Health and Labour Sciences Research Grants
Regulatory Science Policy Research Project for Pharmaceuticals and Medical Devices

Study on Internationally Harmonized Guidelines for Good Manufacturing Practice (GMP), Quality Management System (QMS), Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP), and Pharmaceutical Excipients

Example of How to Write QMS Audit Reports

1. Purpose

Standards for Manufacturing Control and Quality Control for Medical Devices and In Vitro Diagnostic Reagents have been set as requirements for manufacturing/marketing of these by Ministry of Health, Labour and Welfare (MHLW) Ministerial Ordinance No. 169 of 2004 (hereinafter referred to as "QMS Ordinance").

Audits to confirm compliance with the QMS Ordinance are conducted by 12 audit organizations (Pharmaceuticals and Medical Devices Agency [PMDA] and 11 registered certification bodies as set out in Article 23-2-23 Paragraph 1 of the Act [as of April 1, 2021]) in accordance with the "Guidance on Quality Management System (QMS) Audit" [revised in March 26, 2021, PSEHB/CND Notification 0326 No. 12, Administrative Notice of the Compliance and Narcotics Division [CND], Pharmaceutical Safety and Environmental Health Bureau [PSEHB], MHLW; hereinafter referred to as "Guidance on Audit"]).

The Guidance on Audit was released as the standard operating procedure for QMS audit-related activities, and it provides instructions on how to write a "QMS Audit Report" (hereinafter referred to as "Report") that has to be prepared by each audit organization in accordance with international standards such as GHTF/SG4/N33R16:2007. However, the guidance hasn't provided any specific style of the report, and the way of describing audit trail (level of details) for each subsystem, in particular, is left to the discretion of each audit organization.

The Guidance on Audit also specifies that if an on-site audit report that indicates confirmation of compliance by another audit organization within the previous 3 years is submitted, the relevant audit organization is allowed to shift to desktop audit at his/her own discretion. In addition, mutual acceptance of reports between overseas and Japanese regulatory authorities is promoted in recent years. Under these circumstances, our study group decided to provide an example of how to write a Report to enhance the content and ensure consistency, hoping the mutual use of reports prepared by domestic and overseas audit organizations will further be facilitated.

2. Background

- The number of description items and their names shown in this writing example are designed to be consistent, as far as possible, with the description items listed in Attachment 6 of the Notification of the Guidance on Audit. This writing example has been prepared for use for renewal audits of facilities involved in the manufacturing and marketing of medical devices. Each audit organization is expected to flexibly modify the contents of the descriptions on an individual basis.
- In Section 4 (6) "Content of audit" in this example, sample texts are presented for each subsystem listed in "Table 3 Subsystems for Compliance Audit etc." in the Notification of the Guidance on Audit. On the other hand, in order to emphasize audit items of higher importance, audit trails about representative requirements in each subsystem, as shown in Table 1, are only specified in this guidance as examples. It

should therefore be noted that, when writing an actual QMS Audit Report, each audit organization needs to additionally describe, as appropriate, other audit items than those presented in this guidance shown hereinafter.

Table 1: Requirements Considered during Creation of the Example of How to Write QMS Audit Reports

○: Considered
△: Partially considered
—: Not considered

Subsystem	Related major requirements under the QMS Ordinance	Applicability	Remarks
Management	Article 5 General Requirements for Quality Management System	—	
	Article 5-2 Establishment of Quality Management System	—	
	Article 5-3 Operation of Quality Management System	—	
	Article 5-4 Management of Quality Management System	○	
	Article 5-5 Outsourcing	—	
	Article 5-6 Use of Software	—	
	Article 7 Quality Manual	○	
	Article 10 Management Commitment	—	
	Article 12 Quality Policy	○	
	Article 13 Quality Objectives	○	
	Article 14 Quality Management System Planning	—	
	Article 15 Responsibility and Authority	○	
	Article 16 Management Representative	○	
	Article 17 Internal Communication	○	
	Article 18 Management Review	○	
	Article 19 Review Input	—	
	Article 20 Review Output	—	
	Article 21 Provision of Resources	—	
	Article 22 Competence of Personnel Performing Quality-related Duties	○	
	Article 23 Competence, Awareness and Training	○	
	Article 56 Internal Audit	○	
	Article 66 Additional Requirements for Quality Management System	—	
	Article 77 Training	—	(Not applicable to this writing example)
	Article 81-2 (4) Training	—	(Not applicable to this writing example)
Design Control	Article 30 Design and Development	○	
	Article 31 Design and Development Inputs	○	
	Article 32 Design and Development Outputs	○	
	Article 33 Design and Development Review	○	
	Article 34 Design and Development Verification	○	
	Article 35 Design and Development Validation	○	
	Article 35-2 Design Transfer Activities	○	
	Article 36 Control of Design and Development Changes	○	

	Article 36-2 Design and Development Files	○	
Product Documentation	Article 7-2 Product Master File	○	
	Article 26 Planning of Product Realization	△	Only Paragraphs 3 and 4 are considered.
	Article 74 Documents Related to Manufacturing Control and Quality Control	—	(Not applicable to this writing example)
Manufacturing	Article 24 Infrastructure	—	
	Article 25 Work Environment	○	
	Article 25-2 Contamination Control	—	
	Article 40 Control of Production and Service Provision	○	
	Article 41 Cleanliness of Product and Contamination Control	—	
	Article 42 Installation Activities	—	(Not applicable to this writing example)
	Article 43 Servicing Activities	—	(Not applicable to this writing example)
	Article 44 Particular Requirements for Sterile Medical Devices	—	
	Article 45 Validation of Processes for Production and Service Provision	○	
	Article 46 Validation of Sterilization Process and Sterile Barrier System-related Process	○	
	Article 47 Identification	○	
	Article 48 Traceability	—	
	Article 49 Traceability of Implantable Medical Devices	—	(Not applicable to this writing example)
	Article 51 Customer Property	—	
	Article 52 Preservation of Product	—	
	Article 53 Control of Monitoring and Measuring Devices	—	
	Article 58 Monitoring and Measurement of Product	○	
	Article 60 Control of Nonconforming Product	○	
	Article 60-2 Handling of Pre-delivery Nonconforming Products	○	
	Article 60-3 Handling of Post-delivery Nonconforming Products	○	
	Article 60-4 Re-manufacturing	○	
	Article 73 Infrastructure of Manufacturing Sites of Marketing Approval Holder, etc. of Specified Biological Medical Devices, etc.	—	(Not applicable to this writing example)
	Article 75 Process Control	—	(Not applicable to this writing example)
	Article 76 Testing	—	(Not applicable to this writing example)
	Article 80 Infrastructure of Registered Manufacturing Sites of Radioactive In Vitro Diagnostic Reagents	—	(Not applicable to this writing example)

