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As filed with the Securities and Exchange Commission on December 29, 2010

Registration No. 333-169785

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**Amendment No. 3 to**

**FORM S-4**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**LANTHEUS MEDICAL IMAGING, INC.**

(Exact Name of Registrant as Specified in Its Charter)

<b>Delaware</b>	<b>2834</b>	<b>51-0396366</b>
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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**331 Treble Cove Road  
North Billerica, MA 01862  
(978) 671-8001**

(Name, address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

**Michael P. Duffy  
Vice President, General Counsel and Secretary  
331 Treble Cove Road, Building 600-2  
North Billerica, MA 01862  
(978) 671-8408**

(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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See Table of Additional Registrants Below

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**Copies to:**

**Todd R. Chandler, Esq.  
Heather L. Emmel, Esq.  
Weil, Gotshal & Manges LLP  
767 Fifth Avenue  
New York, New York 10153  
(212) 310-8000**

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**Approximate date of commencement of proposed sale of the securities to the public:  
As soon as practicable after the effective date of this Registration Statement.**

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If the securities being registered on this form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a  
smaller reporting company)

Smaller reporting company

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

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**The Registrants hereby amend this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrants shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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## **EXPLANATORY NOTE**

The sole purpose of this amendment is to amend certain exhibits to the registration statement as indicated in Item 21(a) of Part II of this amendment. No change is made to the preliminary prospectus constituting Part I of the registration statement or Items 20, 21(b), 21(c) or 22 of Part II of the registration statement. Accordingly, this amendment consists only of the facing page, this explanatory note and Item 21(a) of Part II and the signatures of the registration statement.

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**Table of Additional Registrants**

<b>Exact Name of Registrant as Specified in its Charter (Or Other Organizational Document)</b>	<b>State or Other Jurisdiction of Incorporation or Organization</b>	<b>I.R.S Employer Identification Number (If None, Write N/A)</b>	<b>Primary Standard Industrial Classification Code Number</b>	<b>Address, Including Zip Code, of Registrant's Principal Executive Offices</b>	<b>Telephone Number, Including Area Code, of Registrant's Principal Executive Offices</b>
Lantheus MI Intermediate, Inc.	Delaware	32-0225450	2834	331 Treble Cove Road, North Billerica, MA 01862	(978) 671-8001
Lantheus MI Real Estate, LLC	Delaware	61-1549164	2834	331 Treble Cove Road, North Billerica, MA 01862	(978) 671-8001

The name, address, including zip code, and telephone number, including area code, of the agent for service for each of the Additional Registrants is:

Michael P. Duffy  
 Vice President, General Counsel and Secretary  
 Lantheus Medical Imaging, Inc.  
 331 Treble Cove Road, Building 600-2  
 North Billerica, MA 01862  
 (978) 671-8408

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 20. Indemnification of Directors and Officers.

In addition to the information set forth below, we maintain director and officer liability insurance for ourself, and all of our subsidiaries, Lantheus MI Holdings, Inc. and Lantheus MI Intermediate, Inc.

Section 145 of the Delaware General Corporation Law (the "DGCL") grants each corporation organized thereunder the power to indemnify any person who is or was a director, officer, employee or agent of a corporation or enterprise, against expenses, including attorneys' fees, judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, other than an action by or in the right of the corporation, by reason of being or having been in any such capacity, if he acted in good faith in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

Section 102(b)(7) of the DGCL enables a corporation in its certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director to the corporation or its stockholders of monetary damages for violations of the directors' fiduciary duty of care, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL (providing for liability of directors for unlawful payment of dividends or unlawful stock purchases or redemptions) or (iv) for any transaction from which a director derived an improper personal benefit.

Section 18-108 of the Delaware Limited Liability Company Act provides that subject to such standards and restrictions, if any, as set forth in its limited liability company agreement, a limited liability company may, and shall have the power to, indemnify and hold harmless any member or manager or other person from and against any and all claims and demands whatsoever.

The certificate of incorporation of Lantheus Medical Imaging, Inc. provides that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. Lantheus Medical Imaging, Inc. maintains director and officers liability insurance for the benefit of its directors and officers.

The certificate of incorporation of Lantheus MI Intermediate, Inc. provides that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which the director derived an improper personal benefit. The certificate of incorporation also gives the corporation the power to indemnify any person who was or is a party or is threatened to be made a party to, or testifies in, any threatened pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature, by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, employee benefit plan, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding to the full extent permitted by law, and

the corporation may adopt by-laws or enter into agreements with any such person for purpose of providing such indemnification. Lantheus MI Intermediate, Inc. maintains director and officers liability insurance for the benefit of its directors and officers.

The limited liability company agreement of Lantheus MI Real Estate, LLC provides that none of the members or any officer of the company is liable to the company or any other person or entity that has an interest in the company for any loss, damage or claim incurred by reason of any act or omission performed or omitted by such party in good faith on behalf of the company and in a manner reasonably believed to be within the scope of authority conferred upon such party by the limited liability company agreement, except that such party will be liable for any such loss, damage or claim incurred by reason of his or her gross negligence or willful misconduct. The indemnity provided by the limited liability company agreement is provided only out of company assets, and that none of the members of the limited liability company has any personal liability related to such indemnity. Lantheus MI Real Estate, LLC maintains director and officers liability insurance for the benefit of its directors and officers.

**Item 21. Exhibits and Financial Statement Schedules.**

(a) Exhibits

<u>Exhibit</u>	<u>Description</u>
3.1†	Certificate of Incorporation of Lantheus Medical Imaging, Inc., as amended.
3.2†	Second Amended and Restated By-Laws of Lantheus Medical Imaging, Inc.
3.3†	Certificate of Incorporation of Lantheus MI Intermediate, Inc., as amended.
3.4†	First Amended and Restated By-Laws of Lantheus MI Intermediate, Inc.
3.5†	Certificate of Formation of Lantheus MI Real Estate, LLC, as amended.
3.6†	Limited Liability Company Agreement of Lantheus MI Real Estate, LLC.
4.1†	Indenture, dated as of May 10, 2010, among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC as guarantors, and Wilmington Trust FSB, as trustee.
4.2†	Registration Rights Agreement, dated May 10, 2010, by and among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc. and Lantheus MI Real Estate, LLC, as guarantors, and Jefferies & Company, Inc.
4.3†	Form of 9.750% Senior Notes due 2017 (included in Exhibit 4.1).
5.1†	Opinion of Weil, Gotshal & Manges LLP.
10.1†	Credit Agreement, dated May 10, 2010, by and among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc., Lantheus MI Real Estate LLC, the lenders from time to time party hereto, Harris N.A., as collateral agent, Bank of Montreal, as administrative agent, Bank of Montreal and NATIXIS as joint bookrunners, Bank of Montreal and NATIXIS as joint lead arrangers, NATIXIS as syndication agent and Jefferies Finance LLC as documentation agent.
10.2†	Pledge and Security Agreement, dated as of May 10, 2010, by and among Lantheus Medical Imaging, Inc., Lantheus MI Intermediate, Inc., Lantheus MI Real Estate, LLC and Harris N.A. as collateral agent.
10.3†	Advisory Services and Monitoring Agreement, dated January 8, 2007, by and between ACP Lantern Acquisition, Inc. (now known as Lantheus Medical Imaging, Inc.) and Avista Capital Holdings, L.P.

