

January 30, 2002

MEMORANDUM TO: Martin J. Virgilio, Director  
Office of Nuclear Materials Safety and Safeguards

FROM: Carl J. Paperiello, Deputy Executive Director */RA/*  
for Materials, Research and State Programs

William Sinclair, Director */RA/*  
Division of Radiation Control  
Utah Department of Environmental Quality

SUBJECT: FINAL REPORT FOR THE INTEGRATED MATERIALS  
PERFORMANCE EVALUATION PROGRAM (IMPEP)  
REVIEW OF THE NRC SEALED SOURCE AND DEVICE  
EVALUATION PROGRAM

On January 8, 2002, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report of the NRC Sealed Source and Device (SS&D) Evaluation Program. The MRB found the NRC program to be adequate to protect public health and safety.

Section 3.0, page 7, of the attached final report presents the two good practices presented by the team and accepted by the MRB. There were no recommendations made by the review team. Based on your letter of December 3, 2001 which described your actions taken in response to the findings in the draft report, no additional information is required. The MRB accepted the team's recommendation to conduct the next IMPEP review in four years.

If you have any questions, please contact David Wesley, C.H.P., Chief, Radioactive Materials Licensing, California Department of Health Services at (916) 323-2759.

We appreciate your staff's efforts during the IMPEP review period, especially during the time of the team's visit.

Attachments:  
As stated

cc: Donald A. Cool, Director  
Division of Industrial and Medical Nuclear Safety  
Office of Nuclear Materials Safety  
and Safeguards, NRC

John Hickey, Chief  
Materials Safety Branch  
Office of Nuclear Materials Safety  
and Safeguards, NRC

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As stated

cc: See next page

Distribution: See next page

\*via e-mail sent to L. Rakovan, STP, attached.

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DATE	1/08/02*	01/11/02	01/16/02	01/30/02		

Martin J. Virgilio

-2-

STP-I-2

cc: Donald A. Cool, Director  
Division of Industrial and Medical Nuclear Safety  
Office of Nuclear Materials Safety  
and Safeguards, NRC

John Hickey, Chief  
Materials Safety Branch  
Office of Nuclear Materials Safety  
and Safeguards, NRC

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IMPEP File

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PDR (YES✓)

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NRC HEADQUARTERS

SEALED SOURCE AND DEVICE EVALUATION PROGRAM

SEPTEMBER 10-14, 2001

# FINAL REPORT

ORGANIZATION OF AGREEMENT STATES

## 1.0 INTRODUCTION

This report presents the results of the review of the Nuclear Regulatory Commission's (NRC) Sealed Source and Device (SS&D) Evaluation Program. The review was conducted during the period of September 10 - 14, 2001 by a review team comprised of technical staff from the Agreement States of California and Texas, and NRC's Office of State and Tribal Programs. Members of the review team are listed in Appendix A. The review was conducted in accordance with the November 5, 1999, NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of March 1, 1999 to September 14, 2001 were discussed with the NRC management on September 14, 2001.

A draft of this report was issued to the NRC for factual comment on November 6, 2001. Martin J. Virgilio, Director, Office of Nuclear Materials Safety and Safeguards (NMSS) sent factual comments by letters dated December 3, 2001. The Management Review Board (MRB) met on January 8, 2002 to consider the proposed final report. The MRB found NRC's SS&D Evaluation Program was adequate to protect public health and safety.

The NMSS Division of Industrial and Medical Nuclear Safety (IMNS) administers the SS&D evaluation program through the Materials Safety and Inspection Branch (MSIB). Section A (the Section), within the MSIB is responsible for conducting safety evaluations of sealed sources and devices that contain radioactive material regulated by NRC. An organizational chart is shown in Appendix B. The Section also conducts generic safety reviews of incidents and accidents where the failure of a source or device is suspected of being a contributing factor. The Section maintains a catalog of SS&D registration certificates for those sources and devices that have been determined to meet acceptable design criteria for licensing and use by individuals. The Section controls and allocates the vendor designation numbers for the registration certificates issued by the NRC and the Agreement States. The Section also distributes copies of completed registration certificates to the 32 Agreement State programs that license the use of the same devices.

