Miller, Debra

From: david_bennett@agilent.com
Sent: Thursday, March 27, 2014 3:41 PM
To: Arribas-Colon, Maria
Cc: Jankovich, John; Herrera, Tomas
Subject: RE: Correction to Company QA Program
Attachments: [Untitled].pdf; [Untitled].pdf; [Untitled].pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Ms. Arribas-Colon,

Please find a final version of the QA/QC Program document reference below as first attachment with second and third attachments referenced in the QA/QC program document. I am following this with a FedEx mailed set of originals which will be addressed to Mr. Jankovich.

Please let me know if you have any further questions.

Dave

From: Arribas-Colon, Maria [mailto:Maria.Arribas-Colon@nrc.gov]
Sent: Friday, March 21, 2014 12:52 PM
To: BENNETT,DAVID S (A-LittleFalls,ex1)
Cc: Jankovich, John; Herrera, Tomas
Subject: RE: Correction to Company QA Program

Mr. Bennett-

Thank you for the information. The information provided in your email looks good, however we will need a final version of the QA/QC Program document you provided in your email. We cannot accept a draft document, the document contains highlighted sections and other small section contains red-line strike out. Please provide a final version of the QA/QC Program document, the information should be submitted in an official company letter via facsimile at 301-415-5955, mail, or as an attachment to an e-mail.

If you have any questions, do not hesitate to contact me.

Thank you,

María del Mar Arribas-Colón, M.S.
Project Manager
U.S. Nuclear Regulatory Commission
FSME/MSSA/LB
Phone: (301) 415-6026
Email: Maria.Arribas-Colon@nrc.gov

From: david_bennett@agilent.com [mailto:david_bennett@agilent.com]
Sent: Thursday, March 20, 2014 3:58 PM
To: Arribas-Colon, Maria
Subject: FW: Correction to Company QA Program

Hi Maria,

Please forgive my delay in responding to your request to support our proposal for biannual auditing of our manufacturing plant in Shanghai, China, but I was working out details with our manufacturing team in China which will take responsibility for performing the ongoing audits (with my overview of course). Our rational for the bi-annual auditing process is as follows:

1) **Initial audit within 6 months of the transfer**: Agilent has committed to perform an audit of the manufacturing site in China within 6 months of the transfer to China. This will be performed in line with NUREG-1556, Vol. 3, Table G.1 "Checklist for Reviewing QA Programs." At this time, I am scheduled to perform that audit in person so as to ensure compliance, and to train the China RSO.

2) **Bi-annual internal managed audits**: We will perform an internal bi-annual audit equivalent to the recommended audit of NUREG-1556, Vol. 3, Table G.1. This will require a change to the Comparison of QA Programs table in the QA / QC Program description dated 1/29/14 as we were originally looking to perform internal ISO 9001 audits of the ECD operation but, upon discovery of the number of similarities between Table G.1 and ISO 9001, determined to perform an internal bi-annual audit against Table G.1 as it addresses certain radiation program issues that are not included in ISO 9001 (see fourth attachment).

3) **Third party certification audits**: NUREG-1556, Vol. 3, section 10.7 includes a statement that *Sealed source and device vendors frequently use and are accredited in accordance with the international/U.S. QA standard ANSI/ISO/American Society for Quality (ASQ) 9001-2000, "Quality Management Systems—Requirements".* Reviewing Table G.1, I discovered that the contents of the table are very similar to ISO 9001 auditing components. The China site is already ISO 9001 accredited and audited annually by an independent accreditation service (please see third attachment). When the ECD manufacturing function is transferred, it will be added to the existing site auditing matrix.

4) **Quarterly Radiation Program Audits**: As committed to in the January 29, 2014 company QA Program letter, the China RSO will perform RSO quarterly radiation program reviews for the Shanghai location. There are components in that review that would support the QA program such as confirmation of training, retention of test results, calibration of measuring instruments, and reviews of procedures impacting manufacturing (see first attachment).

Please let me know if this information is enough to justify our planned biannual inspection of the manufacturing program in Shanghai, China.