Exhibit	Description
10.4†	Amended and Restated Shareholders Agreement, dated as of February 26, 2008 among Lantheus MI Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain management shareholders named therein.
10.5†	Employee Shareholders Agreement, dated as of May 8, 2008, among Lantheus MI Holdings, Inc., Avista Capital Partners, L.P., Avista Capital Partners (Offshore), L.P., ACP-Lantern Co-Invest, LLC and certain employee shareholders named therein.
10.6†	Employment Agreement, dated January 8, 2008 by and between ACP Lantern Acquisition Inc. (now known as Lantheus Medical Imaging, Inc.) and Donald Kiepert.
10.7†	Employment Agreement, dated March 4, 2008 by and between Lantheus Medical Imaging, Inc. and Larry Pickering.
10.8†	Letter Amendment to Employment Agreement, dated January 4, 2010 by and between Lantheus Medical Imaging, Inc. and Larry Pickering.
10.9† *	Sales Agreement, dated as of April 1, 2009, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.
10.10† *	Amendment No. 1 to Sales Agreement, dated as of January 1, 2010, between Lantheus Medical Imaging, Inc. and NTP Radioisotopes (Pty) Ltd.
10.11† *	Manufacturing and Service Contract for Commercial and Developmental Products, dated August 1, 2008, between Lantheus Medical Imaging, Inc. and Ben Venue Laboratories, Inc.
10.12† *	Purchase and Supply Agreement, dated as of April 1, 2010, between Lantheus Medical Imaging, Inc. and Nordion (formerly known as MDS Nordion, a division of MDS (Canada) Inc.).
10.13† *	Amended and Restated Cardiolite License and Supply Agreement, dated January 1, 2004, by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC.
10.14† *	Amended and Restated Supply Agreement (Thallium and Generators), dated October 1, 2004, by and between Lantheus Medical Imaging, Inc. and Cardinal Health 414, LLC.
10.15† *	Agreement Concerning Cardiolite and Technelite Generator Supply, Pricing and Rebates, dated as of February 1, 2008, by and between Lantheus Medical Imaging, Inc. and UPPI.
10.16*	Distribution Agreement, dated as of October 31, 2001, by and between Bristol-Myers Squibb Pharma Company (now known as Lantheus Medical Imaging, Inc.) and Medi-Physics Inc., doing business as Amersham Health.
10.17† *	First Amendment to Distribution Agreement, dated as of January 1, 2005, by and between Bristol-Myers Squibb Medical Imaging, Inc. (formerly known as Bristol-Myers Squibb Pharma Company and now known as Lantheus Medical Imaging, Inc.) and Medi-Physics Inc., doing business as G.E. Healthcare.
10.18†	Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan.
10.19†	Amendment No. 1 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan.
10.20†	Amendment No. 2 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan.
10.21†	Form of Option Grant Award Agreement.
10.22†	Lantheus Medical Imaging, Inc. Employee Bonus Plan—2009.
10.23†	Lantheus Medical Imaging, Inc. 2009 Executive Leadership Team Incentive Bonus Plan.





Exhibit	Description
10.24†	Lantheus Medical Imaging, Inc. Severance Plan Policy.
10.25†	Letter Amendment to Employment Agreement, dated October 19, 2008 and effective as of January 1, 2009 by and between Lantheus Medical Imaging, Inc. and Larry Pickering.
10.26† *	Amendment No. 1 to the Amended and Restated Supply Agreement (Thallium and Generators), dated as of December 29, 2009.
10.27† *	Manufacturing and Supply Agreement, dated as of April 6, 2009, by and between Lantheus Medical Imaging, Inc., and Mallinckrodt Inc. (a subsidiary of Covidien PLC).
10.28†	Amendment No. 1 to the Manufacturing and Supply Agreement, dated as of August 2, 2010, by and between Lantheus Medical Imaging, Inc. and Mallinckrodt Inc. (a subsidiary of Covidien PLC).
10.29† *	Amendment No. 1 to the Agreement Concerning Cardiolite and TechnoLite Generator Supply, Pricing and Rebates, dated as of April 1, 2008.
10.30† *	Amendment No. 2 to the Agreement Concerning Cardiolite and TechnoLite Generator Supply, Pricing and Rebates, dated as of August 1, 2008.
10.31† *	Amendment No. 3 to the Agreement Concerning Cardiolite and TechnoLite Generator Supply, Pricing and Rebates, dated as of May 1, 2009.
12.1†	Statements re Computation of Ratio of Earnings to Fixed Charges.
21.1†	Subsidiaries of Lantheus MI Intermediate, Inc. and Lantheus Medical Imaging, Inc.
23.1†	Consent of Deloitte & Touche LLP Independent Registered Public Accounting Firm.
23.2†	Consent of Weil, Gotshal & Manges LLP (included as part of Exhibit 5.1).
24.1†	Power of Attorney.
25.1†	Form T-1 Statement of Eligibility under Trust Indenture Act of 1939 of Wilmington Trust FSB with respect to the 9.750% Senior Notes Due 2017.
99.1†	Form of Letter to Brokers, Dealers, Commercial Banks, Trust Companies and Other Nominees.
99.2†	Form of Letter to Clients.
99.3†	Form of Letter of Transmittal.
99.4†	Form of Notice of Guaranteed Delivery.

† Previously filed.

\* Confidential treatment requested as to certain portions, which portions shall be filed separately with the Securities and Exchange Commission.

## Item 22. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- i. To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

- ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
- iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

For the purpose of determining liability under the Securities Act of 1933 to any purchaser, the undersigned registrant undertakes that each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

For the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (1) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§ 230.424 of this chapter);
- (2) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (3) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (4) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes to respond to requests for information that is incorporated by reference into the prospectus pursuant to Items 4, 10(b), 11, or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

The undersigned registrant hereby undertakes to supply by means of post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant duly caused this Amendment No. 3 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of North Billerica, Commonwealth of Massachusetts, on December 29, 2010.

LANTHEUS MEDICAL IMAGING, INC.

By: /s/ DONALD R. KIEPERT

Name: Donald R. Kiepert

Title: *President and Chief Executive Officer*

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 3 to the Registration Statement has been signed by the following persons in the capacities indicated on the December 29, 2010.

<u>Signature</u>	<u>Title</u>
<u>/s/ DONALD R. KIEPERT</u> Donald R. Kiepert	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ ROBERT P. GAFFEY</u> Robert P. Gaffey	Vice President, Finance and Information Technology, Treasurer (Principal Accounting and Financial Officer)
<u>*</u> Larry Pickering	Director
<u>*</u> David Burgstahler	Director

\*By: /s/ MICHAEL P. DUFFY

*Attorney-in-Fact*

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant duly caused this Amendment No. 3 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of North Billerica, Commonwealth of Massachusetts, on December 29, 2010.

LANTHEUS MI INTERMEDIATE, INC.

By: /s/ DONALD R. KIEPERT

Name: Donald R. Kiepert

Title: *President and Chief Executive Officer*

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 3 to the Registration Statement has been signed by the following persons in the capacities indicated on the December 29, 2010.

<u>Signature</u>	<u>Title</u>
<u>/s/ DONALD R. KIEPERT</u> Donald R. Kiepert	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ ROBERT P. GAFFEY</u> Robert P. Gaffey	Treasurer (Principal Accounting and Financial Officer)
<u>*</u> Larry Pickering	Director
<u>*</u> David Burgstahler	Director

\*By: /s/ MICHAEL P. DUFFY

*Attorney-in-Fact*

**SIGNATURES**

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LANTHEUS MI REAL ESTATE, LLC

By: /s/ DONALD R. KIEPERT

Name: Donald R. Kiepert

Title: *President and Chief Executive Officer*

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<u>Signature</u>	<u>Title</u>
<u>/s/ DONALD R. KIEPERT</u> Donald R. Kiepert	President and Chief Executive Officer (Principal Executive Officer)
<u>/s/ ROBERT P. GAFFEY</u> Robert P. Gaffey	Treasurer (Principal Accounting and Financial Officer)
<u>/s/ DONALD R. KIEPERT</u> Donald R. Kiepert	President and Chief Executive Officer of Lantheus Medical Imaging, Inc., Sole Member

## Exhibit Index

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- 10.8<sup>†</sup> Letter Amendment to Employment Agreement, dated January 4, 2010 by and between Lantheus Medical Imaging, Inc. and Larry Pickering.
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10.20†	Amendment No. 2 to Lantheus MI Holdings, Inc. 2008 Equity Incentive Plan.
10.21†	Form of Option Grant Award Agreement.
10.22†	Lantheus Medical Imaging, Inc. Employee Bonus Plan—2009.
10.23†	Lantheus Medical Imaging, Inc. 2009 Executive Leadership Team Incentive Bonus Plan.
10.24†	Lantheus Medical Imaging, Inc. Severance Plan Policy.
10.25†	Letter Amendment to Employment Agreement, dated October 19, 2008 and effective as of January 1, 2009 by and between Lantheus Medical Imaging, Inc. and Larry Pickering.
10.26† *	Amendment No. 1 to the Amended and Restated Supply Agreement (Thallium and Generators), dated as of December 29, 2009.
10.27† *	Manufacturing and Supply Agreement, dated as of April 6, 2009, by and between Lantheus Medical Imaging, Inc., and Mallinckrodt Inc. (a subsidiary of Covidien PLC).
10.28†	Amendment No. 1 to the Manufacturing and Supply Agreement, dated as of August 2, 2010, by and between Lantheus Medical Imaging, Inc. and Mallinckrodt Inc. (a subsidiary of Covidien PLC).
10.29† *	Amendment No. 1 to the Agreement Concerning Cardiolite and TechneLite Generator Supply, Pricing and Rebates, dated as of April 1, 2008.
10.30† *	Amendment No. 2 to the Agreement Concerning Cardiolite and TechneLite Generator Supply, Pricing and

Rebates, dated as of August 1, 2008.

