JANE SWIFT
GOVERNOR

ROBERT P. GITTENS
SECRETARY

HOWARD K. KOH, MD, MPH
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Radiation Control Program
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August 15, 2002

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

Dear Mr. Lohaus:

The purpose of this letter is to respond to the draft Integrated Materials Performance Evaluation Program (IMPEP) report dated July 29,2002, which you forwarded to Dr. Howard K. Koh the Commissioner of the Massachusetts Department of Public Health (MDPH). This draft report documents the results of the Agreement State review held here at the Radiation Control Program (RCP) on June 24 – 28, 2002. Dr. Koh has asked me to respond directly to you on the draft IMPEP report and also to represent the MDPH at the Management Review Board (MRB) meeting.

On behalf of the members of the Radioactive Materials Unit of the RCP, I would like to take this opportunity to thank you and the members of the IMPEP Review Team for the positive nature of this draft IMPEP report. We would like to especially compliment Ms. Vivian Campbell, Region IV, Nuclear Regulatory Commission (NRC), who was the team leader for this Massachusetts review. We would also like to compliment the team for the very professional manner in which they performed their activities. The Massachusetts Review Team has both experience and expertise which in our opinion made for a very effective review process and a very positive learning experience for members of our staff. Of course, we are very pleased that the review team's proposed recommendations are that the Massachusetts Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's Program.

SP01

We appreciate the opportunity to comment on the draft report and look forward to the discussions with the Management Review Board and the final report. We have made a few comments and suggestions for corrections which are attached (Attachment A).

Sincerely,

Robert Walker

Robert J. Walker, Acting Director
Radiation Control Program

CC: Commissioner Howard K. Koh, MD, Mph
Nancy Ridley, Assistant Commissioner

ATTACHMENT A

Massachusetts Draft IMPEP Report 2002

There are a few minor corrections that need to be made to the draft report. We have crossed- out the text we think should be removed and redlined the new text we suggest to be incorporated or should affect your text.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on January 16, 1998, eight recommendations and two suggestions were made and transmitted to Dr. Howard K. Koh, Commissioner of the Department on April 15, 1998. The Management Review Board (MRB) directed that a follow-up review of the Sealed Source and Device Evaluation Program (SS&D) be conducted. The follow-up review was conducted during the period June 19- 21, 2000 and the results were transmitted to Dr. Koh on September 28, 2000. The follow-up review resulted in the closure of ~~two of~~ the eight recommendations and the addition of three new recommendations. The team's review of the current status of the recommendations is as follows:

3.4 Technical Quality of Licensing Actions

§ 4

The review team determined that the Program had been using draft NRC guidance for standard license conditions that was issued for comment in 1998. In the draft guidance, the requirement to hold waste for ten half-lives was not included in the decay-in-storage condition. The decay-in-storage condition in current guidance, NUREG 1556 Volume 20 issued in 2000, contains the requirement to hold waste for ten half-lives. The team examined licenses issued by the Program and noted that eight licenses reviewed contained a decay-in-storage condition which did not require the licensees to hold the waste for ten half-lives. The review team noted that the requirement to survey the waste prior to disposal in ordinary trash was present. In addition, the Commonwealth's regulations, 105 CMR 120.530(A), require that radioactive material be held for a minimum of ten half-lives and be monitored at the container surface before disposal. The equivalent regulation in the revised 10 CFR Part 35 (10 CFR 35.92) is silent on the "minimum of ten half-lives. 105 CMR 120.530(A) will be amended to reflect that the ten half-lives is guidance and not a regulation. Storage for decay is discussed extensively in our REGULATORY GUIDANCE NO. 1.1 "Regulatory Guidance For Low-Level Radioactive Waste Minimization". Storage for ten half-lives reduces the radioactivity to 0.1% the initial value. The review team concluded that the modified decay-in-storage did not present a health and safety or a regulatory issue. However, the review team discussed with Program management the possibility that the modified decay-in-storage condition could confuse licensees with regard to the requirements for disposal by this method. Program management did not agree with the review team and does not plan on modifying their decay-in-storage condition.

