



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
WASHINGTON, D.C. 20565-0001

July 12, 1999

Mr. Floyd R. Hamiter, Chief  
Advanced Technology Licensing Project  
Division of Licensing, Registration and Standards  
Bureau of Radiation Control  
Texas Department of Health  
1100 West 49<sup>th</sup> Street  
Austin, Texas 78756-3189

Dear Mr. Hamiter:

This refers to the draft report for the 1999 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. We have reviewed the draft report and are providing comments related to the individual recommendations, along with our proposed actions, in Enclosure 1. Enclosure 2 provides our comments to Appendix C of the draft report.

We appreciate the opportunity to participate in an independent review of the 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 efficiency and effectiveness 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.

In addition to our comments on the individual recommendations, we suggest that your team consider removing Recommendations 5, 6, and 7 from the body of the report, and the ensuing list on page 7 of the summary section of the report. These three recommendations relate to the IMPEP process itself, and not the NRC SS&D program. As such, they should be segregated from those of a programmatic nature. We agree that these issues are important and should be addressed. In fact, an NRC/Agreement States working group will address these issues and make recommendations during the summer of 1999. In addition, they are agenda items for the next All Agreement States meeting in September 1999. Although recent events have prompted an increased focus on resolving these concerns, it should be noted that several vehicles currently exist to address areas of mutual concern, including: the monthly Organization of Agreement States (OAS) conference call, the quarterly IMPEP conference call, and the annual All Agreement States meeting.

If the team accepts our comments, only five recommendations (Nos. 1, 2, 3, 4, and 9) would remain. NRC has already taken action on those Recommendations, as indicated in Enclosure 1. Therefore, we suggest that indicator 2.1.1 should be revised to "satisfactory."

We would also like to address the recommendation in your cover letter "that the program be found adequate to protect public health and safety/adequate with recommendations for improvement." Your recommendation combines two findings as cited in the Handbook

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for Management Directive 5.6, Part IV. Our review of the handbook for MD 5.6 Part IV, paragraph (B), reveals three possible outcomes for overall adequacy findings for programs evaluated under the IMPEP process. Item (B)(1) (page 71) provides for a program to be found adequate to protect public health and safety even if one of the subindicators is found to be satisfactory with recommendation for improvement. In view of the nature of your findings, correction of factual statements, and our responses indicating implemented corrective actions, we request that indicator 2.1.1 be found as satisfactory, and the program finding be adequate to protect public health and safety.

Should you or the team have any questions concerning our comments, please contact Frederick Sturz of my staff at (301) 415-7273.



Carl J. Paperiello, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosures: As stated

F. Hamiter

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Should you or the team have any questions concerning our comments, please contact Frederick Sturz of my staff at (301) 415-7273.

Original signed by:

Carl J. Paperiello, Director  
Office of Nuclear Material Safety  
and Safeguards

Enclosures: As stated

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## COMMENTS TO RECOMMENDATIONS IN DRAFT REPORT

1. The 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)

Comment: We agree with this recommendation. Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted, that several of the SS&D cases identified by the IMPEP team were processed prior to our implementing the practice of routinely including the checklist in the files.

Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and, in particular, maintaining a checklist for all SS&D cases.

2. The team recommends that registry sheets be updated to current standards when they are amended. (Section 2.1.1)

Comment: We understand this recommendation to mean that as older registration sheets are amended, they should be revised in form and content to the "Standard Registration Certificate Formats" as recommended in NUREG-1556, Vol. 3, Appendix H. This would include providing missing information that previously was normally not included on the registration sheet. In so far as this relates to minor administrative matters, then we generally agree. Where this may imply a more substantial review of the registration sheet than requested by the amendment application then, as practicable (i.e., staff resource limitations or no unnecessary burden on the applicant), we will do this in order to provide consistency in registration sheets.

3. The team recommends that the working life of each product be routinely added to the Conditions of Normal Use on each registry sheet per Item 12.6 of NUREG 1556, Vol. 3. (Section 2. 1. 1)

Comment: We agree with this recommendation. We will ensure that all future registration certificates address working life in the Conditions of Normal Use, per format listed in Item 12.6 of NUREG 1556, Vol. 3. It is noted that the team identified this deficiency in only 5 cases of the 26 cases reviewed by the team. The SS&D staff discussed this finding and believe that the working life is typically placed on the registration certificates. In the three cited cases, there was no indication that the issue of working life was not addressed by the review, and the team's comments relate only to a documentation issue, i.e., the information not appearing on the certificate.

Perhaps NUREG-1556, Vol. 3, could be clearer concerning the types of devices in which the working life should be placed on the registration certificate. As a result, during the SS&D BPR Phase II, we will address the issue of working life to (1) provide additional clarification regarding whether working life should be addressed for all product types, (2) review the need to require that the text of the registration certificates address working life, and (3) review need to modify Item 12.6 in NUREG-1556, Vol. 3 to clarify this issue.