In preparation for the review, a questionnaire addressing non-common performance indicator, Sealed Source and Device Evaluation Program, was sent to NRC on July 27, 2001. NRC provided a response to the questionnaire on August 21, 2001. A copy of the questionnaire response can be found on the NRC's Agencywide Document Access and Management System (ADAMS) using the accession number ML012330463.

The review team's general approach for conducting the review consisted of: (1) an examination of NRC's response to the questionnaire; (2) a review of selected safety evaluation casework, (3) a review of staffing and training, (4) a review of incident and allegation files, and (5) interviews with the staff and management to answer questions or to clarify issues. The review team evaluated the information it gathered against the IMPEP performance criteria for this non-common performance indicator and made a preliminary assessment of the NRC SS&D safety evaluation program.

The NRC's response to recommendations made following the previous IMPEP review for the non-common performance indicator, Sealed Source and Device Evaluation Program, are discussed in Section 2.0 below. The results of the current review are presented in Section 3.0

below. Finally, Section 4.0 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by the Section. A response is requested from the Section to all recommendations in the final report.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 30, 1999, five recommendations were made and transmitted to Dr. Carl J. Paperiello, Director, NMSS, on August 11, 1999. The team's review of the current status of these recommendations are as follows:

1. The review team recommends that checklists be used and retained in the SS&D file as recommended in Item 10, NUREG-1556, Vol. 3. (Section 2.1.1)

Current Status: During this review, all SS&D evaluations examined by the team included a checklist if it was reviewed after the effective date of their policy. This recommendation is closed.

2. The review team recommends that NRC conduct a review when registry certificates are updated to current standards and, in consultation with the Agreement States, and develop guidance, e.g., when they are reviewed. (Section 2.1.1)

Current Status: The existing guidance (NUREG-1556, Vol 3, Section 13) already requires a certificate to be amended in its entirety when safety issues are involved. Partial changes are accomplished when administrative issues are involved. When NUREG-1556, Vol. 3 is reviewed as a part of its normal revision cycle, the NRC will coordinate with Agreement States for input. This recommendation is closed.

3. The review team recommends that the working life of each product be routinely added to the Conditions of Normal Use on each registry certificate per Item 12.6 of NUREG 1556, Vol. 3. (Section 2.1.1)

Current Status: All SS&D evaluations reviewed by the team followed the NUREG 1556, Vol. 3 guidance concerning working life. This recommendation is closed.

4. The review team recommends that NRC, in consultation with the Agreement States, develop a process to identify and resolve areas of mutual concern in the SS&D review process. (Section 2.1.1)

Current Status: The NRC convened a working group on SS&Ds, including Agreement State representatives, and that group has issued its report. The NRC will also coordinate with the Agreement States when NUREG-1556, Vol. 3, is revised. This recommendation is closed.

5. The review team recommends that NRC should discontinue the practice of permitting individuals with restricted signature authority to sign as a second reviewer, and re-evaluate the remaining 7 certificates cosigned by staff members with limited signature authority. (Section 2.1.2)

Current Status: The Branch Chief, MSIB, reviewed the seven cases, and no safety issues were identified. The practice of issuing restricted signature authority has been discontinued. This recommendation is closed.

### 3.0 NON-COMMON PERFORMANCE INDICATOR - SEALED SOURCE AND DEVICE EVALUATION PROGRAM

The IMPEP process identifies five common and four non-common performance indicators to be used when reviewing Regional and Agreement State programs. This review was limited to evaluating the non-common performance indicator, Sealed Source and Device Evaluation Program.