§ 5

The Program renews licenses every five years. The review team noted that licensing actions were promptly acted upon, usually within 30 days of receipt. The review team found that the Program staff routinely use detailed licensing checklists when reviewing licensing actions. All

licensing actions are reviewed by a primary license reviewer who closely monitors the timeliness of licensing actions. All completed licensing actions are then reviewed by a secondary license reviewer and the Licensing Supervisor. The Radioactive Materials Unit Supervisor reviews and approves all new licenses and is consulted and approves amendments. The Program Director conducts a secondary management review on selected actions and signs all licensing documents.

3.5 Response to Incidents and Allegations

§ 4

The primary responsibility for coordination of all incidents and allegations rests with the Event Coordinator and Allegation Coordinator, respectively. The initial response and follow-up to incidents and allegations involving radioactive materials are coordinated with the Licensing Supervisor and Radioactive Material Supervisor. Separate written procedures exist for handling incidents and allegations. The allegation procedure is currently being revised. The Program conducts onsite investigations for all incidents that present a potential or actual hazard to public health and safety. Prior to dispatching responders to the site, Program management is advised of all incidents and allegations reported and the planned response. Review of casework indicates that this approach provides effective and appropriate response actions and does not delay the response time. The procedure and report forms are available to the staff when responding to any incident, accident or emergency involving radioactive materials. All incidents and allegations are assigned individual docket numbers for tracking. The events are also entered in a local events database and assigned a sequential event number. Completed incidents ~~and allegation~~ docket files are placed in the corresponding licensee file. Completed allegation docket files are placed in a separate folder and maintained in a secured locked drawer.

4.2.1 Technical Quality of the Product Evaluation Program

§ 5

The team observed that registration certificate MA-1142-D-102-G failed to address an important redundant safety feature. The team noted that this device is manufactured in a foreign country and distributed domestically by a company in Massachusetts. The foreign manufacturer provided its QA/QC procedures in the application, however, the application did not contain QA/QC procedures for the domestic distributor. The team also noted that registration certificate MA-0116-102-B contained inconsistent radiological training requirements. The team recommends that the Program make corrections to registration certificates MA-1142-D-102-G and MA-0116-102-B.

[Comment: As explained during the IMPEP inspection, although the device in SSD Certificate MA-1142-D-102-G is manufactured in a foreign country, the device is, in fact, manufactured by the same company. Wallac Oy in Turku, Finland is wholly owned by PerkinElmer Life Sciences, Inc. The QA/QC procedures for the manufacturer and distributor, PerkinElmer Life Sciences, Inc., are on file. The title page states PerkinElmer with a sub title Wallac QA/QC]. This device is a liquid scintillation counter incorporating a 1µ Eu - 152 check source.

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: AEA Technology QSA, Inc. License No.: 12-8361
Location: Burlington, MA Inspection Type: Routine, Unannounced
License Type: Manufacturing and Distribution Broad Scope Priority: 1
Inspection Date: 7/17-18/01 Inspectors: ~~TG~~, JS AC

File No.: 2
Licensee: Biomeasure, Inc. License No.: ~~2-05391~~ 20-5391
Location: Milford, MA Inspection Type: Routine, Unannounced
License Type: Research and Development Priority: 3
Inspection Date: 4/5/02 Inspector: SL

Comment:
a) Citation wording in notice of violation did not follow standard enforcement language.

File No.: 3
Licensee: CIS-US, Inc. License No.: 60-0053
Location: Bedford, MA Inspection Type: Routine, Unannounced
License Type: Manufacturing and Distribution Priority: 2
Inspection Date: 4/4/02 Inspector: JD

File No.: 4
Licensee: Steris-Isomedix Services License No.: 28-7911
Location: Northborough, MA Inspection Type: Routine, Unannounced
License Type: Panoramic Pool Irradiator Priority: 1
Inspection Date: 4/1/02 Inspector: ~~TG~~ AC

File No.: 5
Licensee: Interstate Nuclear Services License No.: 03-5291
Location: Springfield, MA Inspection Type: Special, Unannounced
License Type: Nuclear Laundry Priority: 2
Inspection Date: 3/10/99 Inspectors: RG, RF

