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MS-16

March 18, 2015

Ms. Robin Elliot
Licensing Assistance Team
Division of Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
2100 renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

SUBJECT: REQUEST FOR THE RENEWAL OF MATERIALS LICENSE NO. 54-28275-02MD

03030793

Dear Robin Elliot,

Please find enclosed our replies to your request for additional information made on March 12, 2015.

1) *Provide information on radiopharmaceutical NAV5001 (I-123) as per Item 7 on TheraSphere of Nordion's reply to RAI2 of February 25, 2015.*

ANSWER:

7A. The maximum activity of NAV5001 per container (F335 lead pot) is 37 mCi at the time of shipment. This results in a maximum dose size of 9.0 mCi at calibration (day after shipping at 1500h PT).

7B. NAV5001 is shipped in the F461 Type A box and uses the F335 shielding vessel (lead pot). The F335 shielding vessel is a cylindrical lead pot and it has a thickness of 0.313" of lead on the bottom, sides and cap.

7C. The maximum radiation level to be expected at the surface of the F335 pot, when containing the maximum dosage, would be 19 mR/h.

447 MARCH RD. OTTAWA, ON, CANADA K2K 1X8 T + 1 613-592-2790 F + 1 613-592-6937 www.nordion.com

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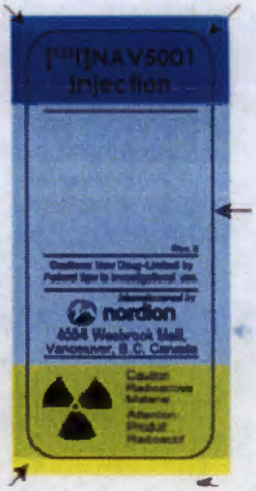
2) *Provide a sample of the NAV5001 (I-123) vial label:*

ANSWER:

A sample is hereby provided.



Should you have additional questions, please do not hesitate to contact me by telephone (613) 592-3400 ext. 2108 or by fax (613) 592-2006 or by email: Luc.Desgagne@nordion.com.

Sincerely,

Luc Desgagné
Senior Licensing Coordinator
Licensing & Compliance
Nordion (Canada) Inc.

CC Jackie Kavanagh, Greg Fulford, Nordion