In conducting this review, three sub-indicators were used to evaluate the NRC's performance regarding their SS&D Evaluation Program. These sub-indicators include: (1) Technical Quality of the Product Evaluation; (2) Technical Staffing and Training; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

#### 3.1 Technical Quality of the Product Evaluation Program

The team evaluated the SS&D technical quality in accordance with the guidance provided in MD Handbook 5.6. Ten case files were selected for review that included work performed by all reviewers. The cross-section sampling included the more complex evaluations completed by Section staff over the review period. The reviewed SS&D actions included new certificates, amendments, transfers, and inactivations. The SS&D certificates issued by the NRC that were evaluated by the review team are listed with case-specific comments in Appendix C.

The selected SS&D registration certificates and case files were reviewed for accuracy, appropriateness for authorization, tie-down statements, and overall technical quality. The casework was evaluated for timeliness, adherence to good radiation safety practice, acceptable engineering practices, reference to appropriate regulations, evaluation of safety evaluation reports, manufacturing Quality Assurance/Quality Control, supporting documents, peer and supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and other supporting data.

Analysis of the casework and interviews with staff and engineering technical support professionals confirmed that the NRC generally follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, issued in July 1998. All applicable and pertinent American National Standards Institute standards, NUREG-1556 Series, NRC Regulatory Guides, and applicable references were confirmed to be available and were used appropriately in performing the SS&D reviews. Appropriate review checklists were used to assure that all relevant materials were submitted and reviewed. The checklists are retained in the case files. Registrations clearly summarized the product evaluation and provided license reviewers with adequate information on areas requiring additional attention to license the possession, use, and distribution of the products. The team determined that product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of likely accidents.

Although it was clear that a second review had been performed in each case, it was not always clear what that second review had consisted of. In order to have a more complete record of the evaluation, the review team discussed with Section staff the benefits of detailing the second review with an additional checklist, or using a second set of initial blocks on the primary reviewers checklist.

The Section has recently developed a database entitled "National Sealed Source and Device Registry System" (NSSDR), to aid staff in effectively and efficiently finding specific information on SS&Ds. Section staff demonstrated the use of this database for the review team and the team found that the database allows the Section to retrieve information expeditiously. The newly developed SS&D database, NSSDR, which permits flexible searches based on manufacturer, model, nuclide, use, and other characteristics, is identified as a good practice.

Section staff also discussed with the review team their use of a spreadsheet to aid in SS&D file organization. The spreadsheet contains information on enclosed documents and like the database, aids Section staff in finding information expeditiously. The addition of a spreadsheet, listing the enclosed documents, at the front of the package of documents for a given action makes it much easier to review each package and find appropriate information, and is identified as a good practice.

Based on the IMPEP evaluation criteria, the review team recommends that NRC's performance with respect to the sub-indicator, Technical Quality of the Product Evaluation Program, be found satisfactory.

### 3.2 Technical Staffing and Training

The team evaluated the NRC SS&D program staffing and training in accordance with the guidance provided in MD 5.6. The Handbook indicates that SS&D staffing and training should be reviewed in the same manner as the common performance indicator, Technical Staffing and Training, except with a focus on training commensurate with the conduct of the SS&D reviews.

At the time of the review, the SS&D program staff consisted of nine individuals. Six were engineers, one was a health physicist, one an engineering co-op, and the other was an administrative assistant. Four of the engineers had full signature authority. These four, along with the administrative assistant, were on staff during the 1999 IMPEP review. The other three staff members were in training for SS&D evaluations and had no SS&D signature authority. Qualifications, including qualification journals, were reviewed for the three. One of the three was a qualified regional license reviewer who specialized in licensing the manufacture of exempt sources and devices. He had signature authority for licensing, but not for SS&D evaluation. The second was previously a journal qualified transportation packaging and dry storage system inspector. The third was a new hire in July with no previous experience.

During the review period, the SS&D program experienced turnover of engineering co-ops and summer hires only. At the time of the review, there were no vacant positions in the program.