4. The team recommends that information pertinent to dimensions, materials, assembly, etc., be included in the SS&D registration sheet per Items 12.3 and 12.5 of NUREG 1556, Vol. 3. (Section 2. 1. 1)

Comment: We agree with this as a recommendation. In fact, the NRC currently includes this information on the certificates. Therefore, we do not believe this to be a deficiency. This issue was identified in only three of the 26 cases reviewed by the team (File Nos. 11, 13, and 14). In the cases in question, the description section in the registration certificate contains basic information, including overall dimensions, sufficient to assist an individual in identifying the device. The diagrams attached to the certificate illustrate the visual appearance of the device, the shutter mechanism, and its mounted configuration. This is in accordance with the guidance in the NUREG. No further action by the NRC is indicated.

5. The team recommends that NRC revise this indicator, incorporating lessons learned from other reviews, to make it more performance oriented. (Section 2. 1. 1)

Comment: We suggest that this issue be removed from the list of Recommendations due to the fact that this is outside the scope of MD 5.6 for the review of SS&D programs.

6. The team recommends that NRC, in consultation with the Agreement States, develop a performance based definition of concurrent review. (Section 2.1.1)

Comment: We suggest that this issue be removed from the list of Recommendations due to the fact that this is outside the scope of MD 5.6 for the review of SS&D programs.

7. The team recommends that NRC, in consultation with the Agreement States, develop a process for identifying and resolving areas of mutual concern in the SS&D review process. (Section 2.1.1)

Comment: We suggest that this issue be removed from the list of Recommendations due to the fact that this is outside the scope of MD 5.6 for the review of SS&D programs.

8. The team recommends that NRC discontinue the practice of granting restricted signature authority to SS&D reviewers. (Section 2.1.2)

Comment: We disagree with this recommendation. Granting restricted signature authority for SS&D reviewers is justified on a case-by-case basis. Inspection Manual Chapter (IMC) 1246 permits the use of interim qualification for 13 categories of license reviewers and inspectors. The current practice for SS&D reviewers, which is based on IMC 1246 format, permits the use of interim qualification, including granting restricted signature authority. IMC 1246 is being revised to clearly incorporate the qualification requirements for SS&D reviewers following the ongoing efforts of the NRC/Agreement States Working Group review of qualifications for SS&D reviewers among other issues.

It should be noted, prior to being granted restricted signature authority, the three reviewers had demonstrated qualification in all aspects of the MD 5.6 criteria (including the health physics categories of understanding of external dose rate, source activity, and nuclide chemical form). They received interim restricted signature authority rather than full signature authority, based only on the fact that they had not completed the Applied Health Physics course at Oak Ridge Associated Universities, which is an NRC training requirement.

9. The team recommends that NRC should discontinue the practice of permitting individuals with restricted signature authority to sign as a second reviewer. (Section 2.1.2)

Comment: We accept this recommendation. Please note that we discontinued this practice in March 1999. It was in place only for a 3-week period in February 1999 to allow processing of ongoing casework prior to the

departure of three reviewers to attend the five week health physics training course at Oak Ridge. A total of 10 cases were processed in this fashion. Three of the 10 cases (File Nos. 3, 16, and 24) were reviewed by the team and no safety issues were identified.

## APPENDIX C

### SEALED SOURCE AND DEVICE CASEWORK REVIEWS

**NOTE:** ALL CASEWORK FILES LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY: NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE REVIEW TEAM.

File No. 1

Registry No.: NR-121-D-103-S

Manufacturer: HQ AFMOA/SGPR

Date Issued: 1/15/98

SS&D Type: (Y) Calibrator

Model: D-0062

#### Comments:

- a) This is a "custom" device for all of the Department of defense and all of its contractors any place in the United States. NUREG-1156, Vol. 3, section 5.2 recommends that no more than two different NRC or Agreement State Licensees be listed as "custom" users of the same product.

#### NRC Response:

The Department of Defense is considered a single custom user for the purposes of these certificates. The certificates are used as a part of the Air Force's permitting process.

- b) This was an amendment to add another authorized sealed source in the device. There is no reviewer checklist to document the review process and demonstrate what items were considered.

#### NRC Response:

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- c) There is no discussion of QA/QC program or whether it is acceptable.

#### NRC Response:

This comment should be deleted. The policy for performing reviews is that the review is limited to the current action unless there is a health and safety issue that prompts re-review of past actions. The review in this case did not encompass review of the QA/QC program, therefore, this comment is not applicable to this report.