	Article 81 Compliance with Regulations for Manufacturing Control and Quality Control of Radiopharmaceuticals	—	(Not applicable to this writing example)
	Article 81-2 Infrastructure of Registered Manufacturing Sites of Marketing Approval Holder, etc. of Re-manufactured Single-use Medical Devices	—	(Not applicable to this writing example)
	Article 81-2 (2) Process Control	—	(Not applicable to this writing example)
	Article 81-2 (3) Testing	—	(Not applicable to this writing example)
	Article 81-2 (6) Traceability of Re-manufactured Single-use Medical Devices	—	(Not applicable to this writing example)
Corrective Actions and Preventive Actions	Article 54 Measurement, Analysis and Improvement	—	
	Article 55 Feedback	—	
	Article 55-2 Complaint Handling	—	
	Article 55-3 Reporting to the Minster of Health, Labour and Welfare etc.	—	
	Article 57 Monitoring and Measurement of Processes	—	
	Article 61 Analysis of Data	○	
	Article 62 Improvement	—	
	Article 63 Corrective Action	○	
	Article 64 Preventive Action	—	
Purchasing Control	Article 37 Purchasing Process	○	
	Article 38 Purchasing Information	—	
	Article 39 Verification of Purchased Product	—	
	Article 84 Control by the Marketing Authorization Holder	○	
Documents and Records	Article 6 Documentation of Quality Management System	—	
	Article 8 Control of Quality Management System Documents	○	
	Article 9 Control of Records	○	
	Article 59 Particular Requirements for Implantable Medical Devices	—	(Not applicable to this writing example)
	Article 67 Retention Period of Quality Management System Documents	○	
	Article 68 Retention Period of Records	○	
	Article 78 Control of Documents and Records	—	(Not applicable to this writing example)
	Article 79 Exceptions in Retention of Records	—	(Not applicable to this writing example)
	Article 81-2 (5) Control of Documents and Records	—	(Not applicable to this writing example)
Customers	Article 11 Customer Focus	—	
	Article 27 Determination of Requirements Related to the Product	○	
	Article 28 Review of Requirements Related to the Product	○	
	Article 29 Communication	—	

Marketing Approval Holder, etc.	Article 69 Reporting Adverse Events, etc.	—	
	Article 70 Relationship with Good Vigilance Practice (GVP)	—	
	Article 71 Duties of General Manager Responsible for Manufacturing and Sales of Medical Devices, etc.	○	
	Article 72 Domestic Quality Assurance Manager	○	
	Article 72-2 Other Items to be Complied	○	
	Article 72-3 Duties of Appointed Marketing Approval Holders for Foreign Manufacturers of Medical Devices, etc.	—	(Not applicable to this writing example)

Report date: December 5, 2023

QMS Audit Report

To: Managing Director
Kokaken Co., Ltd.

Lead Auditor: Hanako Yamada, Principal Auditor, Kokaken Co., Ltd.
Co-Auditor : Taro Sato, Auditor, Kokaken Co., Ltd.

1. Reference Number: 123456

2. Audit dates
(1) Facility 1: August 8, 2023 (from 9:00 am to 5:00 pm)

(2) Facility 2: August 9, 2023 to August 10, 2023 (from 9:00 am to 5:00 pm on each day)
(The audit scope and the time of the audit at each facility are as stated in the audit schedule attached.)

3. Data concerning auditee
(1) General information of the audited company and facilities
a. Facility 1:

Name of the audited company	Iryokiki Maker Co., Ltd.
Address of the audited company	3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo
Name of the audited facility	Headquarters Office, Iryokiki Maker Co., Ltd.
Address of the audited facility	3-3-1 Kasumigaseki, Chiyoda-ku, Tokyo
Number and date of license (registration) of the audited facility	13B1X12345; November 4, 2021

b. Facility 2:

Name of the audited company	Iryokiki Maker Co., Ltd.
Address of the audited company	3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo
Name of the audited facility	Matsuzaka Plant, Iryokiki Maker Co., Ltd.
Address of the audited facility	231-11 Kamiya-cho, Matsusaka-shi, Mie
Number and date of license (registration) of the audited facility	24BZ111111; November 21, 2021

(2) Summary of the audited facility

a. Number of employees
The number of employees at the audited facilities was 40. 10 employees are involved in the marketing or manufacturing of medical devices in the Manufacturing Department, 2 in the Quality Assurance Department, and 3 in the Quality Control Department.
b. Organization in the QMS
Manufacturing Department, Quality Assurance Department, Quality Control Department, Development Department, Purchasing Department, and General Affairs Department
c. Relationship with the facility that manages QMS
The QMS is mainly managed by Facility 1. Main design, main assembly, and storage of finished products are performed at Facility 2 under the management of Facility 1.
d. Summary of activities undertaken at the audited facilities and outsourced roles
Iryokiki Maker Co., Ltd. is mainly engaged in the development, manufacturing, and marketing of catheters, and manufacturing etc. of precision metal mold components. The sterilization process of the audited product has been outsourced to Mekkin Co., Ltd.
e. Status of related quality management system certification standards, such as ISO13485
Iryokiki Maker Co., Ltd. has acquired ISO13485:2016 certification from ABC Co., Ltd.