10.31† \* Amendment No. 3 to the Agreement Concerning Cardiolite and TechnoLite Generator Supply, Pricing and Rebates, dated as of May 1, 2009.

12.1† Statements re Computation of Ratio of Earnings to Fixed Charges.

21.1† Subsidiaries of Lantheus MI Intermediate, Inc. and Lantheus Medical Imaging, Inc.

23.1† Consent of Deloitte & Touche LLP Independent Registered Public Accounting Firm.

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<u>Exhibit</u>	<u>Description</u>
23.2†	Consent of Weil, Gotshal & Manges LLP (included as part of Exhibit 5.1).
24.1†	Power of Attorney.
25.1†	Form T-1 Statement of Eligibility under Trust Indenture Act of 1939 of Wilmington Trust FSB with respect to the 9.750% Senior Notes Due 2017.
99.1†	Form of Letter to Brokers, Dealers, Commercial Banks, Trust Companies and Other Nominees.
99.2†	Form of Letter to Clients.
99.3†	Form of Letter of Transmittal.
99.4†	Form of Notice of Guaranteed Delivery.

† Previously filed.

\* Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

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**CONFIDENTIAL TREATMENT REQUESTED**

**INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED  
AND NOTED WITH "\*\*\*\*\*",  
AN UNREDACTED VERSION OF THIS DOCUMENT HAS ALSO BEEN PROVIDED TO THE  
SECURITIES AND EXCHANGE  
COMMISSION.**

DISTRIBUTION AGREEMENT

This distribution agreement (this "Agreement") is entered into as of October 31, 2001 by and between Bristol-Myers Squibb Pharma Company, a general partnership organized under the laws of the State of Delaware ("BMS") and Medi-Physics Inc., doing business as Amersham Health, a corporation organized under the laws of the State of Delaware ("NA").

RECITALS:

BMS has developed and is the manufacturer of certain terminally sterilized Technetium (Tc-99m) generators, Gallium Citrate Ga-67 Injection, and Xe-133 gas products and possesses certain unique and valuable technology, know-how and other information relating to the manufacture and sales of such products.

NA is, among other things, presently engaged in the business of marketing and selling various radiopharmaceutical products and has substantial experience with respect thereto.

BMS desires to grant, and NA desires to obtain, under the terms and conditions of this Agreement, the right to purchase from BMS and the non-exclusive right to market, distribute and sell such generators, Gallium Citrate Ga-67 Injection, Xe-133 gas products and related accessory products in the territory as hereinafter defined.

NOW, THEREFORE, in consideration of the covenants and agreements hereinafter set forth, the parties hereto agree as follows:

ARTICLE 1. Appointment as Distributor

BMS hereby grants, to NA, under the terms and conditions of this Agreement, the non-exclusive right to market, distribute and sell the terminally sterilized Technetium (Tc-99m) generators, Gallium Citrate Ga-67 Injection and Xe-133 gas products and accessory products

hereafter identified on Exhibit A attached hereto (“Products”) in the \*\*\*\*, to include the \*\*\*\*. In addition BMS agrees to supply to NA Radiopharmacies in \*\*\*\*, solely for unit dose preparation in \*\*\*\*, those Tc-99m Generators, Ga-67 and Xe-133 Products listed on Exhibit A. NA Radiopharmacies in \*\*\*\* are defined as those entities in which NA has at least a \*\*\*\*% ownership position. In addition, BMS agrees to supply Products to those NA non-radiopharmacy accounts that are under contract on the date of this Agreement and listed on Exhibit F, until the expiration of such contract with the NA non-radiopharmacy account. Hereinafter, the term “Territory” shall refer to both \*\*\*\* and \*\*\*\* so described above.

## ARTICLE 2. Supply of Products

2.1 (a) BMS agrees to manufacture and sell to NA \*\*\*\* of NA’s requirements for Products and NA agrees to purchase \*\*\*\* of its requirements for Products from BMS.

(b) The parties are aware that BMS utilizes a \*\*\*\* source for supply of Mo-99, and that BMS is required to purchase \*\*\*\*% of its requirements of Mo-99m from that source. BMS agrees to use commercially reasonable efforts to find an established backup sources for Mo-99 in the event BMS’s supplier fails to provide BMS’s requirements.

2.2 All orders for purchases of Products by NA shall be submitted on NA’s standard purchase order form as from time to time in use by NA (“Purchase Order”). A copy of NA’s current form of Purchase Order is attached hereto as Exhibit B. The terms of this Agreement shall take precedence over any standard terms of any Purchase Order where in conflict.

2.3 Upon the Effective Date (as defined in Section 9.1 hereof) and no later than \*\*\*\* (\*\*\*\*) days prior to each \*\*\*\* during the term of this Agreement, each \*\*\*\* NA shall provide BMS with a written forecast of the numbers and type of Products which NA expects to purchase from BMS during the forthcoming calendar year, as the case may be (the “Annual Forecast”).

2.4 NA shall place firm Firm Orders, setting forth the quantities, delivery schedules and dates, and its shipping instructions on the Wednesday prior to the following Monday through Saturday shipping cycle. Once placed by NA, such Firm Orders may be increased or decreased only with prior BMS approval. Subject to NA's limited right to adjust Firm Orders set forth in the previous sentence, such Firm Orders shall constitute binding contractual obligations of NA.

2.5 Although an Annual Forecast or Quarterly Forecast shall not constitute a binding obligation upon NA to order the quantities specified therein, NA agrees to use all reasonable efforts to make each Annual Forecast and Quarterly Forecast a reasonably accurate prediction of the number and mix of Products NA will actually order for delivery in the relevant period pursuant to its Firm Orders.

2.6 BMS shall use commercially reasonable efforts to ship Products pursuant to NA's Firm Orders. Tc-99m generators shall be made available for shipment \*\*\*\* BMS facility, Billerica, MA each day of manufacture. Days of manufacture of Tc-99m generators are currently \*\*\*\*, \*\*\*\*, \*\*\*\*, \*\*\*\* and \*\*\*\*. Any BMS initiated, permanent changes in the manufacturing schedule shall be mutually agreed upon, prior to implementation. Xe-133 gas products shall be made available for shipment \*\*\*\* BMS facility, Billerica, MA each \*\*\*\* calibrated for the following \*\*\*\*. Gallium Citrate Ga-67 Injection products shall be made available \*\*\*\*, calibrated for the following \*\*\*\*. In the event BMS is unable to deliver all product requirements on a given day, BMS will allocate product to Nycomed in proportion to Nycomed's share of total demand. In the event that delivery of a Product is delayed more than \*\*\*\* hours past the agreed upon local delivery time, BMS will reduce the price NA pays for such Product by \*\*\*\*%. However, after \*\*\*\* (\*\*\*\*) hours delay, NA shall not be required to accept such Product and may make arrangements with BMS to return unopened Product for \*\*\*\* credit. The foregoing shall not apply to delays caused by *Force Majeure* events such as weather conditions, effecting transportation of components or Products, for which there will be no price reduction. Following the \*\*\*\* hour period outlined above, in the



event that NA is required to find an alternate source of Product, BMS shall pay the difference between BMS's price under this Agreement and the price NA is required to pay to obtain such Product, up to a limit of \*\*\*\*% of BMS's original price.

2.7 The purchase prices to be charged NA for calendar year 2001 are shown in Exhibit C1 and the mechanism to calculate future pricing for each Product is set forth in Exhibit C2. Included in the prices of the Products are:

- (a) \*\*\*\* (\*\*\*\*) external generator shields per initial generator standing order (A25);
- (b) \*\*\*\* (\*\*\*\*) elution shields per initial generator standing order (A14);
- (c) \*\*\*\* (\*\*\*\*) packs of any combination of saline and evacs (A15, A17 or A3) per each received generator standing order.
- (d) BMS assures that the prices charged to NA for each Product shall recognize NA's proportion of total BMS volume for each product.

2.8 Delivery of Products to NA hereunder shall be made by BMS via Federal Express, Priority Overnight Service from BMS's manufacturing facility located at 331 Treble Cove Road, North Billerica, Massachusetts. If so requested by NA, BMS will arrange for alternative shipment of Products in accordance with NA's shipping instructions contained in a Firm Order. NA shall reimburse BMS for the difference between Federal Express and any payments made to such alternative carriers by BMS on behalf of NA at the actual cost of such payments. BMS shall incur no liability of any nature whatsoever with respect to its performance of shipping duties on NA's behalf other than because of BMS's gross negligence.