File No : 2  
Registry No.: NR-220-S-101-S  
Manufacturer: MDS Nordion Inc.  
Date Issue: 12/21/98

SS&D Type: (J) Gamma Irradiator, Category, I  
Model: Gammacell 40 & Gammacell Extractor

Comment:

- a) This was an amendment to modify the source movement mechanism. There is no reviewer checklist to document the review process to demonstrate what items were considered.

NRC Response:

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and in particular, maintaining a checklist for all SS&D cases.

File No.: 3  
Registry No.: NR-220-S-112-S  
Manufacturer: MDS Nordion Inc.  
Date Issued: 2/2/99

SS&D Type: (A) Industrial Radiography  
Model: C-337A

Comments:

- a) Correcting error generated in the previous amendment. NRC Form 567 (Request for Sealed Source and Device Evaluation) states in the NOTES that this is a continuation of action #98-70. However, there is no information in the folder concerning this action and the IMPEP review team was not able to request additional files.

NRC Response:

This action was to correct an editorial error, i.e., to replace the attachment. Therefore, it was the continuation of the previous action No. 98-70. Regarding the IMPEP review, please clarify whether (a) Docket No. NR-220-S-112-S, which is the permanent record, was not found or (b) the team did not ask for it.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. In this case, the use of a checklist was not warranted because the action was only administrative (ie., replacing the attachment).

File No.: 4

Registry No.: NR-0396-D-101-B

Manufacturer: Integrated Industrial Systems, Inc.

Date Issued: 3/18/98

SS&D Type: (D) Density Gauge  
Model: RSS-06

**Comment:**

- a) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

File No.: 5

Registration No.: NR-0504-D-111-B

Manufacturer: Nuclear Research Corporation

Date Issued: 1/28/99

SS&D Type: (D) Gamma Gauge  
Model: LS-101

**Comments:**

- a) Several statements in the registry sheet are incomplete sentences that bring into question the completeness of the review. For example, the last paragraph in the "Description" refers to the Model S-6 sealed source (as identified on the first page) as a source holder. This sentence also appears to be the combination of two sentences. The first sentence under "Prototype Testing" has two negatives. These errors bring into question the completeness of the review process. Also, there appears to be no evaluation of the Model S-6 sealed source.

**NRC Response:**

We will change the registration sheet as necessary to correct the confusing language. The S-6 is a source holder as specified in NR-504-D-109-B. This action was an

amendment and the S-6 source holder had been previously approved. Therefore, a review for the S-6 source holder was not performed again in this action.

- b) The applicant's letter dated December 19, 1997, indicates the inclusion of a QA program. However, there is no documentation of this item in the registry sheet.

**NRC Response:**

The QA program document was misfiled and is now in the correct file.

- c) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and in particular, maintaining a checklist for all SS&D cases.

File No.: 6  
Registry No.: NR-0701D103B  
Manufacturer: Metorex Inc.  
Date Issued: 3/18/98

SS&D Type: (U) X-ray Fluorescence  
Model: COURIER 20

No Comments.

File No.: 7  
Registry No.: NR-0701-D-104-B  
Manufacturer: Metorex Inc.  
Date Issued: 11/12/1998

SS&D Type: (U) X-ray Fluorescence  
Model: SIPS PROBE

**Comments:**

- a) In "Conditions of Normal Use," an expected life cycle of 5 years is presented. However, in "Prototype Testing" the device was tested to 300,000 ON-OFF cycles, which the registrant calculates to be more than 6 years at 8 hours per day. The expected life of the device was not clear.

**NRC Response:**

We disagree. Prototype Testing shows only that the device exceeds the expected life. The Conditions of Normal Use specifies the expected life for which the device was designed. It is noted that, although expected lifetime may be used to identify the need

for and frequency for required maintenance, it is not in itself an indication of a requirement to remove the product from service and is useful only as a reference.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and in particular, maintaining a checklist for all SS&D cases.)

File No.: 8

Registry No.: NR-1018-D-101-E

SS&D Type: (N) Ion Generator, explosives detector

Manufacturer: IDS Intelligent Systems

Model: Ion Mobility Spectrometer Detector Series

Date Issued: 12/20/96 (Corrected Pages 1, 2, 4, and 5 on 1/20/99)

**Comments:**

- a) In the original review, there was no indication on review sheet of the identity of the reviewer or when the review was performed.

**NRC Response:**

This comment should be deleted. Brian Smith performed a training review and John Lubinski and Steve Baggett signed the registration certificate as the first and the second reviewers, respectively. Training reviews are not considered part of the official review. The first and second reviewers review the application independent of any training review.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that the original SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file. Use of a checklist is not considered necessary for certificate changes that do not involve safety issues requiring an evaluation (see NUREG 1556, Vol. 3, Section 13.2).

- c) There was no recommended working life listed for this device.