(3) Exclusions and non-application of requirements under the QMS Ordinance
The following requirements are not applicable because the company does not handle the pertinent products.
Article 42 (Installation Activities), Article 43 (Servicing Activities), Article 49 (Traceability of Implantable

Medical Devices), Article 59 (Particular Requirements for Implantable Medical Devices), Article 72-3 (Duties of Appointed Marketing Approval Holders for Foreign Manufacturers of Medical Devices, etc.), Chapter 4 (Manufacturing Control and Quality Control of Biological Medical Devices, etc.), Chapter 5 (Manufacturing Control and Quality Control of Radioactive In Vitro Diagnostic Reagents), and Chapter 5-2 (Manufacturing Control and Quality Control of Re-manufactured Single-use Medical Devices)

(4) Name, address, and process of the critical supplier
Mekkin Co., Ltd.: 3-1 Tahara, Tanigawa-ku, Osaka; Radiation sterilization

(5) Name and title of the authorized person in the audited facility

a. Facility 1

Top Management:	Ichiro Tanaka, Managing Director
Management Representative:	Jiro Tanaka, Manager, Quality Assurance Section, Quality Assurance Department
General Manager Responsible for Manufacturing and Sales of Medical Devices, etc.:	Saburo Tanaka, General Manager, Quality Assurance Department
Domestic Quality Assurance Manager:	Saburo Tanaka, General Manager, Quality Assurance Department

b. Facility 2

Responsible engineering manager:	Koichi Kita, Manager, First Manufacturing Section, Manufacturing Department

(6) Results of previous audit

a. Previous audit

(i) Summary of previous audit		
	Audit date:	November 2, 2020
	Audit type:	Pre-approval compliance audit
	Audit results:	Complied
(ii) Response to previous observations		
	Nonconformity 1: (Grade 3)	A case was found in which the testing results provided by the supplier had been checked during the acceptance testing of the catheter shaft, which is the raw material of the audited product, but the acceptance criteria of the purchased product described in the relevant testing result showed a deviation from the purchase specifications under the management of the audited facility.
	Status of response:	The procedure was revised to ensure that the latest information is provided at the time of on-site audits of suppliers and confirms that the purchasing specifications are appropriate. At the audit of the supplier in July 2021, it was confirmed that this had been conducted in accordance with the revised procedure.

b. Changes from previous audit
Nothing in particular.

c. QMS-related actions, including recall initiation reports etc., taken by the audited company after previous audit
The company initiated a voluntary recall (Class II) of Disposable Medical Device Catheter II (generic name: balloon catheter for stone extraction) on December 12, 2022, because insufficient strength of the joint section between the catheter segment and the balloon portion caused by adhesion failure could not be denied.

(7) Results of inspections/audits by the governments and ISO certification bodies etc.

	December 5 to 8, 2022	ABC Co., Ltd.	Complied
	June 21 to 25, 2021	ANVISA	Complied
	July 6 to 10, 2020	FDA	Complied

4. Data concerning audit

(1) Purpose of audit

To confirm compliance based on the Application for QMS Compliance Audit, dated July 3, 2023.

(2) Standards for audit
QMS Ordinance (MHLW Ministerial Ordinance No. 169 of 2004 revised by MHLW Ministerial Ordinance No. 60 of 2021)

(3) Type of audit
Periodic post-approval compliance audit

(4) Scope of audit
The following subsystems as set in Chapter 2 and Chapter 3 of the QMS Ordinance were audited.
☑ Management, ☑ Design Control, ☑ Product Documentation, ☑ Manufacturing,
☑ Corrective Actions and Preventive Actions, ☑ Purchasing Control, ☑ Documents and Records,
☑ Customers, ☑ Marketing Approval Holder, etc.

(5) Audited product and processes in the audited facilities

Trade name:		Disposable Medical Device Catheter
	Generic name:	Balloon catheter for stone extraction
	Class category:	Class II
	Product type category:	Appendix Table 2 General non-active, non-implantable medical device 6B (general product)
	Processes of the audited facilities related to the audited product:	Manufacturing/marketing, design, main assembly, and storage of finished product

(6) Audit trails
See Attachment.

5. Findings
(1) Contents

Nonconformity # 1: (Grade 1)	Procedure titled "Qualification Criteria" specifies that the internal audit shall be conducted by persons who receive training for the QMS Ordinance, but the internal auditors who conducted the internal audit of 2022 didn't receive the training.

Nonconformity # 2: (Grade 3)	Regarding the balloon supplier which was newly adopted in 2021, on-site audit to the supplier which is required by the procedure wasn't conducted and the supplier was not approved.

(2) Corrective actions and review of the improvements
We confirmed, based on the report on corrective actions to the findings, that corrective actions for the nonconformities were appropriately implemented. It has therefore been decided that there is no effect on the effectiveness of QMS.

Issue date of observation:	August 25, 2023
Receipt date of corrective action report:	October 10, 2023
Confirmation date of corrective actions:	October 13, 2023
Reviewer of corrective actions:	Hanako Yamada

6. Conclusion
(1) Effectiveness of the QMS
We conducted the audit on the status of implementation and maintenance of QMS at the audited facilities within the scope of the audit, and confirmed that the audited facilities have established and are maintaining effective QMS to achieve the quality objectives thereof.
(2) Achievement of the audit objectives
The audit team conducted the audit as per the audit plan and achieved the audit objectives.
(3) Conformity of QMS with the requirements
We judged that there are no particular problems with the compliance of the audited facilities and the product.

Audit results : Complied
Date of decision: November 15, 2023

(Attachment)

1. Top Management		
(1)	Responder	Ichiro Tanaka (Managing Director), Jiro Tanaka (Manager, Quality Control Section, Quality Assurance Department)
(2)	Process of audit	Article 5 to 5-4, Article 7, Article 10, Article 12 to Article 23, Article 56 Article 66
(3)	Audited documents	Quality Management System Standard Code (Quality Manual): SOP001 Version 3 Procedure for Management Review: SOP010 Version 3 Procedure for Change Control: SOP0014 Version 2 Operating Procedure for Internal Audits: SOP011 Version 4 Procedure for Qualification: SOP012 Version 5 Procedure for Training: SOP013 Version 2 Quality Policy: February 1, 2023 Quality Objectives: February 8, 2023
(4)	Records subject to audit	Certificate of Appointment of Management Representative: November 1, 2019 Management Review Minutes: February 14, 2023 Quality Meeting Minutes: July 4, 2023 Internal Audit Plan: FM011-01 Version 2, June 1, 2022 Checklist for Internal Audits: FM011-02 Version 4, December 5, 2022 Internal Audit Report: FM011-03 Version 3, December 15, 2022 List of Qualified Personnel for Operations: FM012-01 Version 2, July 28, 2022 Training Result Report: FM013-01 Version 2, March 3, 2022
(5)	Audited product	Not limited to specified items.
(6)	Content of audit	<u>Quality Management System Standard Code</u> The “Quality Management System Standard Code” (Quality Manual) covers responses included in the QMS Ordinance revised in March 2021 and clearly documents non-applicable requirements and their justifiable reasons. The Quality Manual was revised in May 2021 and the contents of the revision have been notified to all involved personnel through various meetings etc. <u>QMS Organization</u> The responsibilities and authorities of individual departments and members of individual departments are documented in Appendix Table 2 “List of Segregated Duties” of the Quality Manual. Besides the above, a Management Representative was appointed by the Top Management with a “Certificate of Appointment,” dated November 1, 2019, and his/her responsibilities and authority have been specified in the Quality Manual. The specified matters have satisfied the contents set forth in Paragraph 2 of Article 16 of the QMS Ordinance. <u>Quality Policy and Quality Objectives</u> The quality policy was formally expressed by the Top Management as of February 14, 2023. This quality policy was displayed in each office and all employees are instructed to carry the “Mission Statement” that describes the relevant policy with them to ensure notification. The quality objectives are annually established for each department. We confirmed that the quality objectives of the Quality Control Department and the Manufacturing Department in 2023