2.9 All payments for Products by NA shall be made within \*\*\*\* (\*\*\*\*) days after receipt of invoice.

### ARTICLE 3. Distribution and Sale of Products

3.1 NA shall be responsible for compliance with all federal and state rules and regulations which relate to the sale, promotion, distribution, use and final disposition of Products

in the Territory. All communications that NA, its subdistributors, dealers, agents, or affiliates make about the Products in promotional materials or otherwise shall be consistent with the New Drug Applications or other governmental registrations for the Product, fully truthful, based on documented facts, and fairly balanced. NA, its subdistributors, dealers, agents, and affiliates shall not under any circumstances state or imply in promotional materials or otherwise that the Xenon gas vials purchased by NA hereunder can be used with Xenon gas delivery systems other than those purchased by NA hereunder. BMS agrees to supply \*\*\*\* \* (\*\*\*\*) Xenon gun per new customer.

3.2 NA shall ensure that BMS receives a copy of the license renewals or amendments of each NA customer to which Products are to be shipped directly by BMS authorizing their receipt and use of the Products in order to keep current BMS's present file of such licenses (other than in cases where the relevant regulatory authorities permit shipment notwithstanding the failure to supply or provide such copies). BMS shall not be obligated to ship to such NA customers and shall, immediately upon receiving the order from NA, verify the NA customer's licensed status and notify NA immediately if such inability to ship exists so NA may take such steps as are available to it to remedy the position. Such refusal to ship to a customer, whose license file in BMS's custody is not current and which defect is not remedied by NA, shall not be deemed an inability or failure on BMS's part to deliver Product in a timely fashion in order to meet NA's required deadlines.

3.3 NA agrees to provide to BMS copies of NA's initial promotional literature related to Products for BMS to transmit to FDA. BMS will play no role in obtaining approval of that material other than taking any administrative action necessary because of BMS's ownership of the registration.

3.4 NA shall have the sole right to determine the resale price, discount and any other terms and conditions for NA's resale of Products. NA shall have complete control over the manner and methods of the marketing, distribution and sale of Products, and NA may distribute and sell Products directly or through subdistributors, dealers, agents or its affiliates and may hire

or retain marketing or other experts to advise and assist NA in the distribution and sale of Products. Except as specifically stated herein, BMS shall play no role in NA's marketing, distribution and sale of Products.

3.5 Prior to use of any label, labeling, advertising or promotional item related to the Products (hereinafter referred to collectively as "Product Information") by NA, its subdistributors, dealers, agents, or affiliates, including but not limited to any package insert, product label, detail aid, direct mail piece, file card, journal article, or reminder advertisement, NA shall submit a sample of the Product Information to BMS for review. Provided, however that:

(a) NA shall not submit any information about pricing of Products to BMS. If a sample of Product Information contains pricing information, NA shall redact that information from the sample prior to providing it to BMS; and

(b) BMS shall review the Product Information solely for the following purposes: (1) to ensure compliance with the terms of BMS's New Drug Applications or other governmental registrations for the Products; (2) to ensure that the Product Information is within the terms of the labeled indications for the Products and is otherwise consistent with the approved package inserts for the Products; and (3) to ensure that the Product Information is not likely to give rise to any formal or informal action, complaint or comment by or from the United States FDA or the Canadian HPB regarding the Product Information or the Products; and

(c) Review by BMS of a sample of Product Information shall not serve as admission, a representation, or evidence thereof, by BMS, that the Product Information: (1) is correct, accurate, or complete; or (2) is within the scope of or consistent with the Product claims made by BMS; or (3) is in compliance with the terms of this Agreement. Review of Product Information by BMS shall not in any way alter or affect the indemnity given by NA pursuant to Section 6.5 hereunder.

(d) NA shall provide BMS a sample of all Product Information and BMS shall have fifteen (15) working days after receiving the sample within which to review and comment on the Product Information. All comments made by BMS shall be binding on NA, its

subdistributors, dealers, agents and affiliates; which shall implement and incorporate into the Product Information all comments made by BMS. If BMS does not respond within fifteen (15) working days, NA, its subdistributors, dealers, agents, or affiliates may use the Product Information unchanged.

3.6 As market considerations dictate, BMS and NA will consider the implementation of depleted Uranium shielded Technetium-99 Generators.

#### ARTICLE 4. Trademarks

4.1 BMS hereby grants to NA and NA hereby accepts the right to resell the Products supplied by BMS to NA in packages bearing the trademarks listed in Exhibit D ("Trademarks") and in promotional materials related to such Products. The rights granted NA hereunder to use the Trademarks shall in no way affect BMS's ownership of such Trademarks. No other right, title or interest in the Trademarks is established hereby, and nothing herein shall be construed to grant any right or license to NA to use the BMS logo or the BMS trade name, other than as specifically set forth herein. The parties agree and understand that this Section 4.1 does not expand the rights granted to NA under Article 1.

4.2 NA shall not make any use or take any action with respect to the Trademarks to prejudice or infringe BMS's rights thereto including the use of any confusingly similar trademark and shall forthwith, upon objection by BMS, desist from any use thereof or action therewith which is in violation of this Agreement.

4.3 NA will only market the Products using the relevant Trademarks during the term of this Agreement. Upon termination or expiration of this Agreement, NA will cease all use of the Trademarks and the license to use any such Trademarks granted hereunder shall immediately cease and be deemed canceled.

4.4 NA will use the Trademarks in strict accordance with the instructions given by BMS, and shall not make any changes in connection therewith without first obtaining BMS's written consent. NA further agrees that at all times the Trademarks shall be used in accordance with good trademark practice, including notation of the fact that they are trademarks belonging to BMS and use of the appropriate notice of registration. BMS reserves the right to unilaterally determine the adequacy of the use and protection given the Trademarks by NA as set forth herein.

4.5 NA shall promptly notify BMS, in writing, of any conflicting use of, and applications or registrations for, any of the Trademarks, or any acts of infringement, or acts of unfair competition involving the Trademark, after such matters are brought to its attention or it has knowledge thereof. NA further agrees to assist BMS, at BMS's expense, in registering or perfecting BMS's rights to the Trademarks in the Territory.

4.6 In the event of any claim or litigation by a third party against NA alleging that any of the Trademarks imitates or infringes a trademark of such third party or is invalid, NA shall promptly give notice of such claims or litigation to BMS and BMS shall assume responsibility for and control of the handling, defense, or settlement thereof. NA shall cooperate fully with BMS during the pendency of any such claim or litigation. BMS shall keep NA notified of the current status of any trademark claim, litigation or infringement of any of the Trademarks and shall permit NA to assume the handling, defense or settlement thereof if BMS declines to do so.

#### ARTICLE 5. Quality Control and Governmental Approvals

5.1 All Products delivered to NA hereunder shall be manufactured in accordance with Current Good Manufacturing Practices as required by the United States Federal Food, Drug and Cosmetic Act and pursuant to applicable rules and regulations of the United States Food and Drug Administration ("FDA") when applicable. BMS shall manufacture and supply the Products in accordance with the Quality Document attached here as Exhibit E. Each product lot of

Products shall be inspected and tested by BMS prior to shipment to NA or its customers. A certificate of Compliance will be forwarded to NA after each manufactured lot is completed.

5.2 As further set forth herein; NA shall have the right to replacement of or refund for Products, up to the expiration date of such Products, if such Products fail to meet BMS's specifications as set forth in BMS's NDA for such Products or are not of merchantable quality. NA will promptly notify BMS by telephone and telecopy of NA's request for replacement or refund. Such notice shall specify with particularity the nature of the nonconformance and NA will have the Product returned promptly to BMS for examination at BMS's expense. Provided that NA promptly returns the Products to BMS, BMS will promptly replace the Products in question if requested by NA, determine any nonconformance of the returned Products and report back to NA.

In the event that BMS disagrees with NA regarding whether the Products are nonconforming and the parties are unable to resolve the dispute, the Products or samples thereof will be submitted to a qualified independent laboratory agreed upon by the parties. The laboratory will analyze the Products or samples in a manner agreed upon by the parties and the results of that analysis will be a binding determination of whether the Products were or were not nonconforming. If it is determined that the Products were nonconforming, BMS shall bear the cost of the analysis, as well as either providing a refund or replacement Products to NA. If it is determined that the Products were not nonconforming NA shall bear the cost of the analysis, shall not be entitled to any refund on the Products and shall pay BMS for any replacement Products provided by BMS.

