under their own responsibility, and shall be required for their storage condition, storage number, etc., to be indicated such as in the product master formula.

For example, when determining whether a biological raw material of cellular and tissue-based products, such as the human serum albumin used as a stabilizer, should be subject to storage of reserve sample, consideration shall be given to their importance in terms of safety measures for, for example, unidentified infections.

Specifically, for example, if serum, etc., is used in cell culture, a part of the serum shall be stored for those that were used in monitoring viral infection in cultured cell, in monitoring viral disease onset in patients, and in investigating antibody production, etc., against foreign serum components.

In order for infection-related viruses, abnormal prion, unidentified substances, etc., to be detected with higher sensitivity, there may be cases where it is necessary to consider having intermediate products, etc., become subject to storage of reserve sample at an appropriate stage. Solvents, gas, and water used in the manufacturing process are not required to be subject to storage of reserve sample.

"Packaging and labeling materials that may influence quality" shall be, for example, packaging materials used for the purpose of quality assurance and whose product come directly in contact, and even for those that do not come in direct contact with the product, packaging materials, labeling materials, etc., that are used to prevent permeation of moisture, oxygen, etc., and to protect their content.

D. Quality assurance of reference standard, reagent/reagent solution, etc. used in testing

E. Re-testing

Measures shall be taken to prevent inappropriate re-tesings, such as initial testing on errors, etc., at testing rooms when non-standard testing results were obtained, additional testing using identical samples, and re-sampling and re-testing when there was a problem in the sample method or obtained samples.

F. Stability monitoring (excluding products that do not compose a lot)

(a) Manufacturers shall conduct stability monitoring in accordance to an appropriate continuous program to monitor whether the measurement

items that are easily influenced by storage and the measurement items that may affect product quality, safety, or efficacy remain and stay remaining within its specification during the period of shelf life or until expiration date under the storage condition established for a manufactured final product, and those results are required to be recorded and stored.

The phrase "the measurement items that are easily influenced by storage and the measurement items that may affect product quality, safety, or efficacy" shall mean, for example, measurement items such as cell survival rate and potency items that were selected based on the knowledge obtained from, for example, designing and prototype investigation at the stage of research development and stability testing results, among which are easily influenced by temperature, humidity, and other storage conditions.

Measurement items that are clearly thought to have no time-dependent change, such as heavy metal and arsenic, may be omitted.

(b) Manufacturers shall select products and lots for stability monitoring under its responsibility and shall obtain necessary amount of their sample.

Products manufactured every year shall require stability monitoring for those pertaining to at least 1 lot (excluding cases of those that were not manufactured in that year) or to a single manufacturing number. Lots that had a temporary change that influences safety and that had measures taken for deviation shall also be subject to stability monitoring.

G. Storage of retention product pertaining to the final product

For the final product (excluding those products that do not compose a lot), its retention product shall also be stored other than the reserve sample for the same period required in reserve samples. "Retention product" shall be a sample for confirming uniformity with the marketed product, and shall be one that has been obtained from the final product. If the packaging form and storage condition of the retention product are the same as those of the reserve sample, storage of the retention product is not required to be distinguished from the reserve sample.

(22) Paragraph 3 prescribes matters regarding exceptions on imports from countries, etc., with mutual recognition agreement.

(23) The phrase "When the procedures to evaluate conformity with the standards for manufacturing control and quality control in an exporting country are found to be equivalent to those in Japan" prescribed in Paragraph 3 shall refer to the manufacturing that is conducted at the country with the mutual recognition agreement and that applies to this agreement.

(24) The phrase "may be substituted for confirmation of records of the inspection and testing conducted by the foreign manufacturers of regenerative medicine products in an exporting country" indicated in Paragraph 3 shall require attention to the fact that necessary testing is required to be conducted based on the provision in Paragraph 1, Item 2 when any doubt arise on the product quality at appearance testing, etc.

(25) "Periodically check" indicated in Paragraph 3, Item 1 shall require confirmation based on the results of the latest conformity inspection with consideration of how often conformity inspections are conducted by the government of the country of origin.

(26) "Records of inspection and testing" indicated in Paragraph 3, Item 4 shall require the following items to be indicated.

