QSA GLOBAL

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

28 August 2019

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:

Revision 12 (previously reported in our letter dated 16 June 2017):

- 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.

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Revision 13:

- Revised Quality Policy signatory in section 1.1 to new VP/GM.
- Section 1.2 added reference to our holding company, Illinois Tool Works (ITW), simplified list of regulatory references.
- Revised language in section 1.3 to better reflect Leadership engagement in the Quality System.
- Section 1.4, Expanded Quality System description to specifically include addressing opportunities and risks.
- Section 1.5, expanded description of Management Review to better comply with ISO 9001:2015.
- Section 1.6, expanded description of Resource Management to better align with ISO 9001:2015.
- Added section 1.7 to address Risk Management and Identification of Opportunities
- Appendix A, revised ISO 9001 column to adjust clause references to the 2015 standard.
- Appendix B, created additional top-level procedure entries.
- Changed "President" to "Vice President/General Manager" or "VP/GM" throughout document.

Revision 14:

- Updated ISO 13485 reference in section 1.2 to ISO 13485:2016.
- Added reference to ISO 13485:2016 in section 1.5 for management review minimum content requirements.
- Updated ISO 13485 references in section 18 to exclude Cleanliness, Installation & Servicing applicability to medical devices manufactured by QSA Global, Inc.
- Updated ISO 13485 section references in Appendix A to reflect the 2016 standard.

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,

Michael Fuller
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