	are formulated in a form that can evaluate the achievement status thereof. We also confirmed, based on the minutes of the quality meeting held in July 2023, that the achievement status of the quality objectives of the above-mentioned departments had been appropriately evaluated. Management Review Management review procedure was defined in the "Procedure for Management Review." The procedural document specifies that management review shall be conducted once a year, and also defines the attendees, review items, etc. We checked the record of the management review conducted in February 2023. As a result, we confirmed that management review had taken place in the presence of the management as well as the attendees specified in the procedural document, and that the items specified in the procedural document and the QMS Ordinance had been discussed and approved. Internal Communication The following explanation was provided: The quality meeting is held once a month as one of the processes to facilitate information transmission. We checked the minutes of the quality meeting held in July 2023. As a result, the quality meeting had been held in the presence of the representatives of Facilities 1 and 2, including the General Manager Responsible for Manufacturing and Sales (concurrently serving as the Domestic Quality Assurance Manager), Management Representative, and the responsible engineering manager, for intra- and inter-facility information sharing. Change Control The procedure for control of process changes was defined in the "Procedure for Change Control." This procedural document specifies that the assigned person in the relevant department, such as the Quality Assurance Department and the Manufacturing Department, shall evaluate the level of effects on the quality management system, product, and regulatory requirements, and record the results in the "Change Application Form." Internal Audit The internal audit procedure was defined in the "Operating Procedure for Internal Audits." The procedural document specifies that internal audit shall be conducted once a year. The internal audit in 2022 was conducted in December 2022 using the "Checklist for Internal Audits" as per the "Internal Audit Plan." The internal audit results were recorded as an "Internal Audit Report." "Qualification Criteria" specifies that the internal audit shall be conducted by persons who receive training for the QMS Ordinance. But the internal auditors who conducted the above internal audit haven't received the training. Therefore, this was identified as a nonconformity (Finding # 1) The procedural document specifies that observations detected in the internal audit shall be classified as "Nonconformities" or "Observations," and "Nonconformities" should be addressed in accordance with the "Procedure for Corrective Actions." We confirmed that the summary of "Nonconformities" and the number of "Observations" detected in the internal audit in 2022 were reported at the management review held in February 2023. Training

	The training procedure is defined in the “Procedure for Training.” The duties of individual departments and official positions are defined in the “List of Segregated Duties” and the competence required for persons responsible for and assigned to individual duties is defined in the “Eligibility Criteria.” The procedural document specifies that if any additional responsible or assigned person is placed, the relevant person shall undergo the required training based on the “List of Segregated Duties” and “Qualification Criteria,” registered in the “List of Qualified Personnel for Operations,” and then become involved in the relevant operation. After completing training, a training record was prepared on an individual basis. We checked the “Training Result Report” for an operator involved in the catheter tip processing procedure. As a result, we confirmed that this operator became involved in the relevant operation after undergoing training, while the qualified personnel evaluated the result of training and certified the concerned individual.
(7) Status of compliance	A deficiency was observed, and we therefore notified the audited company of it as an observation. For the details of the deficiency and status of improvement, refer to 5. Findings

<table>
<tr><td colspan="2">2. Design Control</td></tr>
<tr><td>(1) Responder</td><td>Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department), Koji Minami (General Manager, Development Department)</td></tr>
<tr><td>(2) Process of audit</td><td>Article 30 to Article 36-2</td></tr>
<tr><td>(3) Audited documents</td><td>Procedure for Design Control: SOP020 Version 8
Procedure for Risk Management: SOP021 Version 6</td></tr>
<tr><td>(4) Records subject to audit</td><td>Risk Management Report: FM021-03, January 10, 2018, March 20, 2018
Design and Development Plan: FM020-01 November 1, 2017, January 26, 2018
Design and Development Input/Output Table: FM020-03, January 19, 2018, February 19, 2018
Design and Development Review Minutes: November 6, 2017, January 26, 2018, February 20, 2018, March 26, 2018
Evaluation Plan for the Strength of the Balloon Joint Section: January 19, 2017
Report on the Result of Testing for the Strength of the Balloon Joint Section: February 12, 2018
Design and Development Validity Confirmation Plan: February 9, 2018
Design and Development Validity Confirmation Result Report: March 9, 2018
Report on the Results of Testing for Mass-production Qualifications: March 15, 2018
Sterilization Validation Result Report: February 15, 2018
Report on the Result of Process Validation Related to Requirements for Catheter Shaft Connection: February 9, 2018</td></tr>
<tr><td>(5) Audited product</td><td>Trade name: Disposable Medical Device Catheter
Generic name: Balloon catheter for stone extraction</td></tr>
<tr><td>(6) Content of audit</td><td><u>Overview of Design Control Process</u>
The design control procedure was defined in the “Procedure for Design Control.” We confirmed that the design control process of the facility consists of the stages shown in Table 1.

Table 1: Design and Development Stages and Their Activities
<table><tr><th>Stage</th><th>Main activities</th></tr><tr><td>1) Stage 1</td><td>Design of the plan</td></tr><tr><td>2) Stage 2</td><td>Development of input and risk management</td></tr><tr><td>3) Stage 3</td><td>Design verification</td></tr><tr><td>4) Stage 4</td><td>Validity confirmation and technology transfer</td></tr></table>
We audited the records of the new design and development project for the product shown in (5) (hereinafter referred to as “this product”) to investigate the status of control of the design control process.