A. Sample name

B. Lot number or manufacturing number, or control number

C. Testing items, testing date, and testing results

D. Content of testing result assessment, date of assessment, name of person who conducted the assessment

(27) The phrase "check the records of inspection and testing" indicated in Paragraph 3, Item 4, shall mean to confirm that the testing pertaining to the product is appropriate judging from its testing results.

(28) The provision in Paragraph 4 prescribes that records are required to be controlled to enable tracking of all stages, from the time of collecting raw material for the biological raw material of cellular and tissue-based product to the time of releasing the product manufactured using this raw material from the manufacturing site, in

case of any problem in the product, etc., or material, or in case of infection due to the product, so that the relevant product may be immediately identified and an investigation on their cause may be conducted.

Form No. 3-3-1

List of Items/Products to be Requested for Testing

Date:

Responsible person in the quality division:

Serial Number	Item/product	Approval No.	Testing institution	Testing item	Testing equipment	Notes	
						(1)	(2)
				1 2 3 4 5			
				1 2 3 4 5			
				1 2 3 4 5			
				1 2 3 4 5			
				1 2 3 4 5			

(Notes)

1. If there are more than two testing institutions, etc., fill in "see Attachment" in the column and attach a separate sheet.
2. The numbers in the column "Testing item" indicate 1: identification test, 2: impurity test, 3: quantitative test, 4: testing in animals, 5: other tests. Circle the items to be requested for testing and fill in the name of the equipment that will be used in the column "Testing equipment." If no. 5 was circled in the column "Testing item", fill in the testing item in the column "Notes (1)".
3. In case of any change in the content, modify the content accordingly and indicate the date of modification in the column "Notes (2)".

Form No. 3-3-2

List of Items to be Requested for Testing
in Raw materials/Packaging and Labeling Materials

Date:

Responsible person in the quality division:

Serial Number	Item	Testing institution	Notes

(Notes)

1. Create the list according to each raw material/material.
2. If there are more than two testing institutions, etc., fill in "see Attachment" in the column and attach a separate sheet.
3. In case of any change in the content, modify the content accordingly and indicate the date of modification in the column "Notes".

Form No. 3-3-3

Testing Application Form

Date:

To:

Manufacturing site:
Address:
Responsible person in the quality division: (seal or signature)

We request testing for the following:

Sample	Lot no. Quantity	Testing item	Precautions for storage

(Note)
Send a specification, testing method, and a necessary amount of sample along with this form.

13. Article 13 (Control of Release from Manufacturing Sites)

(1) This Article prescribes that manufacturers are required to have the quality division to conduct the operation regarding appropriately evaluating manufacturing control and quality control results and of product release acceptance from manufacturing sites. In conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) Although products shall, in principle, be released from the manufacturing site after their testing results and product release have been determined, products may be released before testing results have been obtained for those that are released from the manufacturing site to the manufacturing site in the category of packaging, etc. where only storage of products, etc., or packaging and labeling materials of the same manufacturer, etc. is conducted. In this case, a comprehensive evaluation shall be made on the two manufacturing sites for release acceptance at the manufacturing site in the category of packaging, etc.

Furthermore, in cases where release must be determined before obtaining testing results that require a certain number of days due to short shelf life or expiration date, such as results of sterility testings, release may be exceptionally determined before obtaining testing results as long as the following requirements are met:

A. Such judgment is accepted in the marketing approval document.

B. Measures (including communication with medical institutions, etc., that use cellular and tissue-based products pertaining to the product) are prescribed in advance in the procedures, etc., for when nonstandard testing results were obtained after release of the product.

(3) The phrase "properly evaluate the results of manufacturing control and quality control, and determine whether or not the product can be released from the manufacturing site" indicated in Paragraph 1 shall mean to determine release of manufactured products (including stored products) given that there is accurate knowledge of the manufacturing control status and quality control status, and manufacturers shall not release products if this has not been determined.

(4) The phrase "have an ability to properly and smoothly perform" "duties" indicated in Paragraph 2 shall mean that the manufacturers are required to have judged a person to have the capacity to enable appropriate and smooth conduct of the operation

upon comparing the content of the operation, operational experience, training experience, etc.