**NRC Response:**

This comment should be deleted. This is an exempt product. Per standard format in NUREG-1556, Vol. 3 for an exempt product, the registration certificate does not contain the working life.

- d) There was no QA/QC Program discussed for this device.

**NRC Response:**

This comment should be deleted. This is an exempt product. Per standard format in NUREG-1556, Vol. 3 for an exempt product, the registration certificate does not contain the Quality Assurance and Control Section. However, a copy of QA/QC program is in the background file.

File No.: 9

Registry No.: NR-1025-A-101S

Manufacturer: International Radiography  
and Inspection Services Inc.

Date Issued: 4/17/98

SS&D Type: (A) Industrial Radiography

Model: Control Cable Housings

**Comment:**

- a) Although a copy of the appropriate ANSI Standard (N432-1980) was present in the file, there is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

File No.: 10

Registry No.: NR-0187-S-101-S

Manufacturer: Best Industries

Date Issued: 01/12/98

SS&D Type: Brachytherapy Source Seed

Model: 81 -01

**Comments:**

- a) The percent error for source loadings was not listed on the cover sheet.

**NRC Response:**

This comment should be deleted. The Maximum Activity is listed on the registration

certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.

- b) Brachytherapy sources in a ribbon should be exempt from leak testing. This sheet had a 6 month leak tests listed.

**NRC Response:**

This comment should be deleted. Leak test requirement is for the source, not for a ribbon. The applicant did not request an exemption for the sources because they are in a ribbon.)

- c) Registry sheet does not indicate if the manufacturer's quality assurance program met the guidelines in Regulatory Guide 6.9.

**NRC Response:**

This comment should be deleted. This is not a required statement on the registration certificate. This appears to be a checklist documentation issue. The QA program was reviewed and approved as evidenced by issuance of the certificate. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- d) There was no recommended working life listed for this source.

**NRC Response:**

We will ensure that all future registration certificates address working life in the Conditions of Normal Use, per required format listed in Item 12.6 of NUREG 1556, Vol. 3. The SS&D staff discussed this finding and believe that the working life is typically placed on the registration certificates. In this case, there was no indication that the issue of working life was not addressed by the review, and the team's comments relate only to the documentation issue of the information not appearing on the certificate.

- e) Limitations and/or Other Considerations of Use state that the source ribbon may deteriorate over time from exposure to radiation. It was not noted whether or not chemical affects to the source capsule as a result of this deterioration were considered.

**NRC Response:**

Deterioration was considered. The reviewer determined that the deterioration did not affect the source capsule. Because chemical affects were not a problem it was not necessary to document it in the certificate. As noted below ( item f) this is also a documentation problem related to the lack of a checklist in the file.

- f) No checklist was located in file indicating if key elements of NUREG-1 556, Vol. 3 had been considered during the review.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- g) The description indicates that this is a double encapsulated source. It is also stated that the ends are crimped to form a source. This does not appear to meet the definition of a double encapsulated source.

**NRC Response:**

This comment should be deleted. It is doubly encapsulated by cold weld (i.e., crimping) at each end as specified in description section.

- h) 08/15/1997 amendment addressed an increase in activity only; while no specific review is indicated, the previous description of the source appears to include provisions allowing an activity of 100 mCi; no mention of activity tolerance (+/-) in registry sheet.

**NRC Response:**

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the nominal activity and loading tolerance. This policy was discussed with the team during the IMPEP review.)

- i) 01/12/1998 amendment clarifies Conditions of Normal Use and Limitations and/or Other Considerations of Use that were not included in previous revisions, dating back prior to the beginning of this IMPEP review period.

**NRC Response:**

This is a comment only, therefore, does not constitute a deficiency.

- j) Letter dated 12/09/1997 refers to 06/23/1992 registration certificate, instead of the more recent 08/15/1997 certificate; This request appears to have been open for 5 years?

**NRC Response:**

This comment should be deleted. Turnaround time is not an IMPEP criteria for SS&D area.

- k) Difficult to follow correspondence documents because of duplicates and no apparent order.

**NRC Response:**

The file order is not an IMPEP criteria. We will reorganize the file during the next amendment.

- l) Letter dated 10/97, referenced in 12/09/1997 letter is not in file.

NRC Response:

We will obtain a copy of this letter to place in the file.

- m) There is no reviewer checklist to document the review process to demonstrate what items were considered.

NRC Response:

It duplicates item f) above.

File No.: 11

Registry No.: NR-1048-D-101-S

Manufacturer: SMV America

Date Issued: 11/12/98

SS&D Type: Transmission Attenuation Correction  
Source Holder Source

Model: PS 96

Comments:

- a) It is not apparent from the file that drop tests were performed to ensure that shutter failed in closed position.

