencies.

RHP: A deficiency letter dated September 16, 1998 was found within the license folder. RHP is currently reorganizing all SS&D documentation to insure that the application, reviewer evaluation sheets, deficiency letters, responses to deficiency letters, all telephone communication with the licensee pertinent to application review and a copy of the final sheet (new, amended in entirety or correction) are filed in a consistent, easily retrievable manner. As you are aware, the telephone message logbook was maintained independently by the application reviewer. This logbook has unfortunately been lost. All telephone messages with the licensee pertinent to the application review process will be maintained in the above-described file. Given the facts, this finding is not a safety-related issue.

B. **NRC:** The source used in this device is registered on its own certificate with the American National Standards Institute (ANSI) classification of 77C33232. On the certificate for this device, the ANSI classification is listed as 77C66435. This classification was listed because a promotional page from the source manufacturer listed new test data. This classification cannot be used until the source's registration certificate has been amended or the information on the testing (procedures, results and passing criteria) is submitted and appropriately reviewed.

RHP: Since the source of this device has been approved under ANSI classification 77C33232, this is not a radiation safety-related matter. The manufacturer of the source did specify a new ANSI classification and listed results of tests passed for that classification. The IMPEP review was correct in that an inaccurate ANSI designation was inadvertently documented on the sheet. The device sheet will be modified to reflect the appropriate ANSI classification.

C. **NRC:** The registration certificate does not address whether cleaning the device is considered servicing the device (certificate limits servicing to specifically licensed entities). There was no dose estimate provided for this by the applicant, however the user's manual provides limited instructions on how to clean the surface where the source is located. The RHP needs to clarify with the applicant whether cleaning the device is considered servicing and if so what is the expected dose.

RHP: This question is a valid concern. RHP is in the process of clearly defining all roles of the manufacturer in regard to this generally licensed device. The device sheet will be modified to reflect those clarifications.

D. **NRC:** The source capsule is stainless steel and the rod that holds it in place is aluminum. These "unlike materials" could lead to corrosion of the source. (0.01 in Beryllium window).

RHP: RHP's initial review of the above factors revealed no likely failures due to interactions between these metals. However, this entire matter is being revisited and reevaluated to define interactions of these metals in both normal conditions and accident scenarios.

E. **NRC:** With respect to labeling of the device, the following issues were identified:

1) Registration certificate does not mention the two "Caution Radiation" labels on top of the device under the shutter:

2) The application and registration certificate list the label as durable metal, but the drawing in the application and registration list the label as being aluminum;

3) The application and registration certificate do not say how the label is attached, but the drawing indicates rivets are used;

4) The registration certificate does not say where the label is attached, however, the application says on the bottom of the device.

5) The registration certificate does not mention that the label includes the isotope, activity , and the assay date; and

6) There is no paint on the label (is it etched only)

RHP: There are no radiation safety considerations to any of the above labeling comments. The device is appropriately labeled with the pertinent information in a visible location. There are no mistakes on the sheet on any of the labeling information. Specific comments are addressed below.

1) Item 10.4 NUREG-1556, Vol. # 3 says that the manufacturer must make the label visible and supply to the reviewer the location of the label(s). Item 12.4 does indicate a need to identify location of the labels. Of note, Figure C (which is part of the sheet) does indicate the location of these labels. For example Appendix H (page H-8) of the guide contains an example of the labeling section and incorporates the location of the label by reference to a diagram.

2) Item 10.4 NUREG-1556, Vol. # 3 states the preferred material of labeling is metal. The labels on this device are metal (aluminum), and are durable and should remain legible under normal working conditions for the life of the product.

3) The label diagram was submitted with the application and indicated that 4 rivets attach the label (one at each corner).

4) The SS&D sheet attaches diagram 1 to the labeling description. This method is no different than example Appendix H (page H-8) of the NUREG-1556, Vol. # 3 guide.

5) Certainly the label diagram is part of the certificate and clearly defines what is written on the label including isotope, activity and assay date.

6) Item 10.4 NUREG-1556, Vol. # 3 states that the preferred method for a metal label for a device is engraving or etching. The sheet clearly indicates that the label will be engraved or etched.