14. Article 14 (Validation or Verification)

(1) This Article prescribes that manufacturers are required to have predesignated persons to conduct the operation regarding validation and verification (hereinafter referred to as "validation, etc."). When conducting this operation, quality risk management shall be used as necessary.

(2) "A person, designated beforehand" indicated in Paragraph 1 shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(3) Validation and verification prescribed in Paragraph 1, Item 1 shall be conducted in accordance to the "Validation Standards".

(4) The phrase "when the manufacturing of a new product is started" indicated in Paragraph 1, Item 1 (a) shall mean when intending to initiate manufacturing of the product at the manufacturing site for the first time.

(5) The phrase "when there are changes" "that may significantly affect the quality of the product" indicated in Paragraph 1, Item 1 (b) shall mean when intending to make changes in the raw material, material, manufacturing process, building and facility, etc., that are expected to have a large influence on product quality.

(6) The phrase "other cases where it is found to be necessary for properly implementing the manufacturing control and quality control of the product" indicated in Paragraph 1, Item 1 (c) shall include cases indicated in the "Validations Standards" other than those indicated in Paragraph 1, Item 1 (a) and (b).

15. Article 15 (Review of Product Quality)

(1) This Article prescribes that manufacturers are required to have predesignated persons conduct the operation regarding review of product quality. When conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) Review of product quality shall be conducted via periodic or occasional review and analysis on the results, state, etc., of product quality for the purpose of confirming whether the product is manufactured in an appropriately controlled state or whether further improvement is possible.

(3) "A person, designated beforehand" indicated in Paragraph 1 shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

16. Article 16 (Control of Changes)

(1) This Article prescribes that manufacturers are required to have predesignated persons to conduct the operation regarding control of changes. When conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) This Article shall apply to all changes pertaining to buildings and facilities, procedures, processes, and any other manufacturing control and quality control methods at a manufacturing site for those that may influence product quality.

(3) "A person, designated beforehand" shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(4) Products of the first consecutive multiple lot numbers or manufacturing numbers in which manufacturing or testing was conducted after changes shall require evaluation, etc., (use quality risk management as necessary, and evaluate in accordance to validation at the time of change or to other appropriate methods) to be conducted on the extent of influence due to this change.

(5) The provision in Item 2 prescribes that when making changes approved by the quality division, revisions shall be definitely made on all documents influenced by this change (including avoidance of having older versions and their copies to be used); training shall be conducted in relevant personnel; and other necessary measures shall be taken to appropriately and definitely make the changes.

17. Article 17 (Deviation Control)

(1) This Article prescribes that manufacturers are required to have predesignated persons conduct the operation regarding control of deviations from manufacturing procedures, etc. When conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) This Article shall apply to all deviations from buildings and facilities, procedures, processes, and any other manufacturing control and quality control methods at a manufacturing site.

(3) "A person, designated beforehand" indicated in Paragraph 1 shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(4) The provision in Paragraph 1, Item 2 prescribes operations required in manufacturers for when deviations from manufacturing procedures, etc., were judged serious upon obtaining accurate knowledge of those deviations (consider use of quality risk management when making those judgments).

(5) The provisions in Paragraph 1, Item 2 (a), (b), and (c) prescribe that because "evaluation of influence on product quality due to deviation" and "necessary measures" are important operations, these results and their content are required to be reported to and to be confirmed by the quality division.

(6) The provision in Paragraph 2 prescribes that reporting is required to be made to the manufacturing supervisor of cellular and tissue-based products in order to enable the manufacturing supervisor to execute operations prescribed in Article 6, Paragraph 1, Item 2.

(7) Products of the first consecutive multiple lot numbers or manufacturing numbers in which manufacturing or testing was conducted after any deviation that was not judged serious shall, in principle, be evaluated, etc., on the extent of influence due to this deviation (consider using quality risk management as necessary).

18. Article 18 (Information on Quality, etc., and Measures for Quality Defect, etc.)

(1) This Article prescribes that manufacturers are required to have predesignated persons to conduct the operation regarding information on quality, etc., and measures for quality defect, etc. When conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) The provisions in this Article shall apply to all quality information pertaining to products except in cases for those that are clearly not attributable to the relevant manufacturing site.