<u>Design and Development Plan (Stage 1)</u>
We confirmed that the “Design and Development Plan” had been formulated for individual operations at each stage of design and development, including review, verification, validity confirmation, traceability, and required resources including competence of personnel, in accordance with the “Procedure for Design Control,” and the plan also clearly defines the related departments and their responsibilities. We also confirmed that the “Design and Development</td></tr>
</table>

	Plan" discussed during the design and development review at Stage 2 was updated to reflect the delay in the original schedule. Inputs (Stage 2) Inputs related to product requirements were clearly documented in the "Design and Development Input/Output Table" and approved during the design and development review. We confirmed that the functional, performance, usability, and safety requirements for the intended use, applicable laws and regulations, risk management outputs, information obtained from previous similar designs, and other requirements are incorporated in the entry fields of the "Design and Development Input/Output Table." The risk management procedure was defined in the "Procedure for Risk Management" and outputs are clearly documented in the "Risk Management Report." Outputs (Stage 3) We confirmed that design and development outputs, such as drawings and performance testing, are clearly documented in a form that enables verification against design and development inputs in the output field of the "Design and Development Input/Output Table," and had been approved during the design and development review at Stage 3. We also confirmed, based on the contents of the output field of the "Design and Development Input/Output Table," that all outputs conform to inputs. Design and Development Review It was specified in the "Procedure for Design Control" that design and development review shall be conducted when proceeding to each of the stages shown in Table 1. It was also specified that each design and development review shall take place in the presence of the persons assigned to the practical operation and the responsible persons in the Quality Assurance Department, Sales/Service Department, Manufacturing Department, Development Department, etc. to ensure that the required review is conducted. We confirmed, based on the "Design and Development Review Minutes," that design and development review had taken place in the presence of attendees from the specified departments at the required time points of Stage 1 through Stage 4. We also confirmed that the date of review, attendees, and review result are recorded in the minutes. Design and Development Verification (Stage 3) We checked the verification process, through sampling, for the strength of the balloon joint section, one of the inputs listed in the "Design and Development Input/Output Table." As a result, we confirmed that evaluation had been conducted as per the approved "Evaluation Plan for the Strength of the Balloon Joint Section," and also confirmed, based on the "Report on the Result of Testing for the Strength of the Balloon Joint Section," that the related requirements are satisfied. We further confirmed that the evaluation methods, including those for combined medical devices, evaluation criteria, and the rationale for sample size for evaluation are clearly documented in the plan. Design and Development Validation (Stage 4) The design and development validation plan for this product was clearly documented in the

	"Design and Development Validity Confirmation Plan." The background of the product used, rationale for product selection, evaluation methods including those for other combined products, and rationale for sample size were clearly documented in the plan. We confirmed that the results of confirmation are recorded in the "Design and Development Validity Confirmation Result Report," and that the validation had been conducted as per the plan. We also confirmed that the validity of design had been evaluated as required by using this product under mock environments under which clinicians used animals. Design Transfer (Stage 4) The design transfer procedure was defined in the "Procedure for Design Control" which specifies that the appropriateness of the manufacturing process shall be confirmed by using mass-produced sample products before design transfer. In the "Report on the Results of Testing for Mass-production Qualifications," it was concluded that the manufacturing capacity of the specified manufacturing process satisfied the product requirements and transfer was therefore possible. We also checked the following records created during the development, and confirmed that mass-production of sample products had been carried out based on the set values determined during the design and development stage, and that the acceptance criteria are satisfied. - Report on the Result of Process Validation Related to Requirements for Catheter Shaft Connection Control of Design and Development Changes The design and development change procedure was defined in the "Procedure for Design Changes." No changes to the design of this product had been made at this time; however, we confirmed that the procedural document specifies that procedures that should be followed shall be determined depending on the significance level of the change. Documents Related to Design and Development Records related to the design and development of this product were compiled as a design and development file titled, "Design and Development Records of a Disposable Medical Device Catheter." We confirmed that an administrative number is assigned to the file, and that it is managed in a form that can confirm the contents of records created during design and development and at updates.
(7) Status of compliance	Complied

3. Product Documentation		
(1)	Responder	Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department)
(2)	Process of audit	Article 7-2, Article 26
(3)	Audited documents	Procedure for Risk Management: SOP021 Version 6 Product Master File: DMR-002 Version 8, June 1, 2023
(4)	Records subject to audit	Risk Management Report: FM021-03 Version 1, February 2, 2023
(5)	Audited product	Trade name: Disposable Medical Device Catheter Generic name: Balloon catheter for stone extraction
(6)	Content of audit	We confirmed that the Product Master File of the product shown in (5) had been prepared and retained. We also confirmed that the Product Master File specifies all manufacturing processes in each facility and contains elements set forth in Article 7-2 of the QMS Ordinance. <u>Risk Management</u> The risk management procedure was defined in the "Procedure for Risk Management." This procedural document specifies that risk analysis, risk control, and residual risk evaluation shall be conducted and the final results shall be recorded in the "Risk Management Report." Risk analysis had been performed using the Failure Mode and Effect Analysis (FMEA) and risk identification had been carried out during the manufacturing process and from the aspect of users. We checked the "Risk Management Report" and confirmed that risk management had been conducted in accordance with the procedural document. The "Risk Management Report" had been handled as an input in the design and development process of this product, and that the contents were confirmed during each design and development review.
(7)	Status of compliance	Complied