F. **NRC:** In lieu of prototype testing, an engineering analysis was performed and submitted by the applicant. The analysis was actually a "Reliability Analysis" which concentrated on determining the mean time between failure (MTBF). The analysis used general values for each critical component, not numbers specific to each actual component. There was no information provided on the spring other than there is one. The analysis did not address the typical conditions of use or likely accident scenarios, however, it did address vibration. A major concern with the reliability analysis was the result: The MTBF was just over 9 months for a device that is expected to last 10 years. The user's manual does not adequately address this situation. The analysis did not discuss the expected number of cycles the shutter would likely go through or the adequacy of the spring. No cycle, drop, impact, or vibration tests were performed and impacts on the device were only estimated by engineering analyses.

RHP: All areas pursuant to Item 10.5 "Prototype Resting" NUREG-1556 Vol. 3 guidance will be reevaluated for this device. Item 10.5 states that the applicant must adequately demonstrate that the product will maintain its integrity under normal conditions of use (as defined by the applicant) and likely accident conditions. The nature of the IMPEP comments suggests that the NRC is setting interpretive standards exceeding the guidance. It appears that the NRC has decided that an actual testing of a prototype along with a full-blown engineering analysis is the only acceptable method of prototype testing. To the contrary, Guidance Item 10.5 gives multiple options for appropriate evaluation of the integrity of a device. Also of note, the reviewer initially appears to state that no aspects of an engineering analysis were conducted, and yet in the last sentence makes reference to engineering analyses. The MTBF of 9-months for the device shutter was for a worse case scenario and was never intended to represent the normal working life of the device. The failure rate of the spring is calculated in its most conservative form and is included as one of the potential component failures of the device.

G. **NRC:** The engineering drawings provided are incomplete in that they do not include all the safety critical components (e.g., shutter, rotor, pneumatics and device frame). The clearance of the shutter, how the source is held in place, and the material of the window (mylar or beryllium) was not addressed.

RHP: The applicant supplied a detailed drawing with tolerances for source assembly to the device. RHP has directed the manufacturer to supply detailed engineering drawings for those additional safety critical components identified by the IMPEP reviewer.

H. **NRC:** With respect to dose estimates, the following issues were identified: (1) A justification duty factor of 0.1633 does not appear in the application. The application uses 0.1666 based

on the amount of time the shutter is likely to be open; and (2) The likely accidents were not provided in the application and the dose estimate provided is not specific to any type of accident.

RHP: RHP admits that this error occurred on the sheet. However, the difference between a duty factor of .1633 and .1666 is inconsequential. There is clear justification for the .1666 duty factor in the application. Dose estimates for a breached source accident were provided in the application. RHP will reevaluate this device against other likely accident scenarios.

I. **NRC:** The registration certificate limits removal of the device to the manufacturer or a specific licensee, yet the user's manual contains instructions for the user to follow for removal of the device.

RHP: Response combined with response to Item J.

J. **NRC:** Since the users of this device are generally licensed and are provided no radiation safety training, the accident procedures provided are inappropriate in that the user should not be touching the source breached or not.

RHP: (Answer to I & J) It is the intent of the manufacturer, as stated in the SS&D sheet, that the manufacturer conduct all device removals and handle any accident or emergency scenarios involving this device. RHP agrees that the user manual needs to be clarified in this regard. This clarification will occur during the upcoming modification of this sheet.

K. **NRC:** Conditions of normal use are incomplete ("dry" environment, does not address vibration or corrosive atmospheres).

RHP: Maryland will address vibration and corrosive atmospheres with the manufacturer.

L. **NRC:** The External Radiation Levels section of the Registration certificate, states that the instructions in the user's manual "prohibit personnel from being within a 5 feet radius of the gauge." It goes further to call it a 5-foot exclusion. The user's manual states that people "should" keep 5 foot away from the gauge – this is not a prohibition. The dose at 5 feet was used to demonstrate the less than 500-mRem limit on generally licensed devices. There is no barrier to prevent someone from entering the area.

RHP: A reevaluation of the justification for the distribution of this device for generally licensed recipients will be accomplished.

M. **NRC:** Details of the transfer, installation, and removal of the device do not follow the standard limitations found in NUREG-1556, Vol. 3.

RHP: NUREG-1556, Vol. 3. provides guidance on how limitations may read. The reviewer appears to be stating that all wording given in the limitation portion of an SS&D sheet must be standardized to NRC language. Whereas, NRC may prefer all language to be standardized, but it should be the prerogative of the Agreement State to word limitations in

accordance with their authority as long as it is not less restrictive. RHP will reevaluate all limitations given in this sheet to see if the NRC language would improve or clarify.

