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| | Version Date: 2023-10-13 | Effective Date: 2023-10-13 |
| Title: Expectations regarding Threat to Impartiality from Consultancy Services provided by Participating Auditing Organization | | Project Manager: Hiromi Kumada, PMDA |

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1. Purpose

This document aims to reaffirm and clarify the limits within which an Auditing Organization (AO) must operate in order to satisfy impartiality requirements with regards to consulting.

2. Preamble

Being impartial, and being perceived as impartial, is necessary for the Auditing Organization to perform audit and deliver report and certification that provides confidence. (paraphrase of ISO/IEC 17021-1:2015 4.2.1)

An established link between audit/certification activities and medical device regulatory consultancy services is considered an unacceptable threat to impartiality.

3. Definitions

3.1 Management System Consultancy:

Participation in designing, implementing or maintaining a management system. (ISO/IEC 17021-1:2015 3.3)

EXAMPLES:

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- a) preparing or producing manuals or procedures;
- b) giving specific advice, instructions or solutions towards the development and implementation of a management system; and
- c) acting as Clinical Research Organization for the implementation of a clinical research protocol developed by the manufacturer.

NOTE: Arranging training and participating as a trainer is not considered consultancy, provided that, where the course relates to management systems or auditing, it is confined to the provision of generic information that is freely available in the public domain; i.e. the trainer should not provide company-specific solutions.

3.2 Medical Device Regulatory Consultancy:

Participation in designing, implementing or maintaining a management system ensuring compliance with medical device regulations covering:

- quality management system (or good manufacturing practices);
- device marketing authorization and facility registration; and
- medical device adverse events and advisory notices reporting.

EXAMPLES:

- a) preparing the documentation, or part of it, to be submitted for a marketing authorization (such as device license application file, premarketing notification file, premarket approval submission file, technical documentation, design dossier, etc...), with the exception of the testing reports per recognized standard or a specific pre-established protocol.
- b) giving specific advice, instructions or solutions towards the resolution of quality management system deficiencies identified by a regulatory authority during an inspection.

COUNTER-EXAMPLES:

- a) testing a device and issuing the corresponding testing report per a recognized standard or a specific pre-established protocol, as long as the organization does not provide any specific advice, instructions or solutions addressing the deficiencies detected by the testing.
- b) offering mock audit, pre-assessment audit or gap-audit services.

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NOTE 1: In the context of the Medical Device Single Audit Program, any reference to management system consultancy must be interpreted as medical device regulatory consultancy.

NOTE 2: Arranging training and participating as a trainer, or exchanging technical or regulatory information is not considered consultancy, provided that, where the course or exchanged information relates to management systems, other medical device technical or regulatory requirements or auditing, it is confined to the provision of generic information that is freely available in the public domain; i.e. the trainer should not provide company-specific solutions.

3.3 Consultancy Organization:

Organization offering medical device regulatory consultancy or management system consultancy services.

3.4 Legal entity:

An association, corporation, partnership, proprietorship, trust, or individual that has legal standing in the eyes of law. A legal entity has legal capacity to enter into agreements or contracts, assume obligations, incur and pay debts, sue and be sued in its own right, and to be held responsible for its actions.

4. MDSAP Expectations

- 4.1 An Auditing Organization or any part of the same legal entity shall not offer or provide medical device regulatory consultancy. (ISO/IEC 17021-1:2015 clause 5.2.5)

NOTE: No deviation to this requirement can be accepted.