4. Manufacturing		
(1)	Responder	Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department), Koichi Kita (Manager, First Manufacturing Section, Manufacturing Department), Kozo Nishi (Manager, Quality Control Section, Quality Control Department)
(2)	Process of audit	Article 24 to Article 25-2, Article 40, Article 41, Article 44 to Article 48, Article 51 to Article 53, Article 58, Article 60 to Article 60-4
(3)	Audited documents	Product Master File: DMR-002 Version 8, June 1, 2023 QC Process Flow Chart (Disposable Medical Device Catheter): QC010 Version 7 Procedure for Balloon Welding (PO5124): SOP041 Version 1 Procedure for Final Testing: SOP042 Version 2 Procedure for Assessment of Product Release: SOP043 Version 3 Procedure for Process Validation: SOP044 Version 1 Procedure for Sterilization Validation: SOP045 Version 2 Procedure for Environment Control: SOP046 Version 2 Procedure for Control of Nonconforming Products: SOP047 Version 5
(4)	Records subject to audit	Written Instructions and Records for Material Acceptance Testing: FM041 Version 1, June 2, 2023 Written Instructions and Records for Operations: FM042 Version 7, June 30, 2023 Sterilization Result Record (Mekkin Co., Ltd.): June 28, 2023 Report on the Result of Assessment of Product Release from the Manufacturing Site: FM043 Version 2, June 30, 2023 Validation Plan: DKK01-01, January 23, 2023 Validation Report: DKK01-03, February 24, 2023 Audit Report on Radiation Dose: May 8, 2023 Report on the Results of Measurement of Airborne Particles: June 20, 2023 Report on the Results of Measurement of Airborne Microbes: June 20, 2023 Report on the Results of Measurement of Attached Bacteria: June 26, 2023 Report on the Results of Measurement of Product-attached Bacteria: April 26, 2023 Differential Pressure Control Report: July 3, 2023 Temperature and Humidity Monitoring Results Report: July 4, 2023 Nonconformity Report (NCE#1000): FM047 Version 2, May 9, 2023
(5)	Audited product	Trade name: Disposable Medical Device Catheter Generic name: Balloon catheter for stone extraction
(6)	Content of audit	We audited the status of manufacturing control and quality control particularly for the product shown in (5) (hereinafter referred to as “this product”) to investigate the status of control of the manufacturing process. <u>Manufacturing Control</u> Requirements for this product were defined in the “Product Master File,” and the manufacturing process, facilities, processes requiring process validation, etc. are clearly documented in the “QC Process Flow Chart.” We checked the balloon and the catheter shaft connecting process, which is one of the important processes for this product, through sampling as shown below, and confirmed that the control of this process had been conducted in accordance with the procedure.

	The connection of the balloon and the catheter shaft was performed by laser beam welding. This welding process is automated, and the setup values (output value and time) for welding are defined in the "Procedure for Balloon Welding." The procedural document specifies that the operation of the relevant process shall be recorded as "Written Instructions and Records for Operations," and we confirmed that the date/time, personnel, setup values, etc. of the operation had been recorded therein. Manufacturing Records We confirmed in the following manufacturing and testing records of this product (Batch No.: June 30, 2023, Manufacturing No.: KK0630) that the records had been prepared in a way that could trace the product to the extent of raw materials and identify the quantity manufactured and the quantity approved for distribution. - "Written Instructions and Records for Material Acceptance Testing" - "Written Instructions and Records for Operations" - "Sterilization Result Record (Mekkin Co., Ltd.)" - "Report on the Result of Assessment of Product Release from the Manufacturing Site" Monitoring and Measurement of Products The Quality Control Department was supposed to conduct the final testing and the responsible engineering manager was supposed to assess whether to release the product from the manufacturing site or not. The final testing included the appearance test, sizing test, confirmation of sterilization records, and individual testing methods and frequency are defined in the "Procedure for Final Testing." The test results were recorded in the "Written Instructions and Records for Operations." It was specified in the "Procedure for Assessment of Product Release" that the responsible engineering manager shall assess whether to release the product or not after confirming all manufacturing and quality control records. The results of assessment of the responsible engineering manager on whether to release the product from the manufacturing site or not were recorded in the "Report on the Result of Assessment of Product Release from the Manufacturing Site." Identification Control We confirmed that raw materials before and after acceptance testing, identified by red and green labels, respectively, were stored in the raw material storage area in the warehouse, and those before and after acceptance testing were identified from each other. The "Written Instructions and Records for Operations" was affixed to semi-finished products in the manufacturing process and moved with the products through the process, which enables identification of the products in the different stages. We confirmed that the products before and after authorization of release are stored separately in individual areas in the warehouse, which enables status identification of the products in relation to release of the products. Validation of the Manufacturing Process etc. The procedures for validation of the manufacturing process etc. were defined in the "Procedure for Process Validation." The procedural document specifies that the processes requiring validation shall first be chosen based on the predetermined criteria and the process FMEA results,

	the processes considered subject to validation shall then be summarized in the "Process Validation Master Plan," and then validation shall be conducted. We checked the "Validation Plan" and "Validation Report" concerning the strength of the balloon joint section of this product. As a result, we confirmed that the worst conditions of process parameters had first been examined, and it was confirmed as validation of process performance qualification that the product manufactured on a commercial scale under the specified conditions had satisfied the product specifications. We also confirmed that the method, assessment criteria, and rationale for sample size for evaluation are clearly documented in the Validation Plan. Validation of the Sterilization Process The validation procedure of the sterilization process was defined in the "Procedure for Sterilization Validation." The radiation dose for sterilization was verified using the VDmax25 method, and sterilization validation and audit on the radiation dose for sterilization were conducted in accordance with ISO11137-1 and ISO11137-2. Confirmation of qualification at the time of installation and operation was conducted by the outsource for sterilization. Confirmation of performance qualification was conducted at the manufacturing site, which is the outsourcer of the aforementioned duty. We checked the "Audit Report on Radiation Dose" dated May 2023. Bioburden and absorbed radiation dose falling within the specified ranges was confirmed. It was also tested in the microbiological study that loaded bioburden was killed. Environmental Monitoring Control The procedure for environmental monitoring control in the clean room where assembly and packaging of this product were carried out is defined in the "Procedure for Environmental Control." The control level of the above clean room was ISO Class 7. We confirmed that the monitoring of airborne particles, airborne viable, and surface microbial contaminants is conducted once a month at predetermined locations, and that the monitoring of product bioburden is conducted four times a year. As for these monitoring results, reference values (action limit and alert limit) were established. We checked the results of monitoring, performed in June 2023, of airborne particles, airborne viable, and surface microbial contaminants did not detect any deviations from the reference values. We also checked the results of monitoring, performed in April 2023, of product bioburden and confirmed that all recorded values were below the reference values. Nonconforming Product Control The nonconforming product control procedure was defined in the "Procedure for Control of Nonconforming Products." The procedural document specifies that nonconforming products shall be physically segregated and identified, and that such measures shall be recorded in the "Nonconformity Report." The procedural document also specifies that investigation of the causes of nonconformity and determination of whether to notify external organizations or not shall be conducted jointly by the assigned persons in the Quality Assurance Department and the Manufacturing Department, and measures taken for nonconforming products shall be determined by the director of the Quality Assurance Department. We checked the following records through sampling and confirmed that nonconforming products had been controlled in accordance with the procedure.