(3) "A person, designated beforehand" indicated in Paragraph 1 shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(4) "Records indicating the content of the quality information, results of investigation on the cause, and improvement measures", indicated in Paragraph 1, Item 2, shall include the following:

A. Content of the quality information

(a) Name, structure, property, packaging form, and lot number or manufacturing number of the product subject to quality information

(b) Date and place at which matters pertaining to quality information occurred, and address and name of person who reported the information

(c) Content of quality information and sequence of background to the reporting

B. Results of investigation on the cause

(a) Investigation results of the product pertaining to quality information (name of investigated market, marketing status and usage status of the product, relevance to products other than the lot number or manufacturing number of the product, etc.)

(b) Results of testing, etc., on the reserve sample of the product pertaining to quality information

(c) Results of investigation on the testing records of the product pertaining to quality information

(d) Investigation results of manufacturing record, storage record, and sanitary control record of the product pertaining to quality information

C. Assessment based on results of the investigation on the cause

D. Content of improvement measures

E. Reference of relevant manufacturing records

(5) Because investigation on the cause and measures for the matters pertaining to quality information prescribed in Paragraph 1, Item 1 are important operations that may seriously influence product quality, the provisions in Paragraph 1, Item 2 and Item 3 prescribe that these matters are required to be reported to the quality division and to be confirmed by the quality division.

(6) The provision in Paragraph 2 prescribes that reporting is required to be submitted to the manufacturing supervisor in order for the manufacturing supervisor to appropriately execute the operations prescribed in Article 6, Paragraph 1, Item 2.

19. Article 19 (Measures for Recall)

(1) This Article prescribes that manufacturers are required to have predesignated persons to conduct the operation regarding taking measures for product recalls. When conducting this operation, use of quality risk management shall be put into consideration.

(2) The operation of taking measures for recall of cellular and tissue-based products shall be conducted pursuant to the provisions in the GQP Ordinance by the marketing authorization holder conducting this marketing, and manufacturers shall conduct the operation of taking measures for recall in accordance to the instructions of the marketing authorization holder.

(3) Measures for recall of products pertaining to intermediate products shall be conducted pursuant to this Article by the manufacturers of the product pertaining to this intermediate product.

(4) The provision in Item 1 shall apply to all recalls pertaining to product regardless of whether the recall is attributable to the relevant manufacturing site.

(5) "For a certain period of time" indicated in Item 1 shall be the period until measures have been determined for the recalled product.

(6) The provision in Item 2 shall apply to all recalls pertaining to the product except in cases for those that are clearly not attributable to the relevant manufacturing site.

(7) "Records on a recall action" indicated in Item 2 shall include the following matters:

A. The name of marketing authorization holder of cellular and tissue-based products pertaining to the product that was subject to recall

B. Content of the instruction from the marketing authorization holder on operations pertaining to the recall

C. Name, structure, property, packaging form, quantity, and lot number or manufacturing number of the product that was subject to recall

D. Result of the recall

(8) The provision in Item 2 prescribes that reporting is required to be submitted to the manufacturing supervisor in order for the manufacturing supervisor to appropriately execute the operations prescribed in Article 6, Paragraph 1, Item 2.

20. Article 20 (Self-inspection)

(1) This Article prescribes that manufacturers are required to have predesignated persons conduct the operation regarding self-inspection. When conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) "A person, designated beforehand" indicated in Paragraph 1 shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(3) It shall be desirable, in principle, for personnel who conduct self-inspections to not be in charge of the self-inspection pertaining to the operation that they are engaged in; provided, however, that this shall not apply to cases where there are inevitable reasons, such as of having no other personnel other than in the same division who

has thorough knowledge of the operation, and if the qualification, etc., of the personnel who will conduct the self-inspection has been confirmed in advance.

(4) The phrase "to perform the periodic self-inspections on the manufacturing control and quality control of products at the manufacturing site" indicated in Paragraph 1, Item 1, shall mean that periodic self-inspection is required to be conducted from the perspective of evaluating the appropriateness and effectiveness of manufacturing/quality control operations at the manufacturing sites as well as the necessity for improvement.

