

EDO Principal Correspondence Control

FROM: DUE: 02/14/07 EDO CONTROL: G20070082  
DOC DT: 01/29/07  
FINAL REPLY:

Nicholas N. Owens  
U.S. Small Business Administration (SBA)

TO:

Chairman Klein

FOR SIGNATURE OF :

\*\* PRI \*\*

CRC NO: 07-0082

Chairman Klein

DESC:

ROUTING:

Mid-America Isotopes - Regulatory or Compliance  
Enforcement Issue (Due to SBA: 3/2/07)

Reyes  
Virgilio  
Kane  
Silber  
Johnson  
Burns  
Caldwell, RIII  
Kelley, SBCR  
Cyr, OGC

DATE: 02/05/07

ASSIGNED TO:

CONTACT:

FSME

Miller

SPECIAL INSTRUCTIONS OR REMARKS:

Template: SECY-017

E-RIDS: SECY-01

OFFICE OF THE SECRETARY  
CORRESPONDENCE CONTROL TICKET

Date Printed: Feb 05, 2007 10:20

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PAPER NUMBER: LTR-07-0082      LOGGING DATE: 02/02/2007

ACTION OFFICE: EDO / CFO

AUTHOR: Mr. Nicholas Owens

AFFILIATION: SBA

ADDRESSEE: CHRM Dale Klein

SUBJECT: Requests reassessment of small business size standard

ACTION: Signature of Chairman

DISTRIBUTION: RF

LETTER DATE: 01/29/2007

ACKNOWLEDGED No

SPECIAL HANDLING: Response is requested within 30 days of receipt - due March 2, 2007.

NOTES:

FILE LOCATION: ADAMS

DATE DUE: 02/16/2007      DATE SIGNED:

EDO --G20070082



U.S. SMALL BUSINESS ADMINISTRATION  
WASHINGTON, D.C. 20416

OFFICE OF THE NATIONAL OMBUDSMAN

January 29, 2007

The Honorable Dale E. Klein, Chairman  
U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Mail Stop: O-16C1  
Rockville, MD 20852

Dear Mr. Chairman:

The Office of the National Ombudsman has received a comment from the U.S. Chamber of Commerce's Council on Small Business, on behalf of their member, Mid-America Isotopes, which concerns a regulatory or compliance enforcement issue with the U.S. Nuclear Regulatory Commission (NRC).

Mid-America Isotopes dispenses and compounds unit radioactive drugs for diagnostic tests and therapeutic use, and therefore, is required to be licensed and regulated by the NRC. The NRC provides a licensing fee reduction for small businesses that qualify for the small entity status under the Small Business Administration (SBA) size standards. Mid-America Isotopes has been qualified for the small entity status under the SBA size standard (\$5,000,000 in revenue) and obtained licenses from the NRC for over 15 years.

In January 1, 2003, SBA changed the size standard retail establishments from \$5,000,000 to \$6,000,000 in revenue and in January, 1, 2006, it increased the threshold for determining size for retail from \$6,000,000 to \$6,500,000 in revenue to reflect a correct size determination for the retail industry.

According to the U.S. Chamber of Commerce, Mid-America Isotopes has exceeded the size revenue standards for three years for the \$5,000,000 revenue standard, but would qualify for the small entity status under the current SBA size standards. However, because the NRC has never adjusted its size standards to reflect the size standards changes of SBA, Mid-America Isotopes is subject to a costly 600% increase in its yearly license.

Pursuant to the Small Business Regulatory Enforcement Fairness Act, which requires the Office of the National Ombudsman to receive, substantiate, and report to Congress small business comments, I am forwarding a copy of the U.S. Chamber of Commerce's submission for your review and consideration.

The Mission of the Office of the National Ombudsman:  
FOSTERING A MORE BUSINESS FRIENDLY REGULATORY ENFORCEMENT ENVIRONMENT.

409 3<sup>rd</sup> Street, SW, MC 2120, Washington, DC 20416-0005 Toll Free: (888) 734-3247 Fax: (202) 481-5719  
Website: <http://www.sba.gov/ombudsman> E-mail: [ombudsman@sba.gov](mailto:ombudsman@sba.gov)

The Honorable Dale E. Klein  
January 29, 2007  
Page 2

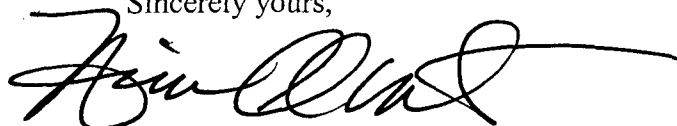
I would appreciate the Nuclear Regulatory Commission's consideration of reassessing this small business size standard. Also, please respond to my office regarding this matter within thirty (30) days of receipt of this letter.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me at (202) 205-7360 or via e-mail at [nicholas.owens@sba.gov](mailto:nicholas.owens@sba.gov).