- 4.2 If the Auditing Organization is a legal entity that is wholly or partly owned by a larger organization, the requirements for impartiality apply to both the Auditing Organization and the organization to which it belongs. (IMDRF/MDSAP WG/N3 (2nd Edition), clause 5.2.10)

NOTE: This requirement, as it relates to medical device regulatory consultancy means that:

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- ISO/IEC 17021-1:2015 clause 5.2.2: The larger organization should have corporate policies or equivalent ensuring that other legal entities within the group do not negatively impact the impartiality of the Auditing Organization.
- ISO/IEC 17021-1:2015 clause 5.2.3: Other legal entities within the group should be transparent with regards to the group's activities that could represent a possible conflict of interest, to enable the Auditing Organization to analyze them. In particular, the list of clients who received medical device regulatory consultancy services should be available to the Auditing Organization and to Regulatory Authority Assessors.
- ISO/IEC 17021-1:2015 clause 5.2.5: While it is not prohibited for a separate legal entity belonging to the same group as the Auditing Organization to provide medical device regulatory consultancy, the independence of the Auditing Organization from the group's Consultancy Organization must be demonstrated and documented. This demonstration should take into account: 1) organizational structure; 2) corporate branding and advertising; 3) contracts and agreements; 4) accounting; 5) top management and operational decision making; 6) individuals involved in the audit and certification activities.
- ISO/IEC 17021-1:2015 clause 5.2.7: While it is not prohibited for a separate legal entity belonging to the same group as the Auditing Organization to provide internal audit services.
 - o this legal entity cannot offer internal audit services to a certified client of the Auditing Organization, and
 - o the Auditing Organization cannot certify a medical device manufacturer to which this other legal entity provided internal audits within three (3) years following the end of the internal audits.
- ISO/IEC 17021-1:2015 clause 5.2.8: The Auditing Organization cannot certify a management system on which a client has received medical device regulatory consultancy services from another legal entity of the

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same group within three (3) years following the end of the consultancy service or of the internal audits.

- ISO/IEC 17021-1:2015 clause 5.2.9: An Auditing Organization cannot outsource auditing services to any Consultancy Organization or to any individual that is part of the staff of the Consultancy Organization, and
- ISO/IEC 17021-1 5.2.9: A Consultancy Organization belonging to the same group as the Auditing Organization cannot market its activities as linked to the Auditing Organization's activities.

- 4.3 The Auditing Organization shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the Consultancy Organization and the certification body poses an unacceptable threat to the impartiality of the certification body. (ISO/IEC 17021-1:2015 clause 5.2.7)

NOTE 1: A relationship that threatens the impartiality of the Auditing Organization can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc. (Note to ISO/IEC 17021-1:2015 clause 5.2.2)

A relationship that represents an unacceptable threat to impartiality is, for example, an Auditing Organization and Consultancy Organization operating under the same brand name.

NOTE 2: Allowing a minimum period of three (3) years to elapse following the end of the management system consultancy is one way of reducing the threat to impartiality to an acceptable level.

- 4.4 An Auditing Organization cannot outsource audits to a Consultancy Organization. (17021-1:2015 clause 5.2.8)

NOTE: While this does generally not apply to individuals contracted as individual external auditors and external technical experts, it does apply to

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individuals that are part of the staff of a Consultancy Organization belonging to the same group as the Auditing Organization. Using an employee of a Consultancy Organization belonging to the same group as the Auditing Organization as an external auditor represents an unacceptable threat to impartiality, regardless whether the Auditing Organization would have contractual agreements with the Consultancy Organization or with the individual.

- 4.5 An Auditing Organization cannot market or offer its activities as linked with any organization that provides management system consultancy services. (ISO/IEC 17021-1:2015 clause 5.2.9)

NOTE 1: An example of unacceptable link is the promotion of both an Auditing Organization’s activities and Consulting Organization activities on the same website.

NOTE 2: When an Auditing Organization and a Consultancy Organization have evident relationship, for example if they belong to the same group, the promotion of each organization’s activities that could be perceived as presenting a conflict of interest should both include a disclaimer that:

- certification would not be simpler, easier, faster or less expensive if the linked Consultancy Organization were used,
- the Auditing Organization cannot audit and certify an organization that obtained medical device regulatory consultancy services from the linked Consultancy Organization during the preceding three (3) years.