	- "Nonconformity Report" (NCE#1000): As the response to a case of nonconforming products due to a mix-up of coating solutions for the catheter, the director of the Quality Assurance Department had determined to discard all the nonconforming products. The reasons for the decision and the contents of investigation were recorded in detail in the above Nonconformity Report. The record of disposal of the relevant products was also attached to the report.
(7) Status of compliance	Complied

5. Corrective Actions and Preventive Actions		
(1)	Responder	Saburo Tanaka (General Manager, Quality Assurance Department), Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department)
(2)	Process of audit	Article 54 to Article 55-3, Article 57, Article 61 to Article 64
(3)	Audited documents	Quality Management System Standard Code (Quality Manual): SOP001 Version 3 Procedure for Corrective Actions and Preventive Actions: SOP050 Version 2
(4)	Records subject to audit	Quality Meeting Minutes: July 4, 2023 Corrective Action Plan and Report: FM050-01 Version 1, CA#2017017, June 2, 2023
(5)	Audited product	Not limited to specified items.
(6)	Content of audit	Data Analysis The data analysis procedure was defined in the "Quality Manual." The procedural document specifies that items subject to data analysis are "Complaints," "Nonconformity in the manufacturing process," "Nonconformity at the supplier side," "Audits," etc. and monthly monitoring results shall be confirmed at the quality meetings. We checked the minutes of the quality meeting held in July 2023 and confirmed that data analysis had been conducted for the specified items. Corrective Actions The procedure for corrective actions was defined in the "Procedure for Corrective Actions and Preventive Actions." When nonconformity was detected, the content of nonconformity was reviewed and the director of the Quality Assurance Department assessed whether to take corrective actions or not. The procedural document specifies that the Management Representative shall verify that corrective actions taken have no harmful effect and confirm that corrective measures taken are effective, and the director of the Quality Assurance Department shall approve them. The progress status of corrective actions was confirmed at the monthly "Quality Meeting." We checked the following records through sampling and confirmed that control of corrective actions had been conducted in accordance with the procedure. - Corrective Action Plan and Report (CA#2017017) - Quality Meeting Minutes, July 2023
(7)	Status of compliance	Complied

6. Purchasing Control		
(1)	Responder	Saburo Tanaka (General Manager, Quality Assurance Department), Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department), Hiroshi Higashi (General Manager, Purchasing Department)
(2)	Process of audit	Article 37 to Article 39, Article 84
(3)	Audited documents	Quality Management System Standard Code (Quality Manual): SOP001 Version 3 Procedure for Purchasing Control: SOP060 Version 2
(4)	Records subject to audit	Suppliers Evaluation Table: FM060-02 Version 1, October 3, 2022 Visit Audit Result Report: June 3, 2022 Periodic Confirmation Result Report: FM090 Version 2, March 9, 2022
(5)	Audited product	Trade name: Disposable Medical Device Catheter Generic name: Balloon catheter for stone extraction
(6)	Content of audit	<u>Supplier Control</u> The procedure for control of suppliers of purchased products was defined in the "Procedure for Purchasing Control." The procedural document specifies that suppliers shall be classified into three categories from A to C depending on the level of effects on the finished product, and items required for pre-selection evaluation (on-site audit, conduct of questionnaires, obtainment of the ISO Certificate, etc.) had been set for each category. As for re-evaluation of suppliers, items required for re-evaluation (data of the acceptance test, status of delivery, periodic on-site audits) and the criteria had been set for each category in the same manner, and we confirmed that the control of suppliers had been conducted, as planned, in accordance with the criteria. We checked the re-evaluation records prepared for the supplier of the catheter shaft in 2022. As a result, we confirmed as follows: The company had classified the relevant supplier as the highest-risk Category A, then had not only conducted an on-site audit but had also evaluated the nonconformity rate in the acceptance test and status of delivery in accordance with the procedure, and had confirmed that the relevant supplier satisfied the criteria. We checked the evaluation and selection records prepared for the balloon supplier which was newly adopted in 2021 and we found that on-site audit required by the procedure was not conducted and the supplier was not approved. Therefore, this was identified as a nonconformity (Finding # 2). The procedure for control of registered manufacturing sites was defined in the "Quality Manual." The procedural document specifies that the QMS operation status of the registered manufacturing site shall be confirmed, as necessary, for appropriate control, in addition to evaluation of the registered manufacturing site in accordance with the "Procedure for Purchasing Control." We confirmed that the "Periodic Confirmation Result Report" had been prepared based on the fact that Mekkin Co., Ltd. had performed the sterilization process and that compliance with the QMS Ordinance had been evaluated on an on-site basis as the role of the Marketing Approval Holder.
(7)	Status of compliance	A deficiency was observed, and we therefore notified the audited company of it as an observation. For the details of the deficiency and status of improvement, refer to 5. Findings.

7. Documents and Records		
(1)	Responder	Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department)
(2)	Process of audit	Article 6, Article 8, Article 9, Article 67, Article 68
(3)	Audited documents	Procedure for Control of Documents and Records: SOP070 Version 6
(4)	Records subject to audit	Distribution List: FM070-001 Version 2, September 12, 2022
(5)	Audited product	Not limited to specified items.
(6)	Content of audit	<u>Control of Documents and Records</u> The procedure for control of creation and revision of quality management system documents was defined in the "Procedure for Control of Documents and Records." This procedural document, defines the author, reviewer, and approver of quality management system documents, and also specifies that a predefined person shall review and approve the documents, etc. Original quality management system documents had been managed in print form. Documents subject to control were supposed to be stamped with a seal as an identifying purpose. When quality management system documents were created or revised, the addresses for distribution were recorded in the Distribution List, and obsolete documents were collected. We confirmed that obsolete documents had been segregated and retained to prevent unintended use of them. The procedure for control of records was defined in the "Procedure for Control of Documents and Records." The procedure had been established to ensure that records are prepared in print form and kept in files in the record creation department. <u>Retention Period of Documents and Records</u> The retention period of obsolete quality management system documents and records was defined in the "Procedure for Control of Documents and Records." This procedural document specifies that documents and records shall be retained for "5 years or the shelf life of the product plus 1 year, whichever is longer." This satisfied the requirements under the QMS Ordinance.
(7)	Status of compliance	Complied