File No.: 6
Licensee: North Shore Medical Center License No.: 44-0161
Location: Salem, MA Inspection Type: Routine, Unannounced
License Type: Medical Institution-QMP required, Brachytherapy and Self Shielded Irradiator Priority: 3
Inspection Date: 4/2/02 Inspector: TC

File No.: 7
Licensee: Venegas Industrial Testing Labs
Location: Nashua, NH
License Type: Industrial Radiography
Inspection Date: 1/28/00
License No.: 56-0184
Inspection Type: Routine, Announced
Priority: 1
Inspector: RW

File No.: 8
Licensee: Delta Airlines
Location: Boston, MA
License Type: Industrial Radiography
Inspection Date: 3/20/01
License No.: 56-0270
Inspection Type: Routine, Announced
Priority: 1
Inspector: KM

File No.: 9
Licensee: New England Medical Center
Location: Boston, MA
License Type: Medical Institution Broad, Gamma Knife, HDR
Inspection Date: 9/18-19/00
License No.: 60-0160
Inspection Type: Routine, Announced
Priority: 1
Inspectors: GS, ~~TC~~ AC

File No.: 10
Licensee: Tufts University School of Medicine
Location: Boston, MA
License Type: Academic Broad Scope
Inspection Date: 10/28-29/99
License Nos.: 00-0450 & 60-0159
Inspection Type: Routine, Unannounced
Priority: 1
Inspector: MW

File No.: 11
Licensee: Medi-Physics dba Nycomed Amersham
Location: Woburn, MA
License Type: Nuclear Pharmacy
Inspection Date: 2/21/01
License No.: 58-0001
Inspection Type: Routine, Unannounced
Priority: 1
Inspectors: MW, JD

File No.: 12
Licensee: Gammamed USA
Location: North Andover, MA
License Type: Medical Products Distribution
Inspection Date: 12/17/99
License No.: 56-0267
Inspection Type: Routine, Announced
Priority: 3
Inspector: KT

File No.: 13
Licensee: Boston Biomedical Research Institute
Location: Boston, MA
License Type: Research and Development
Inspection Date: 2/2-3/99
License No.: 13-7482
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: MS

Comment:
a) Citation wording in notice of violation did not follow standard enforcement language.

File No.: 14
Licensee: Clark University
Location: Worcester, MA
License Type: Academic Type C Broad Scope
Inspection Date: 3/4/99
License No.: 02-2454
Inspection Type: Routine, Unannounced
Priority: 5
Inspector: RF

Comment:
a) Citation wording in notice of violation did not follow standard enforcement language.

File No.: 15
Licensee: Northeastern University
Location: Boston, MA
License Type: Academic Broad Scope
Inspection Date: 2/13/02
License No.: 06-4327
Inspection Type: Routine, Unannounced
Priority: 2
Inspector: MI

File No.: 16
Licensee: Mount Auburn Hospital
Location: Cambridge, MA
License Type: Medical Institution-QMP required, Brachytherapy
Inspection Date: 2/4/99
License No.: 44-0017
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: MB, GS

File No.: 17
Licensee: Anna Jaques Hospital
Location: Newburyport, MA
License Type: Medical Institution-QMP required
Inspection Date: 12/12/00
License No.: 44-0038
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: TB

File No.: 18
Licensee: Longview Inspection
Location: Wellesley, MA
License Type: Industrial Radiography
Inspection Date: 6/15/99
NRC License No.: 42-27593-01
Inspection Type: Reciprocity
Priority: NA
Inspector: RF

File No.: 19
Licensee: Massachusetts General Hospital
Location: Boston, MA
License Type: Medical Institution Broad
Inspection Date: 5/23/00
License No.: 60-0055
Inspection Type: Special, Announced
Priority: 1
Inspectors: JD, GS

File No.: 20
Licensee: John Turner Consulting
Location: Clemsford, MA
License Type: Portable Gauge
Inspection Date: 9/19/01
NH License No.: 423R
Inspection Type: Reciprocity
Priority: NA
Inspector: ~~TC~~
AC

File No.: 21
Licensee: J.L. Shepherd and Associates
Location: Lexington, MA
License Type: Service (source exchange)
Inspection Date: 2/8/00
CA License No.: 1777-19
Inspection Type: Reciprocity
Priority: NA
Inspector: KM

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were performed as part of the IMPEP review.