5.3 All materials and components used in the fabrication of Products shall be traceable by lot number and purchase order invoice number.

ARTICLE 6. Warranties. Indemnities and Insurance

6.1 BMS warrants to NA that all Products purchased by NA under this Agreement:

(a) shall be free and clear of all liens, claims, encumbrances, pledges, security interests or other adverse interests of third parties,

(b) shall be manufactured, supplied and delivered by BMS with all necessary skill and expertise using qualified personnel so as to comply with all applicable regulatory requirements,

(c) shall be of good and merchantable quality, and free from defects in material and workmanship;

(d) shall be manufactured in accordance with the specifications set forth in BMS's NDA, and

(e) shall be manufactured in accordance with the Current Good Manufacturing Practices and other applicable FDA rules and regulations.

6.2 (a) BMS shall defend, indemnify and hold NA, its subdistributors, dealers, agents or affiliates, harmless from any and all demands, claims, actions, suits, judgments, decrees, proceedings, liabilities, costs, losses, damages and expenses, including, without limitation, court costs and attorneys' fees, at any time resulting to any of them as a result of or in connection with (a) any Products which were nonconforming, damaged, or defective at time of delivery to NA whether claimed by or established in favor of any third parties, including purchasers, and (b) any breach by BMS of the warranties provided for herein.

(b) NA shall promptly notify BMS upon receipt by NA of any claim or demand which NA has determined has given or could give rise to a right of indemnification under this Agreement. If such claim or demand relates to a claim or demand asserted by a third party against NA, BMS shall have the right to employ such counsel as is reasonably acceptable to NA to defend any such claim or demand asserted against NA, and BMS shall have control over the conduct of the defense of the claim or demand, provided, however, that BMS shall not settle such claim or demand without the consent of NA unless such settlement requires no more than a monetary payment for which NA is fully indemnified under this Agreement or involves other matters not binding upon NA. NA shall have the right to participate at its cost in the defense of any said claim or demand. So long as BMS is defending in good faith any such claim or demand,

NA shall not settle such claim or demand. NA shall fully cooperate with BMS during the pendency of the claim or demand and shall make available to BMS and its representatives all records and other materials reasonably required by them for their use in contesting any claim or demand asserted by third party against NA. Whether or not BMS so elects to defend any such claim or demand, NA shall not have any obligation to do so and NA shall not waive any rights it may have against BMS hereunder with respect to any such claim or demand by electing or failing to elect to defend any such claim or demand. NA's subdistributors, dealers, agents or affiliates shall also be bound by this section.

6.3 The obligation of BMS to indemnify and defend shall not extend to claims or demands to the extent they are attributable to the independent negligence or intentional malfeasance of NA, its subdistributors, dealers, agents, or affiliates, nor to any claims or demands to the extent that they are attributable to or arising out of statements or actions made by NA, its subdistributors, dealers, agents or affiliates with respect to the Products. The obligation to BMS to indemnify and defend shall also not apply to any claims or demands to the extent that they are attributable to any breach by NA of the terms of this Agreement.

6.4 BMS represents that it is self-insured for the activities to be carried out under this Agreement and that it maintains sufficient reserves covering these activities.

6.5 (a) NA shall defend, indemnify and hold BMS, its directors, officers, agents, affiliates, and employees, harmless from any and all demands, claims, actions, suits, judgments, decrees, proceedings, liabilities, costs, losses, damages and expenses, including, without limitation, court costs and attorneys' fees, at any time resulting to any of them, as a result of or in connection with (a) any negligence or intentional malfeasance by NA, its subdistributors, dealers, agents, or affiliates, and (b) any representation made or other action taken by NA, its subdistributors, dealers, agents, or affiliates related to marketing, selling, or distributing the Products, which are outside the scope of or inconsistent with any Product claims made by BMS, and (c) any breach by NA of the terms of this Agreement. This obligation of NA to indemnify

and defend shall not apply to the extent that claims are attributable to the independent negligence or intentional malfeasance of BMS.

(b) BMS shall promptly notify NA upon receipt by BMS of any claim or demand which BMS has determined has given or could give rise to a right of indemnification under this Agreement. If such claim or demand relates to a claim or demand asserted by a third party against BMS, NA shall have the right to employ such counsel as is reasonably acceptable to BMS to defend any such claim or demand asserted against BMS and NA shall have control over the conduct of the defense of the claim or demand; provided, however, that NA shall not settle such claim or demand without the consent of BMS unless such settlement required no more than a monetary payment for which BMS is fully indemnified under this Agreement or involves other matters not binding upon BMS. BMS shall have the right to participate at its costs in the defense of any such claim or demand. So long as NA is defending in good faith any such claim or demand, BMS shall not settle such claim or demand. BMS shall fully cooperate with NA during the pendency of the claim or demand and shall make available to NA and its representatives all records and other materials reasonably required by them for their use in contesting any claim or demand asserted by third party against BMS. Whether or not NA so elects to defend any such claim or demand, BMS shall not have any obligation to do so and BMS shall not waive any rights it may have against NA hereunder with respect to any such claim or demand by electing or failing to elect to defend any such claim or demand. BMS's subdistributors, dealers, agents, or affiliates shall also be bound by this section.

(c) NA represents that it is self-insured for the activities to be carried out under this Agreement and that it maintains sufficient reserves covering these activities.

6.6 NA will notify BMS of any adverse drug experience associated with the Products of which NA, its subdistributors, dealers, agents, or affiliates become aware. Such notifications will be made in writing, in a manner reasonably agreed by the parties, by means which afford the sender evidence of receipt by BMS within three (3) working days of initial receipt of the report by NA, its subdistributor, dealer, agent, or employee. Such means of notification may include Express Mail, Electronic Mail, courier, or facsimile, but are not so-limited. Advance notification of any fatal or immediately life-threatening experience will be given by telephone. NA is



responsible for insuring prompt follow-up, as necessary to provide BMS with reasonably complete information on each such adverse drug experience, by the same means and within the same time frame of receipt.

Any communication to BMS under the terms of this Section 6.6 shall be directed to the attention of the following individual or to his designee or successor:

Regulatory Affairs  
Bristol-Myers Squibb Pharma Company  
331 Treble Cove Road  
North Billerica, Massachusetts 01862  
Telephone: 978-671-8361  
Telecopy: 978-663-6897

“Adverse drug experience” shall mean any unfavorable and/or unintended change in the structure (signs), function (symptoms), or chemistry (laboratory data) of the body temporally associated with the use of Product or of a derivative thereof in humans, whether or not considered drug related, including the following: an adverse experience occurring in the course of the use of a drug in professional practice, an adverse experience occurring from drug overdose, whether accidental or intentional, an adverse experience occurring from drug withdrawal, and any significant failure of expected pharmacological action. (Failure of a radiopharmaceutical product to localize as expected is not regarded by BMS as an adverse experience, but rather as a complaint, which is referred to BMS’s Marketing and Technical Services personnel for further investigation.)

#### ARTICLE 7. Representation and Warranties.

7.1 BMS hereby represents and warrants to NA as follows:

(a) BMS has the full power, authority and legal right to enter into this Agreement; this Agreement has been duly authorized, executed and delivered by BMS; and this Agreement constitutes a legal, valid and binding obligation of BMS, enforceable against BMS in accordance with its terms.

(b) BMS has executed no agreement in conflict herewith.

(c) The distribution and sale of the Products by NA will not infringe the patents or intellectual property rights of any third party.

7.2 NA hereby represents and warrants to BMS that NA has the full power, authority and legal right to enter into this Agreement; this Agreement has been duly authorized, executed and delivered by NA; this Agreement constitutes a legal, valid and binding obligation on NA enforceable against NA in accordance with its terms; and NA has executed no agreement in conflict with the terms of this Agreement.