N. **NRC:** Attachment Figure E is labeled "confidential." It is not clear whether this drawing can be released to the public.

RHP: This is not a safety consideration, but is a valid observation from the IMPEP reviewer. In clarification, Figure E was created by the applicant and cleared for public release by the applicant prior to its distribution, however the confidential label was not removed. The confidential designation will be removed with the upcoming amendment of the sheet.

O. **NRC:** It is not clear whether the shutter can operate if the device is situated other than vertically, or if the spring is strong enough to return the shutter to the closed position if the device is horizontal.

RHP: The RHP will obtain clarification regarding the intended operation orientation of the device and clarification of operability of safety components if the device is not mounted in its intended orientation.

P. **NRC:** A deficiency letter was issued, but a copy was not in the file.

RHP: Same response as letter A.

Q. **NRC:** The primary reviewer mentioned that there had been numerous deficiency calls to the applicant and that he had documented them in a logbook. This logbook is missing.

RHP: Same response as letter A.

MD-263-D-102-G

A. **NRC:** The attachment to the application, dated October 9, 1997, and a deficiency response, dated January 14, 1998, could not be located in the file.

RHP: It is unclear which attachment the IMPEP reviewer is referring to. All four attachments to the October 9, 1997 application are present in the file and were available at the time of the IMPEP. The deficiency response does appear to be missing and a copy will be obtained.

B. **NRC:** It appears that the licensee did not respond to item 16 (servicing) in the reviewer's deficiency letter. The reviewer stated that this was addressed in later discussions with the applicant, however, there is no documentation in the file.

RHP: This issue was addressed during a December 9, 1997 meeting with the applicant. In the future all pertinent information and responses from the applicant received during meetings will be documented and placed in the application file.

C. **NRC:** The Description section of the registration certificate does not fully address how the source is held in place, the dimensions and materials of construction of the cell, how the source is attached to the device, the dimensions and materials of construction of the outer containers, the general differences between the various models, and the accessibility of the sources.

RHP: All of the above aspects of the device were thoroughly reviewed during the initial evaluation process. The scope of the description items, as listed above, appears to exceed the generic statements given in Section 12.3 of NUREG-1556 Viol 3. RHP will carefully review the application to determine whether additional wording is necessary.

D. **NRC:** The Conditions of Normal Use section of the registration certificate needs to be expanded (e.g., portable, fixed, vibration, humidity extremes), however, other sections of the registration certificate state that the devices are portable and can be fixed.

RHP: All of the above aspects of the device were thoroughly reviewed during the initial evaluation process. The scope of the Conditions of Normal Use, as listed above, appears to exceed the generic statements given in Section 12.3 of NUREG-1556 Viol 3. RHP will carefully review the application to determine whether additional wording is necessary.

E. **NRC:** Some limitations in the registration certificate do not follow the standard limitations found in NUREG-1556, Vol. 3 (e.g., "may" distribute to general licensees, transfer of device, servicing, leak test criteria of 0.005 microcurie).

RHP: The wording of the limitations will be reevaluated. To our knowledge there is no requirement that wording of limitations or even subject matter be verbatim to NRC guidance.

F. **NRC:** A sealed source registration certificate was listed as a reference in the Reference section of the registration certificate. Future changes to the source could result in changes to the registration certificate number (e.g., consolidation of registration certificates, and made inactive and then reactivated).

RHP: This appears to be more of a suggestion than a deficiency. RHP feels that this is a helpful comment and will take this into consideration for all SS&D sheets.

G. **NRC:** In the most recent reference document provided by the applicant, the applicant requested to add three new models. Additional information, such as statements as to the similarities to the other models, drawings of the outer cases with minimum dimensions, methods of fabrication, and materials of construction was not provided.

RHP: The only difference in the new model designations concerned outer case configurations. Additional information, regarding descriptions (similarities and dimensions) will be evaluated when obtained from the manufacturer for those outer cases not already in the file. Given the facts, this finding is not a safety-related issue.

MD-497-S-107-S

A. **NRC:** During a conversation with Nucletron during the summer of 1998, the State was informed that there was a difference in the diameters of the source wire. Specifically, the cable attached to the source capsule is 0.72 mm and this cable is welded to another cable that is 0.9 mm. Nucletron submitted an amendment request on July 20, 1998, however, the State has not amended the certificate. The State performed a review of the package, took into consideration that the cycle tests originally performed on the device were performed with this source, and determined that there was no safety significance to continued use of the sources currently in the possession of licensees. The amendment request contains cycle test data (passed) and other test data. This registration certificate and MD-497-D-108-S will be amended to address these changes. The drawing provided with the original application showed the different diameters, but did not show the weld on the two cables.