Mr. Chairman, thank you for your attention to this matter.

With best wishes and warmest regards, I am

Sincerely yours,

A handwritten signature in black ink, appearing to read "Nick Owens", with a long horizontal flourish extending to the right.

Nicholas N. Owens  
National Ombudsman and  
Assistant Administrator for Regulatory Enforcement Fairness

Enclosures

pc: Mr. Mauricio Vera, Small Business Program Manager, U.S. NRC  
Mr. Gary Jackson, Director, SBA Office of Size Standards

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**From:** gcoratolo@uschamber.com  
**Sent:** Friday, January 26, 2007 3:13 PM  
**To:** SBA National Ombudsman  
**Subject:** Federal Agency Comment Form

Organization Name: U.S. Chamber of Commerce

Address: 1615 H Street NW

City: Washington

State: DC

Zip Code: 20062

Phone: 202-463-5498

Fax: 202-463-3174

Email: gcoratolo@uschamber.com

Contact Name: Giovanni Coratolo

Title: Executive Director, Council on Small Business

Organization Type: none

Members: 3,000,000

Agency Name: U.S. Nuclear Regulatory Commission

Agency Contact: ??

Agency Office: Certification of small entity status for the purposes of annual fees imposed under 10 CFR Part 171

Informed You: No

How Did You Learn: This was submitted through comments by our membership

Confidential: no

Signature: none

Date: none

Comments: This case is being brought by the U.S. Chamber of Commerce on behalf of one of our member companies, Mid-America Isotopes of Ashland, Missouri. Mid-American Isotopes dispenses and compounds unit dose radioactive drugs for diagnostic tests and therapeutic use. Due to the use of radioactive drugs, they are required to be licensed and regulated by the U.S. Nuclear Regulatory Commission (NRC).

The NRC requires yearly licensing and provides a fee reduction for small businesses that is based on the SBA size standards. Certification of size is done by filling out NRC FORM 526 in which the small business certifies size and under penalty of perjury submits the form to the NRC. On page 2 section 1c. of the form it clearly indicates that NRC's size standards on small entity are based on the Small Business Administration's regulations (13 CFR 121). The cost of a license for a small business that is able to certify as a small business with less than \$5,000,000 in revenues and more than \$350,000 in revenues is \$2,300. If the business does not qualify for small business status the cost of a license soars to over \$11,000, a recognized hardship on small businesses that was addressed by the

NRC through this certification process.

Mid-America Isotopes has obtained licenses under the small business entity status from the NRC for over 15 years for which the standard on NRC form 526 has always been \$5,000,000 in revenue. Mid-America Isotopes are considered a retail Pharmacy and SBA's size standard for many years for the retail industry as a whole was \$5,000,000 in revenues.

In January 1, 2003, SBA changed the size standards for retail establishments including pharmacies and drugstores from \$5,000,000 to \$6,000,000 in revenues as the threshold for small entity designation in order to keep up with inflation. Again January 1, 2006, SBA increased the threshold for determining size for retail from \$6,000,000 to \$6,500,000 in revenues to reflect a correct size determination for the retail industry which also includes pharmacies and drugstores.

The regulatory complaint that this member charges is that NRC has never adjusted their size standards to reflect the size standard changes of SBA even though the NRC indicates that they have based their standards on SBA's definition. Because of this they are subjected to a 600% increase in their yearly license.

Currently Mid-America Isotopes have exceeded the size revenue standard for three years for the \$5,000,000 revenue standard, but would qualify for the small entity status under the current SBA size standard. The regulatory burdens and costs of small businesses handling radioactive substances has soared since 2001 and at the very least NRC should adjust their small entity status to take into account inflation as indicated by changes in the corresponding SBA size standard changes.

**U.S. SMALL BUSINESS ADMINISTRATION**

Mail Code: 2120  
409 Third Street, S.W.  
Washington, DC 20416

OFFICIAL BUSINESS  
PENALTY FOR PRIVATE USE, \$300



The Honorable Dale E. Klein, Chairman  
U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Mail Stop: O-16C1  
Rockville, MD 20852