#### ARTICLE 8. Confidentiality

Any and all proprietary information with respect to the Products or the business affairs and activities of either party hereto ("Proprietary Information") which is furnished or disclosed in connection with the Agreement by such party ("Disclosing Party") to the other party hereto ("Receiving Party"), including, without limitation, the specifications for the Products, shall remain the property of the Disclosing Party and shall be treated as confidential. Receiving Party shall not use such Proprietary Information for its own benefit except as specified in this Agreement and shall not disclose such Proprietary Information to others, except to those of its employees whose duties so require, in such event taking all precautions which are reasonably necessary to prevent the unauthorized disclosure of such Proprietary Information by such persons. Information shall not be deemed to be Proprietary Information and such restrictions shall not apply to any such information (i) which is, or subsequently may become, within the knowledge of the general public, without the fault of the Receiving Party; (ii) which may be known to the Receiving party at the time of receipt thereof from the Disclosing Party as shown by competent written records, (iii) which may be proved to have been developed by the Receiving Party, independently and wholly without resort to the Proprietary Information of the Disclosing Party, as shown by competent written records; or (iv) which may subsequently be rightfully obtained from sources other than the Disclosing Party and without confidential restriction in favor of such transmitting party. The parties' respective obligations under this Article 8 shall continue after the expiration or termination of this Agreement for any reason.

ARTICLE 9. Term and Termination

9.1 Unless earlier terminated as provided in this Agreement, the initial term of this Agreement shall commence as of the Effective Date and conclude on December 31, 2005. Thereafter, this Agreement will automatically renew for three (3) year periods. Notwithstanding the foregoing, this Agreement may be terminated at any time by BMS on three (3) years written notice to NA or by NA on six (6) months written notice to BMS.

9.2 Upon the happening of any of the following events, either party shall have the right to terminate this Agreement upon written notice of such termination to the other party:

(a) Any material breach by the other party of this Agreement, which material breach continues for a period of thirty (30) days after the non-defaulting party shall have given notice thereof to the defaulting party, or

(b) The other party becomes insolvent, is adjudicated as bankrupt or otherwise seeks or receives protection under the bankruptcy laws of the United States, has a receiver or trustee appointed for all or part of its assets and business, executes and delivers an assignment for the benefit of its creditors or is liquidated, dissolved or wound-up or

(c) The continuance of an event of force majeure for a period of more than sixty (60) days.

9.3 The objective of this Agreement is to realize in an economical and reasonable way the interests and requirements of both parties. If at any time during the term of this Agreement, this objective is no longer met due to: •

(a) regulatory changes(s), or economic circumstances, which could not have been foreseen at the time of execution of this Agreement causing undue and prolonged hardship; or

(b) any substantial increase in Seller's direct or indirect cost relating to Uranium targets or radioactive waste disposal;

(c) changes in the selling price effected by the entrance into the market of sellers capable of meeting the volume commitments contemplated under this Agreement; then the parties shall negotiate in good faith in an effort to modify this Agreement in accordance with any of the matters described above and such negotiations shall commence within \*\*\*\* (\*\*\*\*) days of one party's written notice to the other of (a) and/or (b) above. During any negotiation period, the pricing increments defined in Exhibit C will continue in effect.

In the event the parties are unable to agree upon a satisfactory modification of this Agreement within \*\*\*\* (\*\*\*\*) days of commencement of negotiations ("negotiation period"), the party requesting the modification may terminate this Agreement within \*\*\*\* (\*\*\*\*) days following expiry of the negotiation period by providing \*\*\*\* (\*\*\*\*) days written notice to the other party.

9.4 The warranties and indemnities contained in this Agreement shall survive any expiration or termination hereof, as shall the confidentiality obligations of the parties pursuant to Article 8 hereof. Otherwise, upon expiration or termination of this Agreement as provided in this Article 9, except as expressly provided herein, the parties shall have no further liabilities, duties or obligations under this Agreement, except for any liabilities, duties or obligations which may have arisen prior to such expiration or termination.

#### ARTICLE 10. Force Majeure

10.1 Neither party will be liable for any failure to fulfill any term or condition of this Agreement, nor will such failure constitute a breach of or default under this Agreement, if fulfillment has been delayed, hindered or prevented by an event of force majeure, including, without limitation, any war, riot, strike, lock-out or other industrial dispute, acts of the elements, acts of any government or agency hereof (including the enactment of any new laws, rules or regulations), sabotage or industrial accident, plant breakdown or failure of equipment, inability to obtain equipment, fuel, power, materials or transportation, or by any similar circumstances beyond its reasonable control.

10.2 Promptly following the date that any event of force majeure commences, the party concerned will advise the other party in writing of the date and nature of the event and the period of time such event is expected to continue. During the existence of such event, the duties and obligations of the parties under this Agreement shall be suspended and the parties will take all reasonable action to assure resumption of normal performance under this Agreement as soon as possible.

ARTICLE 11. Assignment

This Agreement and all rights and obligations arising hereunder may not be assigned or otherwise transferred by either party whether by operation of law or otherwise, unless the other party has given its written consent thereto, which consent shall not be unreasonably withheld, and any such purported assignment or transfer without the other party's written consent shall be null and void. Notwithstanding the foregoing, a party hereto may assign this Agreement and all rights and obligations arising hereunder in connection with the sale of all or substantially all of its business.

ARTICLE 12. General Provisions

12.1 The relationship of BMS and NA under this Agreement shall be that of independent seller and purchaser, and nothing contained in this Agreement and no action taken by either party to this Agreement shall be deemed to constitute either party or any of such party's employees, agents or representatives to be an employee, agents or representative of the other party or shall be deemed to create any partnership, joint venture, association or syndicate between the parties, or shall be deemed to confer on either party any express or implied right, power or authority to enter into any agreement of commitment, express or implied, or to incur any obligation or liability on behalf of the other party.

12.2 Except as specified in Section 6.6 above, any notice, claim; demand, request or other communication required or permitted under this Agreement shall be valid and effective

only if given by written instrument which is personally delivered, sent by facsimile, courier or registered or certified mail, postage prepaid to the addressee as follows:

If to BMS, to:

Bristol-Myers Squibb Pharma Company  
Radiopharmaceutical Division  
331 Treble Cove Road  
North Billerica, Massachusetts 01862  
Attention: Vice President, Manufacturing  
Telecopy: 978-671-9577

If to NA, to:

Medi-Physics, Inc.  
2636 South Clearbrook Drive  
Arlington Heights, Illinois 60005  
Attention: President  
Telecopy: 708-593-8010

Except as specified in Section 6.6 above, any notice, claim, demand, request or other communication given as provided in this Section 12.2, if given personally, shall be effective upon delivery; if given by facsimile, shall be effective one (1) day after transmission; and if given by courier, shall be effective two (2) days after deposit with the courier; and if given by mail, shall be effective five (5) days after deposit in the mail. Either party may change the address at which it is to be given notice by giving written notice to the other party as provided in this Section 12.2.

12.3 This Agreement, together with the Exhibits attached hereto, constitutes the entire agreement, and supersedes all prior agreements and understanding, both written and oral, between the parties with respect to the subject matter of this Agreement; and this Agreement may not be modified or amended except by an instrument in writing executed by the parties hereto.

12.4 No waiver, forbearance or failure by either party of its right to enforce any provision of this Agreement shall constitute a waiver or estoppel of such party's right to enforce such provision in the future.

12.5 Unless expressly provided otherwise herein, the remedies set forth in this Agreement shall not be exclusive but shall be cumulative, and in addition to all other rights and remedies provided by law.

12.6 This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, excluding the conflict of law provisions thereof.

12.7 If any provision of this Agreement shall be found invalid or unenforceable, in whole or in part, by a court of competent jurisdiction, then such provision shall be deemed to be modified or restricted to the extent and in the manner necessary to render the same valid and enforceable, or shall be deemed excised from this Agreement, as the case may require, and this Agreement shall be construed and enforced to the maximum extent permitted by law, as if such provision had been originally incorporated herein as so modified or restricted, or as if such provision had not been originally incorporated herein, as the case may be, provided that the basic intent of the parties has not thus been rendered incapable of achievement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDI-PHYSICS, INC.