Accompaniment No.: 1
Licensee: Steris-Isomedix Services
Location: Northborough, MA
Type: Panoramic Pool Irradiator
Inspection Date: 4/1/02

License No.: 28-7911
Inspection Type: Unannounced, Routine
Priority: 1
Inspector: ~~TC~~
AC

Accompaniment No.: 2
Licensee: North Shore Medical Center
Location: Salem, MA
Type: Medical Institution-QMP required and Brachytherapy and Self Shielded Irradiator
Inspection Date: 4/2/02

License No.: 44-0161
Inspection Type: Unannounced, Routine
Priority: 3
Inspector: TC

Accompaniment No.: 3
Licensee: CIS-US, Inc.
Location: Bedford, MA
Type: Manufacturing and Distribution
Inspection Date: 4/4/02

License No.: 60-0053
Inspection Type: Unannounced, Routine
Priority: 2
Inspector: JD

Accompaniment No.: 4
Licensee: Biomeasure, Inc.
Location: Milford, MA
Type: Research and Development
Inspection Date: 4/5/02

License No.: 20-5391
Inspection Type: Unannounced, Routine
Priority: 3
Inspector: SL

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

File No.: 1
Registry No.: MA-0116-D-102-B
Manufacturer: Eurotherm Gauging Systems, Inc.
Date Issued: 10/3/00

SS&D Type: Beta Gauge
Model No.: HUB-77A

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3.,

as follows:

1) The first page of the certificate should read "CUSTOM DEVICE," not "CUSTOM USE."
2) The ISOTOPE and MAXIMUM ACTIVITY should be on the same line
3) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND/OR CONSIDERATIONS OF USE."
4) REFERENCES section should have the letter senders' names.
5) "DEVICE TYPE" should not be in Attachments

b) The checklist was not signed or dated by the primary or secondary reviewer.

c) The calibration information for the external radiation survey meter was not available in EXTERNAL RADIATION LEVELS Section.
[Comment: Although Section 12.8 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that calibration information for the survey instrument must be provided, it is agreed that this information is useful and will be requested.]

d) The "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE" section did not contain a limitation statement that preventive and corrective maintenance should be performed by the specifically licensed personnel.

e) The application stated that persons having limited training in radiological protection can safely operate the device. However, the certificate stated that the device can be safely operated by persons not having training in radiological protection. No substantial information was available to reach this conclusion.

File No.: 2
Registry No.: MA-1059-D-114-S
Manufacturer: AEA Technology plc
Date Issued: 11/7/01

SS&D Type: Calibrator
Model 773, 77314

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) This certificate is for device so the header should read "SAFETY EVALUATION OF DEVICE," not "SAFETY EVALUATION OF SEALED SOURCE."
   2) International System of Units and special units were not used consistently.
   3) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND/OR CONSIDERATION OF USE."
   4) DEVICE TYPE should not be in Attachments.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The label attachment method was not specified in the LABELING Section.
d) The amendment request letter dated July 26, 2001, was not specified in REFERENCES Section.
e) The superseded registration certificate NR-628-D-114-S was not converted to an inactive status.
   [Comment: The NRC/Division of Industrial & Medical Nuclear Safety has not verified that superceded registrations must be immediately converted to an inactive status.]

File No.: 3
Registry No.: MA-1059-S-276-S
Manufacturer: AEA Technology plc
Date Issued: 9/22/00

SS&D Type: Beta Source
Model No.: KAC.D1, KAC.D2, KAC.D3, KAC.D4, KAC.D5

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) The certificate is for a sealed source, and should read "SEALED SOURCE TYPE," not "DEVICE TYPE."
   2) This is a new certificate so it does not need "(AMENDED IN ITS ENTIRETY)" in the header.
   3) The certificate should read "CUSTOM SOURCE," not "CUSTOM DEVICE."
   4) International System of Units and special units were not used consistently.
   5) ISO standard was used, however, ANSI was cited in LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE and SAFETY ANALYSIS SUMMARY sections.
   6) REFERENCES section should have the letter senders' names.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) No statistical data was given to claim that the capsule can withstand an internal pressure of 50 atm with 90% confidence limit.
d) No calibration date was given for the external dose measurements.
   [Comment: Although Section 12.8 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that calibration information for the survey instrument must be provided, it is agreed that this information is useful and will be requested.]

e) The superseded registration certificate IL-136-S-240-S was not converted to inactive status.
[Comment: The NRC/Division of Industrial & Medical Nuclear Safety has not verified that superceded registrations must be immediately converted to an inactive status.]