The SS&D program was developing a qualifications journal addressing activities to be completed prior to obtaining SS&D signature authority. The training plan associated with the journal specified general and specialized training courses. It also required on-the-job

experience, including the performance of casework under the supervision of an experienced SS&D reviewer. NMSS is working to incorporate the training plan and qualification journal into Inspection Manual Chapter 1246.

Established qualifications for the technical positions include a baccalaureate degree or equivalent training in engineering, physical science, or other closely related discipline as evidenced by a bachelor's degree or equivalent combination of education, training, and experience. Individuals granted signature authority must be able to satisfactorily perform the competency elements established in MD Handbook 5.6, Part II, Section C.2.b. ii. The review team found the training program to be very thorough and sufficient to ensure that the SS&D evaluation program maintains a qualified staff.

Based on these findings, the team concludes that the staff training is adequate. Based on the observation that the staff is meeting its performance goals for product evaluations with respect to both timeliness and quality, the team concludes that the current staffing is adequate.

Based on the IMPEP evaluation criteria, the team recommends that NRC's performance with respect to the sub-indicator, Technical Staffing and Training, be found satisfactory.

### 3.3 Evaluation of Incidents and Allegations Regarding the SS&Ds

The review team used the guidance provided in MD Handbook 5.6 to evaluate the NRC SS&D program's handling of reported defects and incidents involving SS&Ds. The Handbook specifies that the review should be conducted in the same manner as the common performance indicator, Response to Incidents and Allegations. The IMPEP review should be conducted so as to determine if the evaluation of reported defects and incidents was sufficient to detect manufacturing problems or other root causes. The evaluation should also determine if other products may be affected by similar problems. Appropriate action and notifications should take place.

The review team discussed the 17 incidents identified in the questionnaire with the staff and management. The team reviewed the SS&D incident files, NMED reports, and the Generic Assessment Panel's records for seven specific events as discussed in Appendix D. The team was able to determine that NRC has a very strong incident and event reporting process, which the SS&D program fully participates in. Procedures are well and clearly understood by both management and staff and were followed in every case.

The team found that the SS&D program takes coordinated and timely action to track and resolve issues identified from incidents. The level of effort expended on resolving these issues is commensurate with the potential health and safety significance of the incident. Investigations appear appropriately thorough for the risks associated with the incident. Enforcement, or other corrective actions, appear to be promptly and accurately identified to NRC management, the Agreement States, and to NRC licensees and vendors.

The SS&D program staff may conduct site visits and accompany inspections of licensed activities and vendors as a tool to investigate SS&D incidents. The staff generally depends on regional inspectors unless circumstances or issues require special SS&D competency. The team notes that NRC usually depends on the source or device manufacturer to perform root

cause analyses. However, NRC can employ the services of a contractor to independently perform engineering analysis and testing to determine the principal cause of failure.

Records of the actions in response to an incident are typically distributed among several groups, (i.e., SS&D program, Generic Assessment Panel, Regional licensing programs, and possibly the Office of Enforcement and the Office of Investigations). Thus, a full audit of the records for completeness of actions and conformity to NRC procedures was beyond the scope of this review. For example, the team was unable to determine from the SS&D program records if corrective action was taken against licensees when the root cause of an incident was determined to be a performance failure by the licensee. Attempts in three cases to find documentation in ADAMS were only marginally successful.

Consistent with NRC practice, the SS&D program forwards allegations against SS&D vendors and suppliers to NMSS's allegation program. Some allegations are forwarded to the appropriate region for action. The response of the regional programs to allegations is reviewed during regional IMPEP reviews.

The review team discussed the findings of the NRC Allegations Program audit relative to allegations involving the SS&D program and discussed the SS&D allegations received with the NMSS allegations coordinator. Seven allegations were received during the review period, three of which were referred to the appropriate Region or Agreement State. Of the four handled by NMSS, two are closed. The open cases are of unusual complexity or recently received. The results of NMSS's investigation of the closed allegations were provided to the appropriate allegor.