By: /s/ [ILLEGIBLE]  
Title: Vice President

BRISTOL-MYERS SQUIBB PHARMA COMPANY

By: /s/ Donald J. Hayden  
Title: Executive Vice President, Health Care Group

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EXHIBIT A

PRODUCTS

Tc-99M GENERATOR

<u>ITEM #</u>	<u>DESCRIPTION</u>
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	****mCi UNIT, CALIBRATED @****
****	SET OF **** ML SALINE ELUANT VIALS
****	SET OF **** ML SALINE ELUANT VIALS
****	SET OF **** ML EVACUATED COLLECTION VIALS
****	LEAD ELUTION SHIELD
****	MOLY CODDLE RADIATION REDUCER
****	ALUMINUM ION INDICATOR KIT

XENON-133

\*\*\*\* XE-133 \*\*\*\* mCi , \*\*\*\* VIAL TUBE  
\*\*\*\* XE-133 \*\*\*\* mCi , \*\*\*\* VIAL TUBE  
\*\*\*\* XE-133 \*\*\*\* mCi , \*\*\*\* VIAL TUBE  
\*\*\*\* XE-133 \*\*\*\* mCi , \*\*\*\* VIAL TUBE



EXHIBIT A (cont'd)

PRODUCTS

XENON-133

ITEM #	DESCRIPTION
****	XE-133 **** mCi , **** VIAL TUBE
****	XE-133 **** mCi , **** VIAL TUBE
****	XE-133 **** mCi , **** VIAL TUBE
****	XE-133 **** mCi , **** VIAL TUBE
****	XE-133 **** mCi , **** VIAL TUBE
****	XE-133 **** mCi , **** VIAL TUBE

XGUN XENON GUN

GALLIUM-67

****	**** mCi VIAL, CALIBRATED@ 1200 EST. Day Of Calibration
****	**** mCi VIAL, CALIBRATED@ 1200 EST. Day Of Calibration
****	**** mCi VIAL, CALIBRATED@ 1200 EST. Day Of Calibration
****	****mCi VIAL, CALIBRATED@ 1200 EST. Day Of Calibration
****	****mCi VIAL, CALIBRATED@ 1200 EST. Day Of Calibration

MHDLG HANDLING CHARGE PER ORDER

NOTES

- DUPONT RESERVES THE RIGHT TO ADD OR DELETE SPECIFIC ITEMS FROM ITS TOTAL PRODUCT PORTFOLIO GIVING \*\*\*\* DAY NOTICE
- \*\*\*\*=\*\*\*\*, \*\*\*\*=\*\*\*\*, \*\*\*\*=\*\*\*\*, \*\*\*\*=\*\*\*\*, \*\*\*\*=\*\*\*\*
- GENERATORS ARE CALIBRATED ON \*\*\*\*
- GA-67 IS CALIBRATED FOR \*\*\*\* FOLLOWING \*\*\*\* RELEASE
- XENON IS CALIBRATED FOR \*\*\*\* FOLLOWING \*\*\*\* RELEASE
- MOLY CODDLES ARE ONLY SHIPPED VIA COMMON CARRIER (ROADWAY, ETC)

EXHIBIT B

PURCHASE ORDER FORM

Lead Generator and Accessories Order Form

Customer # \_\_\_\_\_

Customer PQ # \_\_\_\_\_

Customer Name \_\_\_\_\_

Address \_\_\_\_\_

City/State \_\_\_\_\_

Zip Code \_\_\_\_\_

New Order:

Product \_\_\_\_\_ Qty \_\_\_\_\_

1<sup>st</sup> shipping date \_\_\_\_\_

Sales order # \_\_\_\_\_

Cancellation

Product \_\_\_\_\_ Qty \_\_\_\_\_

Last shipping date \_\_\_\_\_

Sales order # \_\_\_\_\_

Change

Product \_\_\_\_\_ New Qty \_\_\_\_\_

Product \_\_\_\_\_ New Qty \_\_\_\_\_

Product \_\_\_\_\_ New Qty \_\_\_\_\_

New Size \_\_\_\_\_

1<sup>st</sup> shipping date \_\_\_\_\_

Sales order # \_\_\_\_\_

Comments

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

EXHIBIT C1

PRICING \*\*\*\* THROUGH \*\*\*\*

Item #	PRICE
<b>Tc-99m GENERATOR</b>	
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
<b>TC-99m ACCESSORIES</b>	
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
<b>XENON-133</b>	
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****

EXHIBIT C1 (cont'd)

PRICING \*\*\*\* THROUGH \*\*\*\*

<u>Item #</u>	<u>PRICE</u>
XENON-133	
****	\$ ****
XGUN	\$ ****
GALLIUM-67	
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
****	\$ ****
<u>MISCELLANEOUS</u>	
MHDLG	\$ ****

**EXHIBIT C2**

- A. PRICES ARE PER ITEM AS DESCRIBED IN EXHIBIT A
- B. ADDITIONAL FREIGHT CHARGES. WHERE REQUESTED AND APPROVED, WILL BE ADDED TO THE \$\*\*\*\* MHLDG ITEM
- C. WHEN NECESSARY TO SUBSTITUTE FOR REQUESTED ITEMS DUE TO INVENTORY SHORTFALL, BMS WILL ADJUST PRICES FOR SUBSTITUTED ITEMS TO REFLECT REQUESTED ITEMS TOTAL COST
- D. \*\*\*\* PRICE ADJUSTMENTS FOR EACH PRODUCT, EXPRESSED AS A PERCENTAGE. FOR \*\*\*\* COMMENCING \*\*\*\*, AND IMPLEMENTED ON EACH SUBSEQUENT \*\*\*\* WILL BE CALCULATED AS FOLLOWS:
1. COST, OF MATERIALS PLUS \*\*\*\*% OF \*\*\*\*
  2. NEW PRICING INCORPORATING THE ABOVE WILL BE COMMUNICATED TO NA ON OCTOBER 1 TO ASSIST NA COST FORECASTING, THE OCTOBER 1 COMMUNICATION WILL INCLUDE ANTICIPATED BMS TIMING/INCREASE % ON APPLICABLE PRODUCTS FOR THE COMING \*\*\*\*. THIS INFORMATION MUST BE HELD IN THE STRICTEST CONFIDENCE BY NA  
FOR EXAMPLE, IN THE EVENT THAT THE \*\*\*\* WAS EQUAL TO \*\*\*\*% AND DUPONT COMMUNICATED TO NA ON OCTOBER 1 THAT THE COST OF MATERIAL FOR MO-99 INCREASED BY \*\*\*\*%, THEN THE \*\*\*\* PRICE ADJUSTMENT FOR MO-99, IMPLEMENTED ON \*\*\*\*, WOULD BE CALCULATED AS FOLLOWS: \*\*\*\* PRICE ADJUSTMENT = \*\*\*\*% + \*\*\*\* X \*\*\*\*% = \*\*\*\*%. AS AN ADDITIONAL EXAMPLE IN THE EVENT THE \*\*\*\* ON \*\*\*\* WAS \*\*\*\*% AND THE COST OF MATERIAL FOR GA-67 INCREASED BY \*\*\*\*%. THEN THE \*\*\*\* PRICE ADJUSTMENT FOR GA-67, IMPLEMENTED ON \*\*\*\*, WOULD BE \*\*\*\*%.
- E. SEPARATE FROM THE \*\*\*\* PRICE ADJUSTMENT DESCRIBED ABOVE BMS WILL PASS THROUGH ADDITIONAL PRICE ADJUSTMENTS WHEN BMS HAS ADJUSTED ARMS-LENGTH UNBUNDLED PRICING TO NON-NA, SEGMENTS FROM THE LEVEL DEVELOPED IN THE \*\*\*\* INCREASE PRICE ADJUSTMENT, AS FOLLOWS:
1. BMS WILL PROVIDE \*\*\*\* MONTHS DOCUMENTED ASP CHANGE REALIZED ASP CHANGE
  2. \*\*\*\* DAYS FROM PRESENTATION OF REALIZED ASP CHANGE, NA PRICING WILL BE ADJUSTED
  3. SUCH ADJUSTMENT WILL BE THE DIFFERENCE BETWEEN THE REALIZED ASP CHANGE AND THE \*\*\*\* PRICE ADJUSTMENT. WHETHER IT BE POSITIVE OR NEGATIVE.
  4. FOR EXAMPLE, IN THE EVENT THE REALIZED ASP CHANGE FOR MO-99 ON \*\*\*\* WAS \*\*\*\*% AND THE \*\*\*\* PRICE ADJUSTMENT WAS EQUAL TO \*\*\*\*%. THEN THE ADDITIONAL PRICE ADJUSTMENT FOR MO-99 WOULD BE IMPLEMENTED ON OCTOBER 1 AND WOULD BE CALCULATED AS FOLLOWS: ADDITIONAL PRICE ADJUSTMENT = \*\*\*\*% - \*\*\*\*% = \*\*\*\*%.
  5. ASP Calculation will be carried out as follows:

For the purposes of calculating price changes, average selling price (ASP) will be defined separately for each item and separately for the \*\*\*\* and \*\*\*\*. In each case, the ASP for the period in question will be defined as the total realized revenue, less discounts and rebates, divided by the number of units sold. Free product provided to customers in the form of a discount or incentive will count toward the unit number but replacement product, to address product performance or delivery issues, will not. Free or discounted product made available as part of clinical trial support will also not count in the unit number.