A. GCTP organization chart

B. Operation regarding manufacturing supervisor

C. Personnel

D. Product master formula

E. Sanitary control standard

F. Manufacturing control standard code

G. Quality control standard code

H. Release control from manufacturing sites, validation or verification, review of product quality, control of changes prescribed in Article 16, deviation control prescribed in Article 17, quality information, etc., and measures for quality defect, etc., measures for recall, self-inspection, training, control of documents and records, and other procedural documents necessary for appropriate and smooth manufacturing control and quality control

I. Buildings and facilities

J. Operation regarding manufacturing control (manufacturing division)

K. Operation regarding quality control (quality division)

L. Operation regarding release control from manufacturing site

M. Operation regarding validation or verification

N. Operation regarding quality review of product

O. Operation regarding control of changes

P. Operation regarding deviation control

Q. Operation regarding information on quality, etc., and measures for quality defect, etc

R. Operation regarding measures for recall

S. Improvement measures taken based on past self-inspection results

T. Operation regarding training

U. Operation regarding control of documents and records

V. Operation regarding exception in storage of records

W. Other matters on manufacturing control and quality control at manufacturing sites that require self-inspection

(5) Reporting in document to manufacturing supervisors on self-inspection results prescribed in Paragraph 1, Item 2 shall include the following matters:

A. Date of self-inspection

B. All identified matters and assessment based on self-inspection results

C. Necessary proposal for improvement

(6) "Records" indicated in Paragraph 1, Item 3, shall include explanation on measures that were taken based on self-inspection results.

21. Article 21 (Training)

(1) This Article prescribes that manufacturers are required to have predesignated persons conduct operations regarding training. When conducting this operation, use of quality risk management shall be put into consideration.

(2) "A person, designated beforehand" shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(3) "Personnel" indicated in Item 1 shall mean personnel engaged in manufacturing/quality control operations and other persons who have the possibility of influencing product quality (including personnel for maintenance and cleaning).

(4) "Training" indicated in Item 1 shall mean logical education and on-site training.

(5) The phrase "to systematically implement" indicated in Item 1 shall mean that training is required to be systematically conducted after being periodically evaluated for effectiveness.

(6) The phrase "necessary training on manufacturing control and quality control" indicated in Item 1 shall be necessary training for manufacturing control and quality control of products with consideration of the type and content of the operation conducted by the personnel who will go through training, and shall include training on the following matters (excluding training indicated in Item 2 and Item 3):

A. Principles of GCTP (including outline of purpose, concept, etc., of relevant legislations (including provisions in the Regulations for Buildings and Facilities of Pharmacies, etc. pertaining to the GCTP Ordinance and to cellular and tissue-based products))

B. Principles of Sanitary Control (including outline of purpose, concept, etc., of sanitary control prescribed in the GCTP Ordinance)

C. Outline of GCTP at the manufacturers (or manufacturing site)

D. Matters on the actual operation (including on-site training)

(7) "Training on" "other necessary matters" indicated in Item 2 shall mean training on chemistry, matters on sterility assurance, molecular biology, immunology, embryology, biostatistics, etc., of which is necessary for manufacturing control and quality control of products considering the type and content of the operation conducted by the personnel who will receive the training.

(8) Item 3 prescribes that personnel are required to go through training regarding necessary measures to prevent contamination due to microorganisms, etc., such as on aseptic operation and biohazard control, for those personnel that are engaged in operations at controlled clean areas and aseptic operation areas or areas that handle infectious products, etc., and packaging and labeling materials, as well as those engaged in operations pertaining to cells or tissues of human or animal origin, or pertaining to processing, culture, etc., of microorganisms used in manufacturing of products.

(9) "Status of implementation of training" indicated in Item 4 shall include the following matters:

A. Date of training

B. Content of training

C. Name of person who went through training

D. Name of person who provided training

22. Article 22 (Control of Documents and Records)

(1) This Article prescribes that manufacturers are required to have predesignated persons conduct operations regarding storage of documents and records prescribed in this Ministerial Ordinance. When conducting this operation, use of quality risk management shall be put into consideration as necessary.

(2) "A person, designated beforehand" shall mean a personnel with thorough knowledge of the operation who has been predesignated as the person responsible for this operation, and the responsibility of this personnel shall have been appropriately prescribed in the document prescribed in Article 7, Paragraph 4.