Based on the IMPEP evaluation criteria, the team recommends that NRC's performance with respect to the sub-indicator, Evaluation of Defects and Incidents Regarding the SS&Ds, be found satisfactory.

#### 4.0 SUMMARY

As noted above, the review team recommends that the NRC's performance in the sub-indicators, Technical Quality of the Product Evaluation Program, Technical Staffing and Training and Incidents and Allegations Regarding the SS&Ds be found satisfactory. Accordingly, the review team recommended and the MRB concurred in finding the NRC's overall performance for the SS&D Program to be adequate to protect health and safety. Based on the results of the current IMPEP review, the review team recommended and the MRB concurred that the next review should be in approximately four years.

#### GOOD PRACTICES:

1. The newly developed SS&D database, NSSDR, which permits flexible searches based on manufacturer, model, nuclide, use, and other characteristics, is identified as a good practice. (Section 3.1).
2. The addition of a spreadsheet, listing the enclosed documents, at the front of the package of documents for a given action makes it much easier to review each package and find appropriate information, and is identified as a good practice. (Section 3.1).



## LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	NRC/NMSS/Materials Safety & Inspection Branch Organization Chart (ML013610693)
Appendix C	Sealed Source and Device Casework Reviews
Appendix D	Incident Casework Reviews
Attachment	December 3, 2001 Letter from Martin J. Virgilio NRC's Response to Draft IMPEP Report (ML013340261)

## APPENDIX A

### SS&D REVIEW TEAM MEMBERS

<b>Name</b>	<b>Area of Responsibility</b>
David Wesley, California	Team Leader Technical Quality of Product Evaluations
David Fogle, Texas	Technical Quality of Product Evaluations
Richard Blanton, STP	Technical Staffing and Training Response to Incidents and Allegations

APPENDIX B

Nuclear Regulatory Commission's  
Office of Nuclear Materials Safety and Safeguards'  
Materials Safety and Inspection Branch Organization Chart

ML013610693

APPENDIX B

NAMES AND POSITIONS OF CURRENT  
SEALED SOURCE AND DEVICE EVALUATION PROGRAM\*

Material Safety & Inspection Branch, Branch Chief  
*John Hickey*

Section A, Section Leader  
*Fritz Sturz*

Team Leader - SSD  
*John Jankovich*

- Registration Assistant  
Traci Kime
- SSD Reviewer  
Michele Burgess
- SSD Reviewer  
William Ward
- SSD Reviewer  
Seung Lee
- SSD Reviewer  
Ujagar Bhachu
- SSD Reviewer  
Anthony Kirkwood
- SSD Reviewer  
Jonathan Rivera
- Engr Co-op  
Nima Ashkeboussi

Attachment

December 3, 2001 Letter from Martin J. Virgilio  
NRC's Response to Draft IMPEP Report

ML013340261

Mr. David Wesley, CHP, Chief  
Radioactive Materials Licensing  
California Department of Health Services  
714/744 P Street  
P.O. Box 942732  
Sacramento, CA 94234-7320

December 3, 2001

Dear Mr. Wesley:

This refers to the draft report for the 2001 Integrated Materials Performance Evaluation Program (IMPEP) review of the U.S. Nuclear Regulatory Commission (NRC) Headquarters (HQ) Sealed Source and Device (SS&D) Evaluation Program that you sent to us with your letter dated November 6, 2001. We have reviewed the draft report and are providing comments in the Enclosure.

We appreciate the opportunity to participate in an independent review of HQ's implementation of the SS&D Evaluation Program. The review provided an opportunity for new insights on how we might improve our performance, as well as an opportunity to discuss with Agreement State representatives those initiatives which could result in improved effectiveness and efficiency in the materials program overall. I want to convey my staff's appreciation for the team's willingness to seek feedback from HQ staff and for the professional manner in which the review was conducted.

If you have any questions, please feel free to contact John Hickey, Chief, Materials Safety and Inspection Branch, at (301) 415-7231.