NRC Response:

This comment should be deleted. The licensee did not perform prototype tests for this application, but substituted years of experience in France. Operational history of the product is acceptable by NUREG-1556, Vol. 3 in place of prototype testing.

- b) The ANSI standards suggest that isodose curves be reported at distances of 5, 30 and 100 cm. This registry sheet used 10, 40, 50 and 100 cm.

NRC Response:

This comment should be deleted. The subsection 12.8, "EXTERNAL RADIATION LEVELS" in NUREG-1556, Vol. 3 states that "**Ideally**, the radiation levels listed in this section will include the levels on contact with the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) From the product, and in the beam." Therefore, readings at 10, 40, 50, and 100 cm are permitted by NUREG-1556, Vol. 3.

- c) There is no reviewer checklist to document the review process to demonstrate what items were considered.

NRC Response:

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on

the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and in particular, maintaining a checklist for all SS&D cases.

- d) Registry sheet references a French quality assurance program. No indication is provided that this quality assurance program met the guidelines in Regulatory Guide 6.9.

**NRC Response:**

This comment should be deleted. The licensee provided additional QA commitments in e-mails dated November 4 and November 5, 1998, which are part of the permanent record. Such supplemental QA activities are routine for US distributors of products manufactured overseas. This appears to be a checklist documentation issue. The QA program was reviewed and approved as evidenced by issuance of the certificate.

- e) The diagrams should indicate overall dimensions, materials of construction (stainless, aluminum, etc.) and methods of assembly (type of weld used, tamper-proof screws, etc.).

**NRC Response:**

Currently, NRC includes this information on the certificates. Therefore, we do not believe this to be a deficiency. The description section in the registration certificate contains basic information, including overall dimensions, sufficient to assist an individual in identifying the device. The diagrams attached to the certificate illustrate the visual appearance of the device, the shutter mechanism, and its mounted configuration. This is in accordance with the guidance in the NUREG. No further action by the NRC is indicated.

File No.: 12  
Registry No.: NR-0112-D-102-B  
Manufacturer: Apgee Corp.  
Date Issued: 02/20/98

SS&D Type: Gamma Gauge  
Model: LB 7400 D&F Series

**Comments:**

- a) This registry sheet states that the device is designed to be locked in the open position. The burden for preventing this was placed on licensing and the end user. The burden for correcting this should be placed on the manufacturer in the form of a design change particularly for general licensed devices that have little regulatory oversight.

**NRC Response:**

This comment should be deleted. The locking mechanism was not a part of the amendment request reviewed by the IMPEP team. This design was reviewed and approved in 1983, and therefore is outside the scope of this IMPEP review. In addition, this is not a valid finding for the following reasons:

The certificate states that the devices may be locked in the open position, not that they are designed for this purpose. The certificate further states "General licensees are provided instructions from the distributor to not lock the device in the open position. Specific licensees should have in place appropriate procedures which will ensure the devices will not be locked in the open position." When this device was originally reviewed (1983) there was no requirement that gauges must not be able to be locked in the open position. ANSI N538-1979, "Classification of Ionizing Radiation Gauging Devices," was used as a guide for reviewing the gauge in the 1992 amendment. This classification standard states in section 3.4.1 that the "locking mechanism shall be operated only when the source is in the OFF condition." The procedural requirement placed on the users of the gauge meets this specification. In 1992, during review of an amendment to the certificate, this issue was identified and addressed with the applicant. There was, and continues to be, an insufficient basis to require the manufacturer to make a major modification to [retrofit] these devices so that they cannot be locked in the open position. Standard review practice is that procedural requirements may be considered in place of design changes to add additional safety features. This was done in this case, and the procedural requirement was authorized based on a review of the use conditions of the device and the potential for users to be exposed to the radiation beam as a result of a device being locked in the open position. Current guidance (NUREG-1556, Vol. 3) specifies that devices must not be able to be locked in the open position. This is our current guidance and all new applications are reviewed in this manner. In addition, if an existing device is identified that has a shutter that can be locked in the open position, it is reviewed to determine whether there is a sufficient basis to require a design change to prevent the shutter from being locked in the open, or if a procedural requirement would be sufficient.)

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- c) The labeling section of this sheet should be more descriptive in the language that will appear on the label. The regulations have been cited. The contents of the label should be specifically identified since manufacturers often substitute a logo for the company name or product codes for model numbers. This information is critical to field inspectors and incident responders.

**NRC Response:**

This comment should be deleted. The labeling section is sufficiently descriptive to provide inspectors and incident responders the information needed to perform their duties. For certain portions of the labeling, citing the regulations is all that is necessary. This allows the applicant flexibility as to the exact content and format of the information

contained on the labeling. However, where it was deemed important that additional information be specified concerning the labeling, this was done in the certificate. The applicant provided specific information concerning the design and construction of the labeling and this information is in the background file for this certificate. Referencing the letters in which this information was submitted requires that the applicant not deviate from the specifications provided and approved through the review. This includes information such as the company name and model number.