File No.: 4
Registry No.: MA-1059-D-356-S
Manufacturer: Sirtex Medical Limited
Date Issued: 3/27/02
SS&D Type: Brachytherapy Afterloader
Model No.: SIR-Spheres

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) The certificate is for a device and should read "SEALED SOURCE TYPE," not "DEVICE TYPE" in the header.
   2) The certificate should read "MANUFACTURERS," not "MANUFACTURER," because there are two manufacturers.
   3) The sealed source model designation was not given in the first page.
   4) The certificate should read "CUSTOM SOURCE," not "CUSTOM DEVICE."
   5) The REFERENCES section should have the letter senders' names
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The instructions for handling and storing and the label information for the storage containment were not given in the LABELING Section.
[Comment: Section 12.4 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that instructions for handling and storing be identified in this section. Any specific instructions for handling and storing would more appropriately be identified in Section 12.10, "Limitations and Other Considerations of Use." Moreover, if there are no specific instructions for handling and storing, then no information would be required in those cases.]
d) The radiation profile measurement did not provide the survey meter information including calibration in EXTERNAL RADIATION LEVEL Section.
[Comment: Although Section 12.8 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that calibration information for the survey instrument must be provided, it is agreed that this information is useful and will be requested.]

File No.: 5
Registry No.: MA-1059-S-358-S
Manufacturer: AEA Technology QSA Inc.
Date Issued: 3/11/02
SS&D Type: Neutron Source
Model No.: AMN.V997, AMN.V340

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) The Certificate is for sealed source so it should read "SEALED SOURCE TYPE,"

not "SOURCE TYPE."
2) The Certificate should read "MANUFACTURERS," not "MANUFACTURER," because there are two manufacturers.
3) The Certificate should read "CUSTOM SOURCE," not "CUSTOM DEVICE."
4) International System of Units and special units were not used consistently.
5) The Certificate should read "LIMITATIONS AND/OR OTHER CONDITIONS OF USE," not "LIMITATIONS AND CONDITIONS OF USE."
6) This is a new certificate so it does not need "continue to" words in SAFETY ANALYSIS SUMMARY

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) For X1, the diameter was 7.85 millimeters in DESCRIPTION, however, it was 7.844 millimeters in ATTACHMENT.
d) The calibration information for the survey meter was not given.
[Comment: Although Section 12.8 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that calibration information for the survey instrument must be provided, it is agreed that this information is useful and will be requested.]
e) The superseded registration certificate NR-136-S-136-S was not converted to an inactive status.
[Comment: The NRC/Division of Industrial & Medical Nuclear Safety has not verified that superceded registrations must be immediately converted to an inactive status.]

File No.: 6
Registry No.: MA-1142-D-102-G
Manufacturer: Wallac Oy
Date Issued: 3/21/02
SS&D Type: Liquid Scintillation Counter
Model No.: 1220

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
1) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND OTHER CONSIDERATIONS OF USE."
2) "DEVICE TYPE" should not be in Attachments.
3) International System of Units and special units were not used consistently.

