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January 13, 2006

Thomas K. Thompson
Medical Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA
19406-1415

03030793

RE: Amendment to the Materials License 54-28275-02MD
Mail Control Number 138041

Dear Mr. Thompson,

Further to our telephone discussion of January 11, 2006, please find below the additional information requested with respect to affixing a label on the Iodine 131 monoclonal antibody product vial once it has left the hot cell environment and additional information on the aseptic manufacturing process for the Iodine 131 monoclonal antibody.

1. When the Iodine 131 monoclonal antibody product vials leave the dispensing cell and inspection cell, they are loaded into pre-frozen lead pots (pots are pre-frozen at -70°C). This is to rapidly freeze the product to reduce degradation of the final product and is critical to its quality. Once the vials are loaded into the pots, they immediately freeze making it impossible to affix a label. The vials are kept frozen for the entire length of their shelf life and are only thawed by the pharmacies just prior to infusion.

2. The aseptic nature of this process limits handling of the open Iodine 131 monoclonal antibody product vials significantly. The empty vials are placed on stainless steel trays and dry heat sterilized prior to loading into the class 100 dispensing area through a class 100 pass through. Since the vials are sterilized they cannot be handled individually by the operators and cannot be removed from the trays prior to dispensing. The Iodine 131 monoclonal antibody is not terminally sterilized, as this would denature the product. Hence, it is critical that all aspects of the process remain sterile and that nothing is introduced that could increase non-viable as well as viable contamination. The sterility of the Iodine 131 monoclonal antibody is critical as the product is injected into patients without further processing. Pre-labelling of the vials poses an unacceptable risk to the aseptic controls in the process. This is a validated process approved by the US Food and Drug Administration.

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NMSS/RGN1 MATERIALS-002

If you require additional information, please do not hesitate to contact me by telephone at (613) 592-3400 extension 2421 or by email at marcandre.charette@mdsinc.com.

Sincerely,

Marc-André Charette
International Transport & Nuclear Initiatives
Manager, Regulatory Affairs

Copy to: Peggy Brandt, John Cybulski, Luc Desgagne, Richard Decaire, MDS Nordion