- d) There was no recommended working life listed for this device.

**NRC Response:**

We will ensure that all future registration certificates address working life in the Conditions of Normal Use, per required format listed in Item 12.6 of NUREG 1556, Vol. 3. The SS&D staff discussed this finding and believe that the working life is typically placed on the registration certificates. In this case, there was no indication that the issue of working life was not addressed by the review, and the team's comments relate only to the documentation issue of the information not appearing on the certificate.

File No.: 13

Registry No.: NR-0104-D102-S  
Manufacturer: Picker International  
Date Issued: 02/21/97

SS&D Type: Transmission Line Source Housing  
Model: PRISM 2000XP Step

**Comments:**

- a) The manufacturer committed to FDA's Good Manufacturing Practices for their quality assurance program. It was not apparent that this program had been reviewed against Regulatory Guide 6.9.

**NRC Response:**

This comment should be deleted. This is not a required statement on the registration certificate. This appears to be a checklist documentation issue. The QA program was reviewed and approved as evidenced by issuance of the certificate. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- b) The diagrams should indicate overall dimensions, materials of construction (stainless, aluminum, etc.) and methods of assembly (type of weld used, tamper-proof screws, etc.).

**NRC Response:**

This comment should be deleted. Currently, NRC includes this information on the certificates. Therefore, we do not believe this to be a deficiency. The description section in the registration certificate contains basic information, including overall dimensions, sufficient to assist an individual in identifying the device. The diagrams attached to the certificate illustrate the visual appearance of the device, the shutter mechanism, and its mounted configuration. This is in accordance with the guidance in the NUREG. No

further action by the NRC is indicated.

File No.: 14

Registry No.: NR-1032-D-101-S

Manufacturer: Elscint, Inc.

Date Issued: 10/24/97

SS&D Type: Transmission Line Source Housing

Model: Transact

Comments:

- a) There was no recommended working life listed for this device.

NRC Response:

We will ensure that all future registration certificates address working life in the Conditions of Normal Use, per required format listed in Item 12.6 of NUREG 1556, Vol. 3. The SS&D staff discussed this finding and believe that the working life is typically placed on the registration certificates. In this case, there was no indication that the issue of working life was not addressed by the review, and the team's comments relate only to the documentation issue of the information not appearing on the certificate.

- b) It was not apparent if dose rates "reported" were measured or calculated values.

NRC Response:

This comment should be deleted. This issue was reviewed with the team during the IMPEP review. Based on review of the file, it appeared that the rates were measured.

- c) The diagrams should indicate overall dimensions, materials of construction (stainless, aluminum, etc.) and methods of assembly (type of weld used, tamper-proof screws, etc.)

NRC Response:

This comment should be deleted. Currently, NRC includes this information on the certificates. Therefore, we do not believe this to be a deficiency. The description section in the registration certificate contains basic information, including overall dimensions, sufficient to assist an individual in identifying the device. The diagrams attached to the certificate illustrate the visual appearance of the device, the shutter mechanism, and its mounted configuration. This is in accordance with the guidance in the NUREG. No further action by the NRC is indicated.

File No.: 15

Registry No.: NR-0103-S-109-S

Manufacturer: BEBIG Trade, Inc.

Date Issued: 08/10/98

SS&D Type: Ophthalmic Brachytherapy Source

Model: SrO, A53

Comments:

- a) The percent error for source loadings was not included on the cover page of the registry sheet.

NRC Response:

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.

- b) It was not apparent if dose rates "reported" were measured or calculated values.

NRC Response:

This comment should be deleted. This issue was reviewed with the team during the IMPEP review. Based on review of the file, it appeared that the rates were measured.

- c) Registry sheet numbers go from NR-01 03-S-1 09-S to NR-01 03-S-1 08-S on the attachments.

NRC Response:

This comment should be deleted. Both NR-103-108 and NR-103-109 have the correct headings on all pages.

File No.: 16

Registry No.: NR-01056-D-101-S

Manufacturer: GammaMed

Date Issued: 02/25/99

SS&D Type: High Dose Rate Afterloaders

Model: GammaMed 12it & 12i

Comment:

- a) The manufacturer provides a portable interlock mechanism for this device that should be addressed in the registry sheet as part of the services provided.

NRC Response:

This comment should be deleted. In the registration certificate, the interlock is addressed. Specifically, in the second paragraph on Page 5 of 16, it states that "... each unit may be interlocked to the treatment room door. Therefore, any time the door would be opened, the source would automatically retract."