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) It was not clear why MD-0741-S-101-S was superceded because there was no amendment request from the distributor.
[Comment: The distributor, PerkinElmer Life Sciences, Inc., specifically requested this amendment by letter on February 7, 2002.]
d) Important features information such as overall dimension, manufacturers, models, operating pressures, filtration, relief valves, and reliability data for compressed air and pneumatic systems, on-off indicator, safety interlocks, fail-safe shutter, tamper-proof assembly methods, etc. were not given in the DESCRIPTION Section.
[Comment: This device contains a 1 microcurie Eu-152 source. This source is an exempt quantity. The external dose rate is less than 0.1 millirem per hour at 10 centimeters unshielded. Considerations for safety interlocks, fail-safe shutters, and

tamper-proof assembly methods were not considered necessary since the source is an exempt quantity with a dose rate that would not exceed regulatory limits for exposure, even in an unshielded condition. Specific data such as operating pressures, filtration, relief valves and reliability data for compressed air and pneumatic systems are manufacturer specific and were considered for the operation of this unit, although not specifically written into the certificate.]

e) The Drawing No. 10360835 was cited in the DESCRIPTION Section; however, Drawing No.10360835-A was provided in the application.

f) The label attachment method, size, and location were not given in the LABELING Section.

g) The Label # 2 should provide the name of distributor because the manufacturer is a foreign company.
[Comment: As previously described, the manufacturer is in a foreign country but is not a foreign company. Wallac is owned by PerkinElmer Life Sciences, Inc.]

h) The Drawing No. 10360835 in Attachment # 2 was cited in the DIAGRAM Section, however, the Attachment # 3 showed it as 1036354.

i) The survey meter information including calibration date was not given in EXTERNAL RADIATION LEVELS Section.

j) The foreign manufacturer provided its QA/QC procedures, however, there was no QA/QC procedures for the distributor located in the Commonwealth over the foreign manufacturer.
[Comment: As explained during the IMPEP inspection, although the device in SSD Certificate MA-1142-D-102-G is manufactured in a foreign country, the device is, in fact, manufactured by the same company. Wallac Oy in Turku, Finland is wholly owned by PerkinElmer Life Sciences, Inc. The QA/QC procedures for the manufacturer and distributor, PerkinElmer Life Sciences, Inc., are on file.]

File No.: 7
Registry No.: MA-1059-S-198-S
Manufacturer: AEA Technology, QSA Inc.
Date Issued: 9/25/01

SS&D Type: Neutron Source
Model No.: AMN.CYn

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) Certificate should read "SEALED SOURCE TYPE," not "SOURCE TYPE" in the first page.
   2) Use maximum, not nominal ± 10%, format for MAXIMUM ACTIVITY.
   3) International System of Units and special units were not used consistently.
   4) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND OTHER CONSIDERATIONS OF USE."
   5) On page 6 of 7, the section header and content is out of order.

b) The checklist was not signed or dated by the primary or secondary reviewer.

c) The survey meter information including calibration was not given in EXTERNAL RADIATION LEVELS Section.
[Comment: Although Section 12.8 of NUREG 1556, Volume 3, "Applications for Sealed

Source and Device Evaluation and Registration," does not specify that calibration information for the survey instrument must be provided, it is agreed that this information is useful and will be requested.]

File No.: 8
Registry No.: MA-1059-S-240-S
Manufacturer: AEA Technologies, QSA, Inc.
Date Issued: 10/30/01
SS&D Type: Neutron Applications
Model No.: AMN.PEn

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) The certificate should read "SEALED SOURCE TYPE," not "SOURCE TYPE."
   2) International System of Units and special units were not used consistently.
   3) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND OTHER CONSIDERATIONS OF USE."
   4) This is new certificate so it does not need "continue to" words in the SAFETY ANALYSIS SUMMARY section.
b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The isotope of reference source for AMN.PE2 and the calibration information for the survey meter were not given in EXTERNAL RADIATION LEVELS Section.
   [Comment: Although Section 12.8 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that calibration information for the survey instrument must be provided, it is agreed that this information is useful and will be requested.]
d) The containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in the certificate was missing in SAFETY ANALYSIS SUMMARY Section.
e) The reference dated February 26, 2002, was not cited, and the letter dated June 29, 2001, was cited twice in the REFERENCES Section.
f) The superseded registration certificate IL-136-S-240-S was not converted to inactive status.
   [Comment: The NRC/Division of Industrial & Medical Nuclear Safety has not verified that superceded registrations must be immediately converted to an inactive status.]

File No.: 9
Registry No.: MA-1059-D-802-S
Manufacturer: AEA Technologies, QSA, Inc.
Date Issued: 10/30/01
SS&D Type: Gamma Source
Model No.: BDC.L

Comments:

a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
   1) The certificate should read "SEALED SOURCE TYPE," not "SOURCE TYPE."

