



**QSA GLOBAL**

**QSA Global, Inc.**

40 North Avenue

Burlington, MA 01803

Telephone: (781) 272-2000

Toll Free: (800) 815-1383

Facsimile: (781) 359-9191

16 June 2017

ATTN: Document Control Desk  
Director, Division of Spent Fuel Management  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, MD 20852

Regarding: 24 Month Report for QA Program 0400


Dear Sir or Madam,

Pursuant to the reporting requirements of 10 CFR 71.106(b), QSA Global, Inc. advises that our QA Program, as described under Quality System Manual QSM-1 Revision 11 on file with your office, has been changed as allowed under 10 CFR 71.106(b) in the following manner:

- Text clarifications in section 1.2 expanding the scope by adding "security, and other applications", and by adding applicable international regulatory requirements incorporated into our program.
- Section 1.4 was clarified to specify clearly both the Quality Assurance and the Quality Control aspects of the quality system support processes.
- Section 1.6.1 was clarified to reference a competency requirement for staff performing work affecting quality.
- Section 3.0, Design control requirements was clarified to indicate that the requirements of ISO 13485 section 7.3 do apply to medical device manufacture unless otherwise specified under contract.
- Section 17.1, under the Awareness training definition, replaced "affect" with "effect". Also under the Verification definition, replaced "is" with "are". Both changes were made for grammatical correctness.
- Appendix C, updated the Key Process Model chart to include Quality Assurance along with Quality Control under the Support Processes section.


These changes did not reduce any prior commitments in QSA Global, Inc.'s NRC approved quality assurance program. As such, these changes were allowed under 10 CFR 71.106(b) and are notified as required under that same section. Should you have any questions or wish to discuss this notification further, please feel free to contact me.

Sincerely,

 e-Signed by Lori Podolak  
on 2017-06-14 17:23:20 GMT

Lori Podolak  
Senior RA/QA Specialist  
Ph: (781) 505-8241  
Fax: (781) 359-9191  
Email: [Lori.Podolak@qsa-global.com](mailto:Lori.Podolak@qsa-global.com)

Enclosure: QSM-1 Revision 12

 e-Signed by Michael Fuller  
on 2017-06-14 19:03:42 GMT  
\_\_\_\_\_  
RA/QA Director

June 14, 2017

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Date