Sincerely,

*/RA/*

Martin J. Virgilio, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosure: Comments

cc: D. Fogle, Texas Dept. of Health  
R. Blanton, NRC/OSTP

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Enclosure

NRC Staff's Comments on Draft Report Entitled  
"Integrated Materials Performance Evaluation Program  
Review of NRC Headquarters  
Sealed Source and Device Evaluation Program  
September 10-14, 2001"

A. General Comments:

1. Draft Report Section 3.1, Paragraph 4.

IMPEP Audit Team's comment:

Although it was clear that a second review had been performed in each case, it was not always clear what that second review had consisted of. In order to have a more complete record of the evaluation, the review team discussed with Section staff the benefits of detailing the second review with an additional checklist, or using a second set of initial blocks on the primary reviewers checklist.

NRC's Response:

We agree with the Audit Team's comment. We will modify the checklist to include a space for both the first and the second, concurring, reviewers' initials.

2. Draft Report Section 3.3, Paragraph 5.

IMPEP Audit Team's comments on NRC's incident review:

Records of the actions in response to an incident are typically distributed among several groups, (i.e., SS&D program, Generic Assessment Panel, Regional licensing programs, and possibly the Office of Enforcement and the Office of Investigations). Thus, a full audit of the records for completeness of actions and conformity to NRC procedures was beyond the scope of this review. For example, the team was unable to determine from the SS&D program records if corrective action was taken against licensees when the root cause of an incident was determined to be a performance failure by the licensee. Attempts in three cases to find documentation in ADAMS were only marginally successful.

NRC's Response:

We agree with the Audit Team's comments. Prior to ADAMS, all records were in hard copy format. The Section did not duplicate records for incidents that we had reviewed for the Generic Assessment Panel (GAP) in the SS&D files. Upon completion of the safety assessment, the Section transferred the entire file, which comprised of the incoming event notification, correspondence, staff safety analysis, and close-out

memorandum (documents that are noted in the Comments above), to GAP. Therefore, the records were not available for the IMPEP audit team within NRC's SS&D system. To facilitate future audits and accessibility of records, we will open a folder for SS&D incident reviews in ADAMS, and keep records for all future incident reviews in the folder.

B. Specific Comments:

1. Appendix C, File Number 3.

IMPEP Audit Team's comment:

Other than second signature on registry sheet, documentation of concurrence review not in file.

NRC's Response:

We agree with the Audit Team's comment. See response to General Comment No. 1.

2. Appendix C, File Number 4.

IMPEP Audit Team's comment:

Other than second signature on registry sheet, documentation of concurrence review not in file.

NRC's Response:

We agree with the Audit Team's comment. See response to General Comment No. 1.

3. Appendix C, File Number 5.

IMPEP Audit Team's comment:

Other than second signature on registry sheet, documentation of concurrence review not in file.

NRC's Response:

We agree with the Audit Team's comment. See response to General Comment No. 1.

4. Appendix C, File Number 7.

IMPEP Audit Team's comment:

There are no limitations or considerations of use with regards to the apparatus which delivers the spheres [i.e. MDS Nordion Theraspheres] to the patient.

NRC's Response:

We agree with the Audit Team's comment. When the certificate was originally issued, it covered the spheres only, and not the delivery apparatus. The vendor has redesigned the delivery apparatus and requested an amendment on September 6, 2001. The next registration certificate, to be issued upon completion of the on-going safety review, will address the issue of the delivery apparatus.

5. Appendix C, File Number 8.

IMPEP Audit Team's comment "a.:"

This certificate was transferred from the state of Utah, so the full registry number was changed by converting agency code from Utah to the NRC, but there was no indication on the certificate that it formerly had that agency code.

NRC's Response:

We agree with the comment. The guidance on how to assign registration numbers (Appendix I, NUREG-1556, Vol. 3.) does not specify how to address previous registration certificate numbers in new certificates. In practice, both the NRC and the Agreement States frequently display the previous registration number in parenthesis under the new one. We will address the issue in the next edition of NUREG-1556, Vol. 3. In the meantime, we will issue a corrected page for NR-0569-S-101-S to indicate the earlier registration number in Utah.