2) The PROTOTYPE TESTING section was incomplete.
3) International System of Units and special units were not used consistently.
4) The title should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND/OR CONSIDERATIONS OF USE."

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The limitation statement "The source shall only be distributed to persons specifically licensed by the NRC or an Agreement State" was missing in "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE.
d) The references dated March 28, 1984, and August 30, 1984, were not available.

File No.: 10
Registry No.: MA-1078-S-102-S
SS&D Type: Brachytherapy Source
Manufacturer: Implant Sciences Corporation
Model No.: 3500
Date Issued: 3/5/02

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
1) The certificate should read "MANUFACTURER/DISTRIBUTOR," not "MANUFACTURER/DISTRIBUTOR" in the Page 1 of 1.
2) Megabequerel was missing in the MAXIMUM ACTIVITY.
3) International System of Units and special units were not used consistently.
4) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND/OR CONSIDERATIONS OF USE."
5) REFERENCES section should have the letter senders' names.

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The instructions for handling and storing and the label for the storage container were not cited in the LABELING Section.
[Comment: Section 12.4 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that instructions for handling and storing be identified in this section. Any specific instructions for handling and storing would more appropriately be identified in Section 12.10, "Limitations and Other Considerations of Use." Moreover, if there are no specific instructions for handling and storing, then no information would be required in those cases.]
d) The reference dated January 22, 2002, was not available.
e) The cover letter dated February 18, 2002, stated that Model 3500 replaced Model 3000 (MA-1078-S-101-S). However, Model 3000 was not converted to inactive status.

File No.: 11
Registry No.: MA-1078-S-101-S
SS&D Type: Brachytherapy Source
Manufacturer: Implant Sciences Corporation
Model No.: 3000
Date Issued: 9/8/00

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:

1) International System of Units and special units were not used consistently.
2) The section head should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND CONSIDERATIONS OF USE."
3) REFERENCES section should have the letter senders' names.

b) The checklist was not signed or dated by the primary or secondary reviewer.
c) The instructions for handling and storing and the label for the storage container were not cited in the LABELING Section.
[Comment: Section 12.4 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that instructions for handling and storing be identified in this section. Any specific instructions for handling and storing would more appropriately be identified in Section 12.10, "Limitations and Other Considerations of Use." Moreover, if there are no specific instructions for handling and storing, then no information would be required in those cases.]
d) The letter dated June 6, 1999, was not available, however, the letter dated June 16, 1999, was available in the background file.

File No.: 12
Registry No.: MA-1059-S-336-S
SS&D Type: Gamma and beta line sources
Manufacturer: AEA Technology QSA Inc.
Model No.: AMC.LA1 and SIC.LA1
Date Issued: 3/27/01

Comments:
a) The registration certificate did not consistently follow the format in NUREG-1556, Vol. 3., as follows:
1) The certificate should read "SEALED SOURCE TYPE," not "SOURCE TYPE."
2) The certificate should read "MANUFACTURERS," not "MANUFACTURER" because there are two manufacturers.
3) The certificate should read "CUSTOM SOURCE," not "CUSTOM DEVICE."
4) International System of Units and special units were not used consistently.
5) The section header should read "LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE," not "LIMITATIONS AND/OR CONSIDERATION OF USE."
6) "SEALED SOURCE TYPE" should not be in Attachment.

b) The checklist was not signed or dated by the primary or secondary reviewer
c) The transport Holder Number was X0845 in DESCRIPTION, however, it was X8045 in ATTACHMENT.
d) The labeling attachment method and the size of label were not available in LABELING Section.
e) The handling instructions (ref HI001 or HI013) were not available in LABELING Section.
[Comment: Section 12.4 of NUREG 1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," does not specify that instructions for handling and storing be identified in this section. Any specific instructions for handling and storing would more appropriately be identified in Section 12.10, "Limitations and Other Considerations of Use." Moreover, if there are no specific instructions for handling and storing, then no information would be required in those cases.]

File No.: 13
Registry No.: MA-8114-D-801-G

SS&D Type: Beta gauge