File No.: 17

Registry No.: NR-0220-S-103-S

Manufacturer: MDS Nordion

Date Issued: 12/21/98

SS&D Type: Gamma Irradiator Source

Model: C-188 (Series), Types 1-12; C-306 (series), 1-3

**Comments:**

- a) The percent error for source loadings was not listed on the cover page.

**NRC Response:**

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.

- b) No recommended working life was listed in the Conditions of Normal Use.

**NRC Response:**

We will ensure that all future registration certificates address working life in the Conditions of Normal Use, per required format listed in Item 12.6 of NUREG 1556, Vol. 3. The SS&D staff discussed this finding and believe that the working life is typically placed on the registration certificates. In this case, there was no indication that the issue of working life was not addressed by the review, and the team's comments relate only to the documentation issue of the information not appearing on the certificate.

- c) Limitations and/or other Considerations of Use should include a reference to water chemistry considerations for storage of these sources. At a minimum, would have expected a reference to 10 CFR 36.33. Manufacturer's often have additional limitations for storage conditions.

**NRC Response:**

This comment should be deleted. Corrosion issues for Irradiator sources are reviewed in accordance with 10 CFR 36.21(a)(4). 10 CFR 36.33 is addressed in licensing and is outside the scope of the SS&D review.

- d) Limitations and/or other Considerations of Use did not discuss provisions for transportation of these sources. Types of containers used and heat build-up during transportation were not addressed.

**NRC Response:**

This comment should be deleted. This is not an area that is addressed during an SS&D evaluation. Transportation issues are not normally addressed in the registration certificates. NUREG-1556, Vol. 3 does not list transportation issues. However, transportation issues are addressed only if they are part of the normal operating conditions for the device, such as radiography equipment or portable gauges. Regarding transportation, it is the licensee's responsibility to ensure that the conditions of use or limitations are not exceeded during transportation.

- e) There is no documentation of the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and in particular, maintaining a checklist for all SS&D cases.

File No.: 18

Registry No.: NR-0300-D-870-S

Manufacturer: Gamma Industries

Date Issued: 10/21/98

SS&D Type: Radiography Exposure Devices

Model: 180

**Comment:**

- a) No information or notes in file to support inactivation in accordance NUREG-1556, Vol. 3, Section 13.4.

**NRC Response:**

This comment should be deleted. The Model 180 device is no longer manufactured or distributed by Gamma Industries, Inc. and Gamma Industries, Inc. is no longer in business. The device was originally approved for licensing purposes by the Louisiana Division of Radiation Control. NRC attempted to obtain copies of all information submitted by the registrant in support of the evaluation. However, NRC could not locate all the information. Therefore, the registration certificate is being converted to an inactive registration certificate.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

This comment should be deleted. The Model 180 device is no longer manufactured or distributed by Gamma Industries, Inc. and Gamma Industries, Inc. is no longer in business. The device was originally approved for licensing purposes by the Louisiana Division of Radiation Control. NRC attempted to obtain copies of all information submitted by the registrant in support of the evaluation. However, NRC could not locate all the information so it was not practical to use a checklist.

File No.: 19

Registry No.: NR-0460-S-902-S

Licensee: 3M

SS&D Type: Radiography Exposure Devices

Model: 7B8L

**Manufacturer:**  
**Date Issued:** 01/26/96

No Comments.

**File No.:** 20  
**Registry No.:** NR-0122-D-101-S  
**Manufacturer:** BetaControl (formerly Baumer of America)  
**Date Issued:** 9/16/96; amendment: 11/1/1996

**SS&D Type:** Transmission Gauge  
**Model:** MK 1.0

**Comments:**

- a) Amendment added a new Sr-90 sealed source to the certificate. However, only page 1 was changed; some mention of the new source should be included elsewhere in the registry (i.e., in the Description at least).

**NRC Response:**

This comment should be deleted. The format for a device registration certificate includes listing sources used in the device on page 1 of the certificate. The description for a device certificate is used to describe the device, and unless there is a unique circumstance, descriptive information relating to the sources are not included in the description. In addition, information regarding when particular sources were approved for use in the device is typically not included in the certificate.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- c) No tolerance for source activity is listed on certificate.

**NRC Response:**

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.

**File No.:** 21  
**Registry No.:** NR-155-D-118-S  
**Manufacturer:** Department of the Army

**SS&D Type:** Chemical Agent Detector  
**Model:** M43A1

Date Issued: 07/28/1995

Comments:

- a) "Manufacturer" and "Distributor" appear to be switched on cover page (refer to first limitation, page 4 of 5)

NRC Response:

We will amend this certificate to correct this discrepancy.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

NRC Response:

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

File No.: 22

Registry No.: NR-348-D-109-B

Manufacturer: Hewlett Packard

Date Issued: 7/27/1995

SS&D Type: Gas Chromatography Detector Cell

Model: 19233/19235

Comments:

- a) No tolerance for activity is listed on certificate.