IMPEP Audit Team's comment "b.:"

External radiation levels are generally calculated or measured at the maximum activity. The radiation levels for this certificate were calculated for 30 millicuries, while the maximum activity of the source was 80 millicuries.

NRC's Response:

We disagree with the comment. The certificate states that the vendor, Radiation, Safety & Nuclear Products (RSNP) "has the seeds irradiated in a reactor. Upon arrival at RSNP, each seed has a maximum activity of 80 mCi (2.96 GBq)." However, the 80 mCi activity decays in storage at the vendor's site before shipment to customers, and the actual activity to be used depends on the user hospital's request up to the maximum activity of 30 mCi (1.35 GBq). Therefore, the certificate specified the activity level for the user with 30 mCi. For the vendor, the external radiation levels can be calculated linearly.

6. Appendix C, File Number 9.

IMPEP Audit Team's comment:

Several documents were listed in the references which appear to be incorrect. A letter dated 7/26/99 was included but the only letter available with that date was one from the NRC. The reference was probably meant to have been a letter dated 7/21/99, however that letter was subsequently superseded by a letter dated 1/20/00.

NRC's response:

We agree with the comment. The date of 7/26/99 shown for one of the references in the registration certificate is a typographic error. The correct date is 6/21/99, as the comment above noted. We will issue a corrected page.

7. Appendix C, File Number 10.

IMPEP Audit Team's comment "a":

This certificate includes the model SIH-24, however, NR-355-D-106 includes the model SI series. Based on the model designation, it would seem that the model SIH-24 should be listed on NR-355-D-106 instead of NR-355-D-105.

NRC's response:

We disagree with the comment. The Model SIH-24 smoke detector had been listed in the earlier editions of both certificates. When we revised the amendments, dated December 7, 2000, we decided not to delete the listing of the Model SIH-24 from NR-0355-D-105-E because some users may have had their device registrations on file under this number. For clarification, we included a statement in both certificates which explains that "[a]s of December 1999, Hochiki America Corporation discontinued the manufacture of their products with the prefix of SIH-24..." The continued listing of the Model SIH-24 in both certificates is necessary for the users of the previously manufactured units. Since this model is no longer manufactured, but still in use, the certificates reflect the needs of the users correctly and should not be changed.

IMPEP Audit Team's comment "b":

The diagrams of an exempt device are not included.

NRC's response:

We disagree with the comment. Registration certificates for exempt products usually do not include diagrams. The certificate is in conformance with the guidance in NUREG-1556, Vol. 3, Appendix H (pp. H-17, H-18).

8. Appendix D, File Number 2.

IMPEP Audit Team's comments:

- a) No information in file to support the conclusions that licensee personnel damaged the cable, and that the cable was damaged by not following operating instructions.
- b) No copy of the INC root cause analysis referenced in file documents.
- c) The copy of the ~~May 13~~ **May 3**, 1999, memo from Jankovich to Combs is partially unreadable.
- d) Not able to find a file in ADAMS.

NRC's response:

We agree with the Audit Team's comment. See response above to General Comment No. 2 regarding maintaining records in SS&D files. We have also located, since the audit, a clear and readable copy of the memorandum dated May 3, 1999, noted above. We placed the document into the permanent record.

9. Appendix D, File Number 6.

IMPEP Audit Team's comments:

Per Generic Assessment Panel (GAP) records, the incident was closed 3/6/01 by the Materials Safety Inspection Branch-B Section Chief, but there was no copy in the SS&D file.

NRC's response:

We agree with the Audit Team's comment. See response above to General Comment No. 2 regarding maintaining records in SS&D files.

C. Editorial Comments

NRC's editorial comments are on the following pages. We have entered the changes in the text of the document below as ~~strike-outs~~ (for text to be removed) and **bolds** (for text to be added).