RHP: Cycle testing results for the source cable were submitted and evaluated with the initial device FDA 510K application information. This information was resubmitted and reevaluated in July 1998. Prior to the 1999 IMPEP, RHP had initiated with the manufacturer, a complete review of all the manufacturer's current sheets. This review was initiated pursuant to recent RHP concerns regarding the company's compliance with COMAR 26.12.01.01Section C.37(e) (10 CFR 32.210(f)). The above amendment request sheet will be addressed in accordance with the above review and ongoing compliance considerations.

B. **NRC:** The source registration certificate lists the maximum activity as 10 Ci. The high dose rate brachytherapy device model this source is used with lists its maximum activity as 12 Ci for storage until decayed to 10 Ci for use. Nucletron requested that this registration certificate be amended to increase the maximum activity to 12 Ci in an amendment requested dated July 20, 1998. The State has not amended the registration certificate.

RHP: This comment will be addressed as part of the review described in Item A.

C. **NRC:** In the Description section of the registration certificate, the metal plug and the metal flexible cable does not fully describe the types of materials and dimensions (i.e., stainless steel plug and cable).

RHP: The Description section will be modified to fully describe the types of materials and dimensions of all physical aspects of the above source.

D. **NRC:** A February 8, 1997 letter is not referenced in the Reference section of the certificate, even though it contains information on the dose rates at different distances.

RHP: The dose rates indicated above were in addition and in clarification of dose rates previously provided and referenced in the sheet. RHP will add this letter to this sheets Reference section.

E. **NRC:** Attachment I is labeled as proprietary. It is unclear whether this drawing can be released to the public.

RHP: RHP admits that the reviewer failed to remove the proprietary marking from the sheet prior to distribution. However, the manufacturer had approved the attachment for general certificate distribution. This sheet is currently being reviewed for modification in its entirety. The proprietary marking will be removed as part of that process. Given the facts, this finding is not a safety-related issue.

F. **NRC:** No cycle test results could be located in the file with application. The primary reviewer recalled seeing the results. Information on what types of tests to perform was found in the files (25,000 cycles straight and 1500 cycles through a 26-mm diameter ring). However, cycle test results were provided in the July 20, 1998 amendment request.

RHP: Cycle testing results for this source were available in the FDA 510K application which was concurrently submitted with the MD-497-D-108-S application. Though made available, the 510K information was not evaluated by the IMPEP reviewer.

MD-479-D-108-S

A. **NRC:** The drawings for this device do not show materials of construction or dimensions with tolerances. The sheet states that the treatment unit from the MD-497-D-104-S registration certificate can be used with this system as well as new treatment unit, but the new unit is fully not described in the certificate.

RHP: The MD-479-D-108 device is described in the description section as similar to the previously approved MD-497-D-104-S device (incorporated by reference) followed by description of those aspects that are different. This has always been an acceptable method of describing a device.

B. **NRC:** Although this model can use the existing treatment unit in the MD-497-D-104-S registration certificate, the source wire's diameter was decreased. This resulted in some changes in the device, as described in a deficiency response by the applicant. The applicant has not provided new drawings on this treatment unit.

RHP: This comment will be addressed as part of the review described in Item A.

C. **NRC:** The specific prototype tests performed (such as the cycle tests) are not included in the Prototype Testing section of the registration certificate.

RHP: Cycle testing was evaluated in accordance with the manufacturer's submittals. The Prototype Testing section will be reworded to include these results.

D. **NRC:** Documents submitted by the applicant dated February 6, 1997 and November 24, 1997 were not included in the References section of the registration certificate.

RHP: These documents will be added to the References section of the certificate.

E. **NRC:** The drawing of the source in the attachments is labeled as "proprietary." It is unclear as to whether this drawing can be released to the public.

RHP: RHP admits that the reviewer failed to remove the proprietary marking from the sheet prior to distribution. However, the manufacturer had approved the attachment for general certificate distribution. This sheet is currently being reviewed for modification in its entirety. The proprietary marking will be removed as part of that process. Given the facts, this finding is not a safety-related issue.