The initial error distribution 1 m of the measuring equipment is appropriate in this case, but it will eventually lead to the above economic loss, when this equipment becomes less accurate with the frequency and duration of use and when used in this condition without calibration and checking. Yet, if it is calibrated at regular intervals of appropriate length, this loss can be prevented, thereby making a substantial contribution to improving production efficiency and lowering production costs. But this is not all. It will also help the manufacturer establish a reputation for product reliability and thus open up a potential for market expansion.

7.3 Benefits Expected at the National Level

It has already been pointed out that the implementation of this plan will warrant significant hopes for major benefits to be achieved from standardization and quality control. The following are considered to be the most important advantages for Chile:

(1) Benefit of standardization as making a contribution to Chile's economic development

The manufacturing industry is the leading sector in the development of the national economy. On both the demand (because of the high resilience of demand depending on income, it follows that the demand for industrial products will increase with increase in national income) and supply (the effect on the other industrial sectors is significant and the proportion of added value is high) sides, there is a significant correlation with economic development. For this reason, the proportion of the manufacturing industry's output in the gross national product can be considered as one of the most important factors indicating the economic development of the country. In Chile, the manufacturing industry has a roughly 20% share in the nation's gross national product. This share has tended to stagnate for the last ten years.

For the development of Chile's industry, however, it is essential to look for foreign markets since the domestic market is rather small (with a population of only approximately 13 million people). By product category, it is clear that the major export item is minerals, especially copper which account for a large share of Chile's exports. By contrast, manufactured products have a small share in the nation's exports. And even among these so called "manufactured products," it would be noted that agricultural, forestry, and fishery products such as food and paper/pulp account for the majority while the industrial products do not appear to expand their share position and are still at a rather low level. Generally, the trend has been for primary export items such as natural resources to cause the exchange rate to rise excessively while the nation's export competitiveness for industrial manufactured products is dropping. In Chile, this phenomenon is so marked that it may be diagnosed as the "Dutch malaise" visiting Chile, a trend seen in many developing countries. In the case of Chile, it remains to be analyzed to judge whether this is true of Chile or not, but it should be clear in any event that the excessive reliance on raw materials/natural resources exports with their enormous price volatility is not desirable from the viewpoint of achieving stable economic growth. Rather than raw materials exports, the essential task will be to diversify and upgrade exports. The Chilean government fully recognizes the essential need for diversifying the range of export products and in particular expanding the export of high value-added products. Towards this end, the government operates official incentive schemes, including reimbursements for exports of non-traditional products.

It is more important, however, to increase the competitiveness for manufactured products in a more radical manner. This necessitates the promotion of industrial standardization as the essential prerequisite. There is much hope for the present plan also on the part of the Chilean government. Thus, the interviews with the leading personalities of the MINECOM have demonstrated that while the share of manufactured industrial products, that is, products excepting the industrial products in the former sense of the

export statistics -- namely products from the agricultural, forestry and fishery sector --, accounts for a mere 18% at present, the government is most anxious to increase this share and believes that industrial standardization may make a significant contribution toward this objective.

To foster the development of a high value-added industry and enhance its level, it is only too logical that the prerequisite condition for achieving these objective will be to establish a system of national standards for metrology and diffuse this to the industrial sector through the calibration of their measuring equipment.

In 7.2, we have already dealt with the role of standardization as a contributory factor to the development of individual companies. The role of standardization in contributing to the development of the national economy is even greater, because the companies are the main bearers of a nation's economy. Especially in a country like Chile which aims for a basic policy of a private sector-led style free market economic policy, the development of the national economy can be interpreted as the projection of the development of the nation's companies. National standardization has a much greater impact than the in-house standardization of individual companies because it adjusts and coordinates the borders between the individual companies and industries. This demonstrates all the more how much national standardization can contribute to economic development.

At present, Chile's industry is structurally much dependent on the agricultural and mineral sectors. Yet, even so, it has maintained a sound rate of economic growth so solid that it may be even considered as exceptional for South American countries. If this plan is executed and industrial standardization promoted, Chile will gain a more advanced industrial structure and transform itself into an industrial nation capable of maintaining stable high-rate economic growth, a process that will be speed up by industrial standardization.

(2) Benefits in terms of enhancing health for the people of Chile and contributing to the protection of life and welfare as well as to the conservation of the environment

This will not become possible until three conditions are jointly fulfilled: a) establishment of standards of a practical content substantiated by scientific data, b) consistent enforcement of the appropriate standards through the certification system, and c) measure with reliable measuring equipment. In the case of Chile, serious atmospheric pollution in big cities and water contamination of the rivers and seas due to discharge of factory effluents are noticed. These problems are largely due to the lack of either of the above conditions.