- 4.6 Providing internal audit services to an organization prohibits the Auditing Organization from offering certification services to this organization for a period of 2 years following the last internal audit performed for this organization. (ISO/IEC 17021-1:2015 clause 5.2.6)

- 4.7 Mock audits, gap audits or pre-assessment audit may be offered to certified medical device manufacturers as long as the Auditing Organization does not provide specific advice, instructions or solutions to

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address deficiencies. Deficiencies identified during such an audit must be taken into account when grading nonconformities under the program. (IMDRF/MDSAP WG/N3 (2nd Edition) clause 9.4.3)

NOTE 1: The Auditing Organization should further mitigate the appearance of conflict of interest by ensuring that the auditors performing the mock audit, gap audit or pre-assessment audit of a manufacturer are not involved in the certification audit and certification decision.

NOTE 2: The scope of a mock audit, gap audit or pre-assessment audit offered to a certified client should be different from the pre-existing scope of certification. It would otherwise be seen as an internal audit prohibited according to ISO/IEC 17021-1 Clause 5.2.6.

- 4.8 The Auditing Organization must document any involvement in medical device regulatory consultancy undertaken by any personnel (including top management) prior to taking up employment with the Auditing Organization at the time of employment. (IMDRF/MDSAP WG/N3 (2nd Edition) clause 5.2.4)

NOTE: The documents should include the beneficiaries of the medical device regulatory consultancy services.

- 4.9 An individual cannot be involved in the audit and certification activities relative to a medical device manufacturer if he/she:
- Was an employee or provided medical device regulatory consultancy services of the specific manufacturer or of any company belonging to the same organization, at any time during the prior 3 years. (IMDRF/MDSAP WG/N3 (2nd Edition) clause 5.2.5)
 - Provided medical device regulatory consultancy services to this specific manufacturer, its authorized representative or its supplier in the past three (3) years. (ISO/IEC 17021-1 clause 5.2.10 and IMDRF/MDSAP WG/N3 (2nd Edition) clause 5.2.3 - 3rd and 4th bullets)

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OR

- Has a spouse or child who meets the conditions specified above.

NOTE 1: This applies to the Auditing Organizations employees, to external auditors and to external technical experts.

NOTE 2: If an individual is part of the staff of a Consultancy Organization, this individual cannot be involved in the audit and certification activities relative to a medical device manufacturer to which the Consultancy Organization provided medical device regulatory consultancy services to this specific manufacturer, his authorized representative or a his supplier in the past three (3) years.

5. Contact

If you have any questions relating to this guidance, please contact MDSAP@fda.hhs.gov.

6. Document History

| VERSION No. | VERSION DATE | DESCRIPTION OF CHANGE | AUTHOR NAME/PROJECT MANAGER |
|-------------|--------------|---|-----------------------------|
| 001 | 2014-10-07 | Initial Document | Alba M.C.L. Pismel |
| 002 | 2016-08-15 | Document was revised to reflect ISO 17021-1:2015 revisions. Following minor changes were made throughout the document: page 1 ISO/IEC 17021-1:2015, clause 4.2.1 and clause 3.3; page 2 ISO/IEC 17021-1:2015 clause 5.2.5; pages 3, 4, 5 and 6 ISO/IEC 17021-1:2015, clauses 5.2.2;5.2.3; 5.2.5; 5.2.6; 5.2.7 and 5.2.8 | Liliane Brown, FDA |

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| 003 | 2018-10-16 | Minor corrections throughout to replace "ISO/EIC" with "ISO/IEC" and remove extraneous parentheses Adjusted formatting | Kimberly Lewandowski-Walker, FDA Keith M Smith, TGA Hiromi Kumada, PMDA |
| 004 | 2023-10-13 | Periodic Review Adjusted formatting | Hiromi Kumada, PMDA |

Version 004
Approval

Approved: ON FILE
CHAIR, MDSAP RAC

Date: 2023-10-05