(3) Provision in Item 1 prescribes that creation or revision of documents requires their approval, distribution, storage, etc., pursuant to procedures, etc.

The documents shall be periodically reviewed and renewed depending on their content, etc. Copies of the original document for regular use shall be made in accordance to procedures, etc., in order to prevent mistakes.

When abolishing documents, measures shall be taken in accordance to procedures, etc., to prevent unintended use of those abolished documents.

(4) Provision in Item 2 prescribes that when creating or revising procedures, the date of creation or revision, the name of the responsible person, content, and reason shall be indicated in the procedures, etc., and history pertaining to any other revisions before this revision shall be stored and shall have them distinguished from the latest revision status.

The history pertaining to revisions of procedures, etc., shall be stored so that the date, content, etc., of those past revisions can be identified for at least 5 years (or a period of 1 year plus shelf life if 1 year plus the shelf life of the product pertaining to the procedure is longer than 5 years).

In case where copies (measures shall be taken of identification labeling to prevent confusion, etc., with the original) of the procedure, etc., exist, revision of this

procedure, etc., shall have its copies to be definitely revised, such as by distributing, replacing, etc., its copies concurrently at the time of revising the original.

(5) Provision in Item 3 prescribes that records are required to be stored for a period of 30 years plus shelf life for products pertaining to specified regenerative medicine products, and for 10 years plus shelf life for other products pertaining to cellular and tissue-based products, in order to enable investigation, etc., in case infection occurs due to those products. When abolishing documents, measures shall be taken in accordance to procedures, etc., to prevent unintended use of those abolished documents.

(6) Necessary records on testing results shall be stored to enable investigation on the cause of any health hazard in patients, etc., due to use of cellular and tissue-based products pertaining to the product.

23. Article 23 (Exceptions for Storage of Records)

(1) This Article prescribes matters regarding exceptional requirements on records of products pertaining to the cellular and tissue-based products specified by the Minister of Health, Labour and Welfare.

(2) "Regenerative medicine products designated by the Minister of Health, Labour and Welfare" shall be separately specified in the future accordingly.

24. Miscellaneous (electromagnetic records)

Manufacturers may take the method of utilizing electromagnetic record medium or technology of information communication in accordance to the following procedures regarding contracts, reports, or instructions for when concluding agreements via document prescribed in this Ministerial Ordinance. When conducting this operation, use of quality risk management shall be put into consideration.

(1) Storage of records

Records (excluding raw data) prescribed in this Ministerial Ordinance may be stored in electromagnetic record medium instead of documents if the requirements of the "Utilization of Electromagnetic Records and Electronic Signatures in Applications Pertaining to Approval or Licensing of Drugs" (PFSB Notification No. 0401022, dated April 1, 2005) are met, and at the same time, the following measures are taken.

A. In protecting records, the following measures shall be taken to prevent deliberate or accidental rewriting, deletion, and confusion of records stored in electromagnetic record medium.

(a) The device for entering records into the electromagnetic record medium shall be one that can recognize predesignated operators and that prevents entry, revision, and deletion of records by those other than designated persons.

(b) Entry, revision, and deletion of records via procedures that had not been specified in advance shall be forbidden.

(c) Entry, revision, and deletion of records shall require for its records to be kept on their content, reason (in cases of revision or deletion), date of operation, information to identify the operator, such as the name of the personnel or identification number, and a specific indicator to identify the electromagnetic record medium on which entry was conducted; provided, however, that this shall not apply to cases where audit trail is automatically recorded and pre-established procedures enables this recorded audit trail to be confirmed.

(d) Reserve records (backup) shall be created and stored to prevent records from being lost.

B. Facilities and methods shall be established for when printing the records stored in electromagnetic record medium and displaying them on a display unit.

C. The following matters shall be established in advance regarding control of electromagnetic record medium for storing records.

(a) Storage method, storage period, storage place, and the responsible person for storing the electromagnetic record medium

(b) Measures for preventing degradation and damage of the electromagnetic record medium

(c) Measures for when degradation or damage occurs on the electromagnetic record medium

(2) Contracts for agreements

A. Manufacturers shall be able to use methods of electronic data processing system or other information communication technologies instead of documents when concluding contracts for agreements prescribed in this Ministerial Ordinance if consent has been obtained from the other party.