Improved health, hygiene, the protection of life and property, and the conservation of the natural environment are all issues arousing worldwide interest. Products of a quality not fulfilling these benefits will not be welcomed by the market and, more than this, will even do great damage to the image of Chile's exports in general. Consequently, the increased export of products with the quality features required to ensure that these problems will not arise, will be essential since it will be the basis for the nation's economic development. This underscores the importance of promoting national standardization. In the case of Chile, the food and allied industries, including fishery products and fruit, occupy a very important position and because of the high value of exports concerned, it will be of particularly great importance to look for this kind of philosophy.

(3) Benefit in terms of the contribution made by metrology system to fair trade

Correct measurement are the basis for fair and correct trading. This goes for the general consumer as much as for companies. It is therefore most relevant also for the nation to attempt to establish a national metrology system as part of the commitment shown toward policy measures such as industrial development, consumer protection, environmental conservation, and a fair tax

system.

(4) Benefit in terms of the contribution made by metrology system to research and development in the science and technology domain

In the research and development area in all technical fields spanning the natural sciences and their application sectors, facts and observation are taken in their pure scientific, objective context to create the basis for proving theories. The establishment of a metrology system and the provision of standards of high accuracy will ultimately reduce the elements of uncertainty surrounding the application of new techniques. It can also make a contribution to the promotion of modernization for production equipment and the development of products using new techniques.

CONTENTS OF ANNEX

ANNEX 5-1

ORGANIZATIONAL STRUCTURE OF INN AS ACCREDITATION BODY

1. Secretariat

It is proposed that INN should establish the following organizational structure to act as an accreditation entity:

Senior Executive in Charge of the Secretariat:	1 Executive
Office Staff	2 Persons
Office secretary cum typist	1 Person
Total	4 Persons

2. Council

This should be the Supreme Decision-Making Organization for accreditation of certification bodies.

3. Evaluation Committee

The members of Evaluation Committee should be selected by the Council. This Committee should concentrate on assessment duties. The Committee's members should be selected to ensure impartiality and neutrality in the conduct of their duties. Appointment may be on the basis of extraordinary (ad hoc) task assignment, and a composition of 5 - 6 members is considered adequate.

4. Auditors Carrying Out Audit with a View to Accreditation

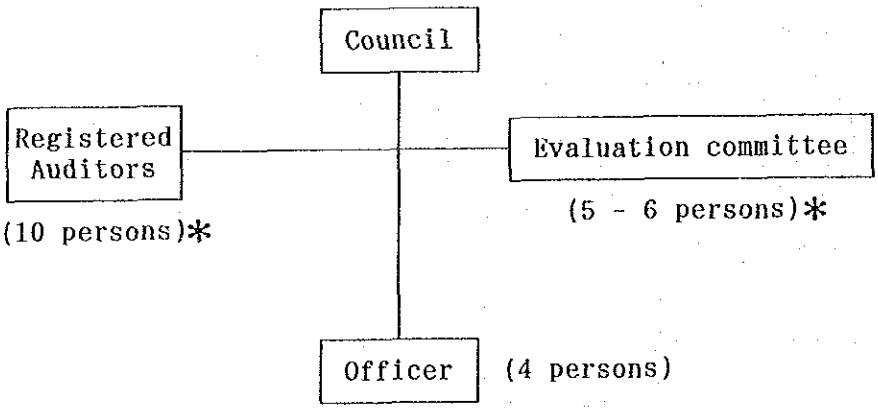
These auditors should meet pre-determined qualification requirements or should possess knowledge and/or experience equivalent or superior thereto. Registration of the auditors should be for extraordinary task assignment only. The most realistic definition of the qualification requirements would be to stipulate that persons will be deemed qualified if they meet the registration requirements for Registered Auditors. It is most desirable that Auditors should have a

long experience in the practical tasks of examination work, with a sound reputation. It is considered adequate that the number of qualified Auditors to be enlisted should initially be kept around 10 persons. The qualification requirements for the Auditors should best be in accordance with Qualification criteria for Auditor laid down in ISO 10011-2.

5. Financial Resources for Accreditation Entity

Accreditation fees and surveillance charges should be imposed to recover costs. The government will have to step in with the provision of aid until the Accreditation Service has been consolidated.

Organization Chart for INN Acting as an Accreditation Entity



* Note: Appointment may be on an ad-hoc assignment basis.

ANNEX 5-2

PROCEDURE FOR FOR ACCREDITATION OF CERTIFICATION BODIES

(EXAMPLE)

1. A certification body seeking INN accreditation to acquire INN-approval certification service status shall lodge an application for accreditation with INN and INN shall give consideration to the application (examination of the application).

2. Applicants having been successful in step 1. above, may previously be presented with instructions to prepare a quality manual. These instructions should contain specific conditions to be fulfilled by the certification organization.

The examination procedures for 1. and 2. above shall be carried out by qualified auditors of INN as Registered Auditors.