NRC Response:

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.

- b) Amendment request was submitted in 1992. Request was to combine two essentially identical detector cells into one certificate. Certificate was issued in 1995.

**NRC Response:**

This is a comment only, therefore, does not constitute a deficiency.

- c) No expected useful life is listed in the certificate.

**NRC Response:**

We will ensure that all future registration certificates address working life in the Conditions of Normal Use, per required format listed in Item 12.6 of NUREG 1556, Vol. 3. The SS&D staff discussed this finding and believe that the working life is typically placed on the registration certificates. In this case, there was no indication that the issue of working life was not addressed by the review, and the team's comments relate only to the documentation issue of the information not appearing on the certificate.

- d) While QA manual is referenced in certificate, it is not included in file.

**NRC Response:**

The QA program document had been misfiled and has been placed in the correct file.

File No.: 23

Registry No.: NR-0687-D-101-S

Manufacturer: Theratronics International, LTD

Date Issued: 3/12/1998

SS&D Type: Teletherapy unit  
Model: T1000, T1000E & Elite 100

**Comments:**

- a) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. It should be noted that this SS&D case was processed before MSIB implemented the practice of routinely including the checklist in the file.

- b) Letter dated November 24, 1997 from applicant is not in file; QA manual (Sept 29, 1997) is not in file.

**NRC Response:**

We will obtain a copy of letter and QA manual and place them in the file.

File No.: 24

Registry No.: NR-0687-D-105-S  
Manufacturer: Theratronics International, LTD  
Date Issued: 2/23/99

SS&D Type: Teletherapy Unit  
Model: Theratron 780 Series ( 780, 780C,  
T780E, Phoenix & Elite 80)

Comments:

- a) According to questionnaire, amendment was performed 3/12/1998; no information pertaining to this amendment was found in the file; volume 2 was found on the second request.

NRC Response:

We do not understand this comment and request clarification of this deficiency.

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

NRC Response:

Using and maintaining a checklist is a worthwhile practice. NUREG-1556, Vol. 3 was published as a final document in July 1998. Subsequently, in the Fall of 1998 the NRC staff commenced using a checklist and placing it in the docket files for all cases. Perhaps the guidance in Item 10, NUREG-1556, Vol. 3, is not as clear as it could be on the use of checklists. Therefore, during the ongoing SS&D BPR Phase II, we will examine the need to modify the existing guidance to clarify the importance of using and in particular, maintaining a checklist for all SS&D cases.

File No.: 25  
Registry No.: NR-1064-D-101-G  
Manufacturer: Advanced Gauging Technologies, LLC  
Date Issued: 01/11/1999

SS&D Type: Gamma Gauge  
Model: AGT 400

Comments:

- a) New device application.

NRC Response:

This is a comment only, therefore, does not constitute a deficiency.

- b) Certificate indicates QA/QC program on file with NRC, but information is not included in the device file.

NRC Response:

This comment should be deleted. The QA program document was in the device file.

- c) Certificate does not include tolerance on maximum activity (+/-); just indicates nominal activity.

**NRC Response:**

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.

File No.: 26

Registry No.: NR-8105-D-801-S

Manufacturer: ThermoRetec (formerly TMA/Eberline)

Date Issued: 01/05/1999

SS&D Type: Instrument Calibrator

Model: 8150-120-Cs

**Comments:**

- a) Certificate does not include tolerance on maximum activity (+/-); just indicates nominal activity.

**NRC Response:**

This comment should be deleted. The Maximum Activity is listed on the registration certificate (versus Nominal Activity), and by the definition of maximum, the Maximum Activity would include the maximum activity and loading tolerance. This policy was discussed with the team during the IMPEP review.)

- b) There is no reviewer checklist to document the review process to demonstrate what items were considered.

**NRC Response:**

This comment should be deleted. When the State of New Mexico relinquished its authority to conduct SS&D evaluations, the background files for this device were not transferred to NRC. Without the background files, it was not practical to use a checklist.

- c) No correspondence with applicant regarding inactivation. There is a final letter to applicant and no documentation of information requested by reviewer to support inactivation.

**NRC Response:**

This comment should be deleted. When the State of New Mexico relinquished its authority to conduct SS&D evaluations, the background files for this device were not transferred to NRC. A meeting was held at ThermoRetec on December 16, 1998 to discuss this device's current status. At the end of meeting, ThermoRetec requested this device be transferred to inactive status by the fact that this device and source are no longer manufactured by ThermoRetec and ThermoRetec does not have any intention to produce it in the future. The results of the meeting were documented in a letter to the applicant dated January 5, 1999.