Correspondence between ISO13485:2003 and MHLW MO 169 revised in 2014, Chapter 2

| MHLW MO 169, Chapter 2<br>Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices, etc. | ISO 13485:2003<br>Medical devices -- Quality management systems -- Requirements for regulatory purposes | Note for understanding the requirements of MHLW MO 169 revised in 2014, Chapter 2 |
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| Section 1 General Rules | 1.2 Application | |
| 4 | 1.2 (paragraph 2-4) | Article 4 specifies the way of application of this chapter to the organization.<br>Article 4(1) specifies that the requirements of design and development (Article 30 to Article 36) don't be applied to Class 1 products.<br>Article 4(2) of the ordinance specifies the rule of non-application of the requirements. The content of the item is identical to the description of 1.2, paragraph 2 of ISO13485:2003.<br>Article 4(3) specifies that in case, whether either of the provisions specified in the Article 4(1), (2) is applied to, describe the details of such application in the quality manual. |
| Section 2 Quality Management System | 4. Quality management system | |
| 5 | 4.1 | |
| 6 | 4.2.1 | |
| 7 | 4.2.2 | |
| 8 | 4.2.3 | The document retention period required by the ordinance is specified by Article 67. |
| 9 | 4.2.4 | The record retention period required by the ordinance is specified by Article 68. |
| Section 3 Management responsibility | 5. Management responsibility | |
| 10 | 5.1 | |
| 11 | 5.2 | |
| 12 | 5.3 | |
| 13 | 5.4.1 | |
| 14 | 5.4.2 | |
| 15 | 5.5.1 | |
| 16 | 5.5.2 | |
| 17 | 5.5.3 | |
| 18 | 5.6.1 | |
| 19 | 5.6.2 | |
| 20 | 5.6.3 | |
| Section 4 Resource Management | 6. Resource Management | |
| 21 | 6.1 | |
| 22 | 6.2.1 | |
| 23 | 6.2.2 | |
| 24 | 6.3 | |

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| 25 | 6.4 | |
| Section 5 Product realization | 7. Product realization | |
| 26 | 7.1 | |
| 27 | 7.2.1 | |
| 28 | 7.2.2 | |
| 29 | 7.2.3 | |
| 30 | 7.3.1 | |
| 31 | 7.3.2 | |
| 32 | 7.3.3 | |
| 33 | 7.3.4 | |
| 34 | 7.3.5 | |
| 35 | 7.3.6 | Clinical evaluations and/or evaluation of performance of the medical device conducted based on the requirement of PMD Act (Japanese Medical Device legislation) are required to be performed as part of design and development validation by this article. |
| 36 | 7.3.7 | |
| 37 | 7.4.1 | |
| 38 | 7.4.2 | |
| 39 | 7.4.3 | |
| 40 | 7.5.1.1 | |
| 41 | 7.5.1.2.1 | |
| 42 | 7.5.1.2.2 | The requirements of Article 42 are only applied to ”installation-control-required medical devices”, which are specified in Article 114-55(1) of the Ministerial Ordinance for enforcement of PMD Act. The installation-control-required medical devices are the devices that need assembling for installation and need control for the assembling to prevent occurrence of public health hazard. The devices are designated to by the notification of the Ministry of Health, Labor, and Welfare. |
| 43 | 7.5.1.2.3 | |
| 44 | 7.5.1.3 | |
| 45 | 7.5.2.1 | |
| 46 | 7.5.2.2 | |
| 47 | 7.5.3.1 | |
| 48 | 7.5.3.2.1 | |
| 49 | 7.5.3.2.2 | The requirements of Article 49 are only applied to “specially designated medical devices”, which are specified by the Article 68-5 of PMD Act.<br>The devices are designated by the Minister of Health, Labour and |

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| | | Welfare as those whose location is needed to be traceable to prevent occurrence or spread of hazards to the public health and hygiene, among those which is used by means of implantation in the human body and intended to be used outside the facilities providing medical treatment.<br>Specially designated medical devices are included in the “active implantable medical devices and implantable medical devices” which are required to be complied with the requirement in 7.5.3.2.2 of ISO13485:2003. So the organization complied with the requirement of Article 49 of MHLW MO 169, when they are complied with the requirement of 7.5.3.2.2 of ISO13485:2003.<br><br>The requirements of maintenance of distribution record in ISO13485:2003, which are the second and third sentence of 7.5.3.2.2, are only applicable to the Marketing Authorization Holder. When the organization is the person operating the registered manufacturing site, the requirements are not applicable to him/her. |
| 50 | 7.5.3.3 | |
| 51 | 7.5.4 | |
| 52 | 7.5.5 | |
| 53 | 7.6 | |
| Section 6 Measurement, analysis and improvement | 8 Measurement, analysis and improvement | |
| 54 | 8.1 | |
| 55 | 8.2.1 | |
| 56 | 8.2.2 | |
| 57 | 8.2.3 | |
| 58 | 8.2.4.1 | |
| 59 | 8.2.4.2 | The requirements of Article 59 are only applied to “specially designated medical devices” (see the note for Article 49 of the ordinance).<br>Specially designated medical devices are included in the “active implantable medical devices and implantable medical devices” which are required to be complied with the requirement in 8.2.4.2 of ISO13485:2003. So the organization complied with the requirement of Article 59 of MHLW MO 169, when they are complied with the requirement of 8.2.4.2 of ISO13485:2003. |
| 60 | 8.3 | |
| 61 | 8.4 | |
| 62 | 8.5.1 | Article 62(6) specifies the requirements of establishment of procedures to notify adverse events for the Marketing Authorization |

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| | | Holder and the person operating the registered manufacturing site.<br>The Marketing Authorization Holder shall establish documented procedures to notify adverse events which meet reporting criteria specified by the Article 228-20(2) of the Ministerial Ordinance for Enforcement of PMD Act, to the Minister of Health, Labour and Welfare. When the organization is the person operating the registered manufacturing site, the information shall be notified to “the Marketing Authorization Holder” instead of “the Minister of Health, Labour and Welfare”. The person shall establish the documented procedure for it. |
| 63 | 8.5.2 | |
| 64 | 8.5.3 | |