6. Example

BMS provides NA new pricing on October 1 to be effective the following \*\*\*\* that is based upon a \*\*\*\*% increase in the cost of materials for MO-99, \*\*\*\*% for Gallium-67, and \*\*\*\*% for Xenon-133. The \*\*\*\* is \*\*\*\*%. BMS also provides NA on October 1 anticipated BMS timing /increase % on MO-99, GA-67 and XE-133 for the coming calendar year as set forth below. The Price Increase as a percentage of last year's price is as follows:

A. \*\*\*\* Communication to NA October 1

	<u>MO-99</u>	<u>GA-67</u>	<u>XE-133</u>
Cost of Materials increase	****%	****%	****%
****% August 1 ****	****%	****%	****%
**** Increase	****%	****%	****%
"Non-NA" Forecast Increase	****%	****%	****%
Timing	****	****	****

Assume that the \*\*\*\*month weighted average ASP for MO-99 during the period from \*\*\*\* price increase is a Realized ASP Change of \*\*\*\*%, and that the \*\*\*\*month weighted average ASP for GA-67 and XE-133 from the \*\*\*\* price increase is a Realized ASP Change of \*\*\*\*% and \*\*\*\*% respectively. The off cycle price adjustment as a percentage of the calendar's year price is as follows:

B. "Off cycle" Communication to NA

<u>Communication Timing</u>	<u>****</u>	<u>****</u>	<u>****</u>
Realized "Non NA" ASP Increase	****%	****%	****%
Adj. to NA Pricing	****%	****%	****%
Timing	****	****	****

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**EXHIBIT D**

**TRADEMARKS**

<u>Trademark</u>	<u>Country</u>	<u>Registration Number</u>
TECHNELITE	USA	1,812,837
TECHNELITE	Canada	424737

**EXHIBIT E**

**QUALITY DOCUMENT**

**1. GUIDING PRINCIPLES**

Regarding the working relationship between the Quality Departments of NA and BMS Pharmaceuticals (Medical Imaging) for the Product(s) (refer to the Appendix):

- 1.1 Unless otherwise specified, NA refers to NA Quality and the Contractor refers to BMS Pharmaceuticals (Medical Imaging) Quality.
- 1.2 The Contractor has the responsibility to evaluate/monitor any new U.S. NDA requirements and notify NA of any changes in requirements in a timely manner.
- 1.3 The Contractor has responsibility to operate within the Product registration documentation and shall provide Product that meets all criteria throughout its shelf life.
- 1.4 The Appendix of this document specifies the Product(s) currently covered by this Agreement. This Agreement may be amended as new products are added or deleted.

**2. MAINTENANCE OF COMPLIANCE BETWEEN THE PRODUCT REGISTRATION AND THE PROCESS**

**2.1 Technical Changes**

- 2.1.1 The Contractor is responsible for maintaining a change control system that will:
  - 2.1.1.1 review and approve all changes;
  - 2.1.1.2 evaluate the impact of changes on validation status;



2.1.1.3 evaluate the impact of changes on product registration, and

2.1.1.4 evaluate the impact of changes on product safety and efficacy.

2.1.2 The Contractor is responsible for maintaining a system to implement compendial changes.

## **2.2 Other Changes**

2.2.1 All parties, prior to implementation, must approve proposed changes in the storage and/or shipping of the Product.

## **3. BATCH RELEASE**

3.1 The Contractor will manufacture and test the Product according to established, approved procedures and current Good Manufacturing Practices.

3.2 Batch review and release of the Product and all of its components will be the sole responsibility of the Contractor.

3.3 The Contractor will have a formal retest policy and procedure in place that is in accordance with applicable regulations.

3.4 The Contractor will notify NA, within 48 hours, in the event that any test reveals contamination, lack of sterility, or degradation beyond specifications in any batch of Product. The Contractor will file any reports required by the applicable regulations.

#### **4. BATCH DOCUMENTATION**

- 4.1 Originals of all batch documents will be retained by the Contractor according to regulatory and Contractor requirements; these records will be maintained for a period of one (1) year following the Product lot's expiration date.

#### **5. RETAIN SAMPLES**

- 5.1 The Contractor shall retain, under proper storage conditions, samples of the Product as required by the regulations for a period of:
  - 5.1.1 At least three (3) months following the Product lot's expiration date for radioactive products,
  - 5.1.2 At least one (1) year following the Product lot's expiration date for non-radioactive products.

#### **6. STABILITY**

- 6.1 The Contractor will ensure that a product monitoring (stability testing) program is in place for the Product.
  - 6.1.1 The Contractor is responsible for performing stability testing in accordance with the filed stability schedule. Samples shall be stored and tested at appropriate intervals, as described in the approved stability protocol.
  - 6.1.2 If a confirmed result indicates the Product has failed to remain within specifications, the Contractor is required to notify NA within three business days. Notification will include a discussion of the issues, available data, and a path forward.

- 6.1.3 In all cases, the Contractor must investigate any confirmed out of specification (OOS) result. A copy of the completed investigation report shall be sent to NA within thirty business days of the initial confirmation of the OOS.

## **7. COMPLAINTS**

- 7.1 NA will receive and summarize all customer complaints in accordance with the regulations. Product complaints will be forwarded to the Contractor for evaluation and investigation. The Contractor will provide NA all appropriate and reasonable technical assistance necessary to respond to a complaint. Following investigation, the Contractor will summarize the investigation and provide within 60 days a report to NA. NA will provide a response to the complainant and provide a summary back to the Contractor. Within three working days of receipt, NA will promptly communicate to the Contractor, product complaint reports that may require reporting to the regulatory authorities. The Contractor has sole responsibility for determining when a regulatory authority must be notified of the results of a Product complaint.

## **8. RECALL**

- 8.1 The Contractor will maintain a procedure for handling product recalls.
- 8.2 NA has the responsibility to provide any data or information that could result in Product recall within an appropriate time frame. The Contractor will evaluate all information and has sole responsibility for the decision to recall any Product lot.
- 8.3 NA will provide to the Contractor any information required to perform a Product recall.

## **9. ANNUAL PRODUCT REVIEW**

- 9.1 Each year the Contractor will conduct an Annual Product Review, which will minimally contain for each Product manufactured:
- 9.1.1 Total number of batches made, number of batches released, number of batches rejected, and number of batches recalled.
  - 9.1.2 A review and summary of customer complaints.
  - 9.1.3 A listing and discussion of any recalls.
  - 9.1.4 A listing and discussion of any changes.
  - 9.1.5 A listing and discussion of stability data.
  - 9.1.6 Overall discussion, evaluation and conclusions.

## **10. AUDITS**

- 10.1 NA may schedule periodic audits of the Contractor's facilities. If requested, access for additional Product specific audits will be granted.
- 10.2 NA shall have the right to visit the Contractor's plant where the Product is manufactured on any business day upon reasonable prior notice to Contractor. During any such visit, NA shall have the right to audit the Contractor's manufacturing and quality control procedures, records, reports, and facilities as well as any regulatory correspondence applicable to the Product to ensure that the Contractor complies with the Product registration and with Good Manufacturing Practices.

## **11. INSPECTIONS/LEGAL ACTIONS**

- 11.1 The Contractor shall notify NA of regulatory agency inspection results and/or legal actions

that impact the Product.

## **12. SUPPLIER QUALIFICATIONS**

12.1 The Contractor will maintain a formal supplier qualification and management program.

## **13. TRAINING**

13.1 Each person engaged in the manufacturing, processing, packing, or holding of the drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current applicable manufacturing regulations as they relate to the employee's functions. Training in applicable manufacturing regulations shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with requirements applicable to them.

## **14. VALIDATIONS**

14.1 The Contractor must maintain a formal validation program for:

- 14.1.1 Facilities
- 14.1.2 Equipment
- 14.1.3 Methods
- 14.1.4 Cleaning
- 14.1.5 Process

14.2 Validations may be prospective, concurrent or retrospective but in all cases, critical parameters and acceptance criteria will be documented.

The following is a listing of BMS Pharmaceuticals, Medical Imaging, Quality Department contacts.

- Dennis M. Brown, Vice President, Quality, (978) 671-8499
- William D. Mann, Director, Quality Assurance (978) 671-8375

**EXHIBIT F**

List of NA Accounts on the Effective Date of This Agreement

- \*\*\*\*
- \*\*\*\*
- \*\*\*\*