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Br.2

Mr. Stephen Courtemanche  
United States Nuclear Regulatory Commission  
Region One Office  
(Nuclear Materials Safety Branch 2  
Division of Nuclear Materials Safety)  
475 Allendale Road  
King of Prussia, PA 19406-1415

03036136

SUBJECT: Request Changes to License 29-30779-01

July 15, 2009

RECEIVED  
MATERIALS  
2009 JUL 17 AM 10:38

FEDERAL EXPRESS MAIL

Dear Mr. Courtemanche:

We are requesting that Condition No. 16 be removed from our license.

Condition 16 states that the helium-3 purified to remove tritium cannot be used for human consumption (primarily because there were no data at the time the license was issued to support the use of purified material for medical application). Because our license does not permit the use of the Department of Energy (DOE) helium-3 in human studies we have qualified all of the medical applications with foreign supplied material. The tritium specification for the foreign supplied material is  $1.3 \text{ E-}10 \text{ Ci/L}$  ( $1.3 \text{ E-}07/\mu\text{Ci/mL}$ ).

As a means of comparison, to the aforementioned specification, we have enclosed a spreadsheet showing many batches of DOE helium-3 we purified to remove tritium over the past six years. All DOE batches were analyzed using the foreign supplied material as a standard. As you can see from the attached file, 91.7% of the batches represented in our data were below the tritium specification established by the foreign laboratory.

Our foreign vendor has not supplied any product to us in 2009 and as a result we have depleted our foreign based inventory. We do still have some material from our last purification of DOE helium-3 and we would like to begin using this product for medical applications.

The National Institute of Health (NIH) is currently funding several University research hospitals to study certain Chronic Obstructive Pulmonary Diseases (COPD). These studies utilize helium-3 to examine the diseased areas of the lung. We can supply a list of the research groups requiring the product and also the names of the researchers if required.

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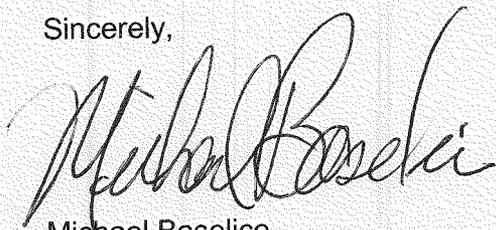
The material we produce from DOE product almost always exceeds the specification of the foreign sourced material. As a result, we request that Condition No. 16 be removed or amended to include the use of the purified DOE material in human studies with a specification of  $1.3 \text{ E-}10 \text{ Ci/L}$  ( $1.3 \text{ E-}07/\mu\text{Ci/mL}$ ).

It is our understanding we may require to submit a Technical Assistance Request to the NRC in Washington in order to get this amendment.

If you have any questions regarding these requests or the attached data, please contact me at (908) 477-4397.

Also, if desired, we would be happy to meet with NRC staff in King of Prussia and provide the additional data.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Baselice". The signature is fluid and cursive, with the first name "Michael" written in a larger, more prominent script than the last name "Baselice".

Michael Baselice  
RSO, Spectra Gases Inc.

cc: Jack Faught, Executive Director, Overseeing Isotopes, Spectra Gases, Inc.

Department of Energy (DOE) Polished Cylinders  
He-3 Raw Data

July 15, 2009

Conversion Factor: 1000

<u>Date(s) Processed</u>	<u>Cylinder ID/Description</u>	<u>Avg Result (uCi/m3)</u>	<u>Avg. Estimated Value (Ci/L)</u>	<u>Avg. Estimated Value (uCi/mL)</u>
5/18/2004	116065	0.27	8.94479E-12	8.94479E-09
5/27/2004	H-107187	0.21	2.90769E-11	2.90769E-08
7/8/2004	824181Y	0.35	5.90625E-11	5.90625E-08
10/13/2004	AF-144272	0.3	5.78571E-11	5.78571E-08
6/13/2005	NK13555	0.04	4.40816E-12	4.40816E-09
6/14/2005	824127Y	0.01	1.10204E-12	1.10204E-09
6/21/2005	483197Y	0.02	2.91892E-12	2.91892E-09
7/14/2005	824167Y	0.01	1.35E-12	1.35E-09
7/14/2005	TWC 741782	0.32	8.64E-11	8.64E-08
12/8/2005	483193Y	0.21	2.1E-11	2.10E-08
12/14/2005	76901	0.32	1.08E-10	1.08E-07
12/15/2005	NK02389	0.21	7.0875E-11	7.0875E-08
6/13/2006	116115	0.36	5.71765E-11	5.71765E-08
1/24/2007	8240854	0.87	7.83E-10	7.83E-07
1/29/2007	13345	0.7	6.51724E-11	6.51724E-08
4/2/2008	55732	0.38	3.15692E-11	3.15692E-08
4/7/2008	TW07-387651	0.27	1.86923E-11	1.86923E-08
4/10/2008	TW07-387649	0.605	4.08375E-11	4.08375E-08
7/15/2008	484070Y	0.34	2.62286E-10	2.62286E-07
1/8/2009	3960630Y	0.57	9.92903E-11	9.92903E-08
1/8/2009	38175644	0.57	2.79818E-10	2.79818E-07
4/7/2009	3960633Y	0.04	3.32308E-12	3.32308E-09
4/13/2009	3817562Y	0.92	7.7625E-11	7.7625E-08
4/20/2009	3817563Y	0.07	5.90625E-12	5.90625E-09

This is to acknowledge the receipt of your letter/application dated

7/15/09, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-30779-01)  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143925  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)  
(6-96)

Sincerely,  
Licensing Assistance Team Leader