8. Customers	
(1) Responder	Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department), Koji Minami (General Manager, Development Department), Kozo Nishi (General Manager, General Affairs Department)
(2) Process of audit	Article 11, Article 27 to Article 29
(3) Audited documents	Iryokiki Maker Price List: Version 120 Procedure for Information Provision to Customers: SOP081 Version 1 Procedure for Customers' Opinion Collection: SOP080 Version 1 Disposable Medical Device Catheter Catalogue 20221101
(4) Records subject to audit	Order Form (Agency: Nakayama Medical Instruments Co., Ltd.) dated March 22, 2023, revised Order Form dated March 24, 2023 Confirmation/Approval Records for Disposable Medical Device Catheter Catalogue Inquiry Form (Yamamoto Hospital) dated April 10, 2022
(5) Audited product	Not limited to specified items.
(6) Content of audit	<u>Determination of Requirements Related to Products</u> <Determination of Customer Requirements Related to Design and Development> The Development Department obtained requests etc. for development of new products or improvement of existing products from the agency. The Development Department clarified product requirements by adding their own requirements considered necessary as the Marketing Approval Holder (requirements necessary for designated or intended use, requirements required under laws and regulations [e.g., Japanese Industrial Standards (JIS)] to the obtained information, and incorporates them into the design and development inputs. The need for training of customers was clarified through design and development (usability, risk management, etc.). <Determination of Customer Requirements Related to Existing Products> Products of which design and development had been completed and which had become available for release on the market were listed with the specific product code in the price list. The agency filled out an order form designated by the audited facility with the information such as the product code, quantity, desired delivery date, and delivery destination (medical institutions etc.), and sent it (via email or fax) to the General Affairs Department of the audited facility. <u>Review of Requirements Related to Products</u> <Review of Customer Requirements Related to Design and Development> Design and development inputs, including product requirements, had been confirmed by design and development review and recorded. Training of customers had been planned as design and development outputs (user training plan). <Review of Customer Requirements Related to Existing Products> The General Affairs Department had confirmed that the product could be delivered as requested by the agency (product in stock or production capacity) based on the transmitted order form, and

	recorded the result in the order form. The General Affairs Department also provided the Manufacturing Department with the instruction to deliver the product in stock or manufacture the product. When the content of the order form was changed, the General Affairs Department confirmed it in the same manner and corrected the instruction for the Manufacturing Department. We confirmed the set of procedures shown above in the order form from the agency Nakayama Medical Instruments Co., Ltd.
(7) Status of compliance	Complied

9. Marketing Approval Holder, etc.		
(1)	Responder	Saburo Tanaka (General Manager, Quality Assurance Department), Jiro Tanaka (Manager, Quality Assurance Section, Quality Assurance Department)
(2)	Process of audit	Article 69 to Article 72-2
(3)	Audited documents	Quality Management System Standard Code (Quality Manual): SOP001 Version 3 Operating Procedure for Quality Control: SOP041 Version 2 Procedure for Recall: SOP091 Version 3
(4)	Records subject to audit	Record of the Results of Assessment of Product Release on the Market: FM091 Version 1, June 30, 2023 Report on the Result of Assessment of Product Release on the Market: FM092 Version 2 Application Form for Important Process Changes: FM093 Version 3 Notification Form for Quality etc. Information Processing: FM080-001 Version 1 Agreements for Manufacturing Control and Quality Control (Mekkin Co., Ltd.): June 8, 2018
(5)	Audited product	Trade name: Disposable Medical Device Catheter Generic name: Balloon catheter for stone extraction
(6)	Content of audit	<u>Duties of the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc.</u> It was defined in the "Quality Manual" that the General Manager Responsible for Manufacturing and Sales is the director of the Quality Assurance Department. The duties of the General Manager Responsible for Manufacturing and Sales were also defined in the "Quality Manual." <u>Domestic Quality Assurance Manager</u> It was defined in the "Quality Manual" that the Domestic Quality Assurance Manager is the director of the Quality Assurance Department (concurrently serving as the General Manager Responsible for Manufacturing and Sales). The procedure for assessment to release the product on the market was defined in the "Operating Procedure for Quality Control." The procedural document specifies that the responsible engineering manager shall assess whether to release the product on the market or not, record the result of assessment in the "Record of the Results of Assessment of Product Release on the Market," and report monthly to the Domestic Quality Assurance Manager through the "Report on the Result of Assessment of Product Release on the Market." We verified, through sampling, the result of assessment to release the audited product (June 30, 2018, trade name: Disposable Medical Device Catheter, Manufacturing No.: KK0630) had been reported to the Domestic Quality Assurance Manager in accordance with the procedure. We confirmed the following procedure: If a change is made to the manufacturing method, testing method, etc., which may significantly affect the product quality, the information should be provided to the Management Representative and the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. using the "Application Form for Important Process Changes." We also confirmed the following procedure: If information related to the product quality etc. is obtained, the information should be provided to the Management Representative and the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. by issuing a "Notification Form for Quality Information Processing," and corrective actions should be taken as appropriate.

	The recall procedure was defined in the "Procedure for Recall." The procedural document specifies that the matter of recall shall be kept in the record and be reported in writing to the General Manager Responsible for Manufacturing and Sales of Medical Devices, etc. Agreements with the Registered Manufacturing Site Facility 1 (Marketing Approval Holder) and Facility 2 (registered manufacturing site) are facilities within the same QMS and under the same legal entity. We confirmed that notification of the Marketing Approval Holder and the responsible person in case of a nonconformity, a change that affects product quality, or a defect, are defined in the Quality Manual. We also confirmed that the Marketing Approval Holder had signed the agreement with Mekkin Co., Ltd., a contract sterilization facility. We also confirmed that this agreement contains the scope of outsourced activities, manufacturing control and quality control methods, prior communication for change-related information, and others.
(7) Status of compliance	Complied