Lastly, my original request of Feb. 27'th below referred to an error on my part in the QA/QC program descriptive regarding audits of our radioactive source supplier, Eckert & Ziegler Isotope Products in California, USA. I want to ensure this issue is addressed as the description of the bi-annual program above addresses a bi-annual audit of the final device manufacturing in China. Referring to the fourth attachment (QA QC Program Revised 3 20 14.docx), I have highlighted the portion of the program description in yellow that addresses the bi-annual audit of the manufacturing site in China and highlighted in blue the erroneous audit of the source supplier in California. Both need to be bi-annual. Please let me know if these changes would be better addressed in a correction letter issued by Mr. Hoppy.

I am fully aware that an Agilent function within the US must oversee the auditing processes of the Chinese manufacturing site. I am the focal point for reviews of audits, corrective actions, and storage of completed forms for NRC review.

Thanks,
Dave

-----Original Message-----
From: Arribas-Colon, Maria [mailto:Maria.Arribas-Colon@nrc.gov]
Sent: Wednesday, March 05, 2014 1:22 PM

To: BENNETT,DAVID S (A-LittleFalls,ex1)
Cc: Herrera, Tomas; Jankovich, John
Subject: RE: Correction to Company QA Program

Mr. Bennett-

I apologize for the confusion. In my email dated February 28, 2014, I was referring to the manufacturer (Agilent Technologies, Shanghai Company Limited) the when I used the term "vendor". Please reply to my email dated February 28, 2014, providing information on why the frequency of two-years audits is acceptable.

Thank you,
-Maria

-----Original Message-----
From: david_bennett@agilent.com [mailto:david_bennett@agilent.com]
Sent: Friday, February 28, 2014 4:38 PM
To: Arribas-Colon, Maria
Subject: RE: Correction to Company QA Program

Ms. Arribas-Colon,

Sorry for any confusion but Eckert & Ziegler Isotope Products (EZIP) has been the name of our sealed source vendor since 2008, as shown in the attached State of California registry. They previously were simply Isotope Products Laboratories (IPL). This is not the manufacturer of Agilent's radioactive device which is moving to China. Unfortunately, I'm working from home and can't detail the history of IPL but can do so when I return to work next week if you wish. As shared with the original e-mail, we negotiated the two year frequency of EZIP with the NRC between 2009 and 2010 (second attachment) . Regrettably, I did not update our registry to reflect the name change from Isotope Products Laboratories to Eckert & Ziegler Isotope sooner.

Please let me know if this has answered your questions.

I'll be available by cell phone at 302-275-5727 for the rest of today if you wish to speak in person.

Regards,
David Bennett
-----Original Message-----
From: Arribas-Colon, Maria [mailto:Maria.Arribas-Colon@nrc.gov]
Sent: Friday, February 28, 2014 2:09 PM
To: BENNETT,DAVID S (A-LittleFalls,ex1)
Cc: Herrera, Tomas; Jankovich, John
Subject: RE: Correction to Company QA Program

Mr. Bennett-

This is a response to your email below regarding the biennial audit of your manufacturer in a China. Please provide information why frequency of two-years audits is acceptable for a new vendor. Furthermore, the provisions of Section 8.5 Improvement of ISO Q9001-2008, address a continual monitoring of the effectiveness of the quality management system. Traditionally, the number of defective units and the results of final leak tests are monitored and, the performance would affect the audit frequency over time.

Please address this issue, so that we could proceed with the review of your request.

Thank you,
-Maria

-----Original Message-----
From: david_bennett@agilent.com [mailto:david_bennett@agilent.com]
Sent: Thursday, February 27, 2014 8:35 AM
To: Arribas-Colon, Maria
Subject: FW: Correction to Company QA Program

Dear Ms. Arribas-Colon,

While reviewing the documentation for the amendment to transfer our production line to China, I observed an error in one of the statements covering the QA programs comparison included in the amendment request letter dated January 29, 2014 (see highlighted line in first page of attachment). Both QA program descriptions reflect a semi-annual audit of the radioactive source vendor. This should have read "Biennial auditing of the radioactive source vendor" as supported by the letters dated January 23, 2009, January 11, 2010, and March 17, 2010 (also in the attachment). Please let me know if we need to submit a formal correction.

Regards,
David Bennett
RSO
302-636-8262

C.c. David Hoppy