3. A site investigation visit shall be arranged to assess the operating premises of the certification organization having filed the approval application (site investigation).

   Such site investigation visits should be made only to the organizations having cleared the quality manual evaluation procedures. Normally, two qualified auditors will carry out the investigation as a team. The auditing procedure shall be to inspect whether or not the applicant implements quality control as described in his quality manual and whether or not the accreditation criteria are violated in some aspects. The applicant concerned should best be present during the site investigation wherever possible so as to confirm the examination conditions.

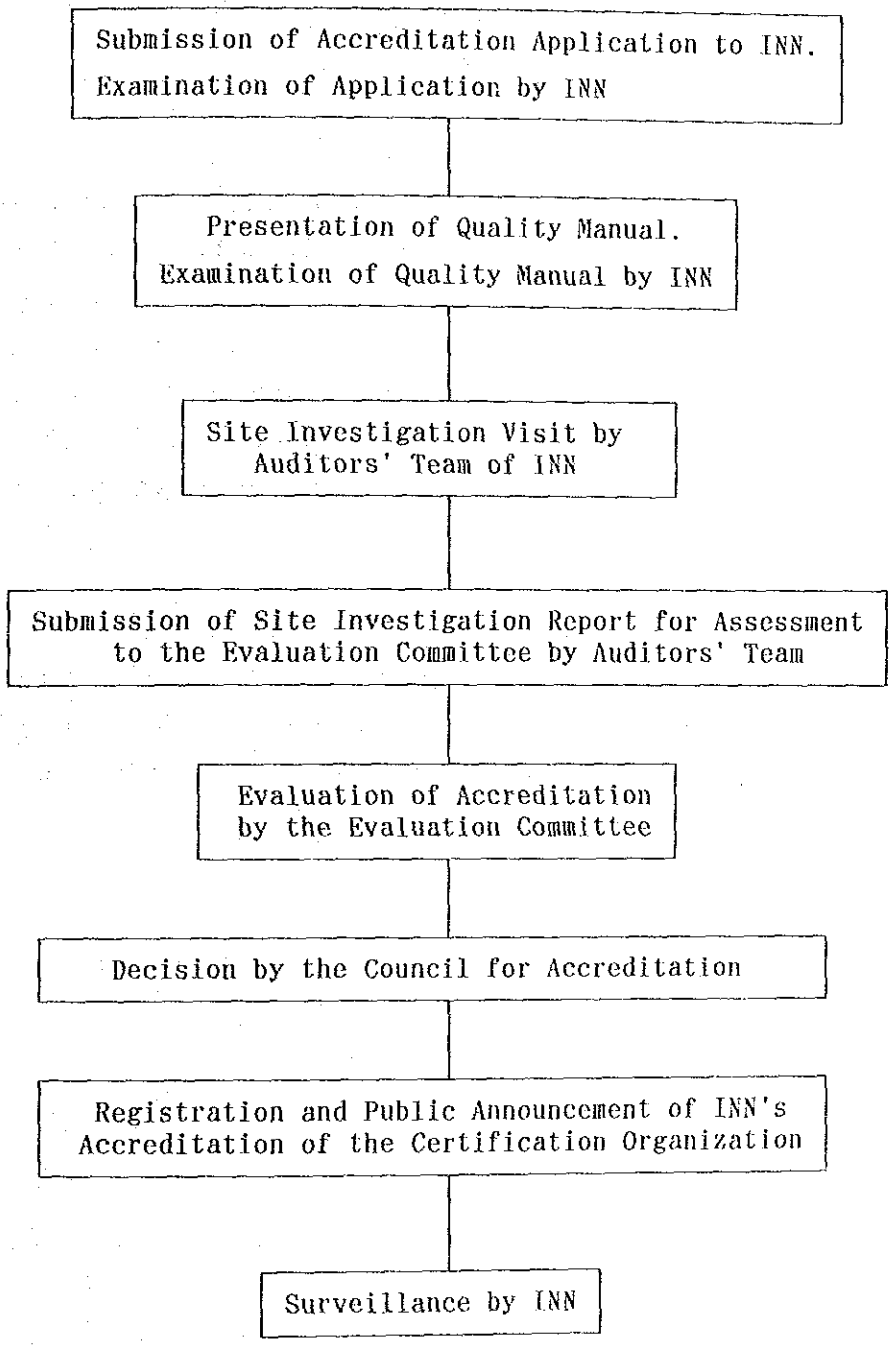
4. The auditors having carried out the site investigation shall sum up their findings in a report for submission to the Evaluation Committee (submission of Site Investigation Report).

5. The Evaluation Committee should examine the above Report and any or all other reports related thereto so as to assess whether or not accreditation can be granted to the applicant and submit a report to the Council for its final decision.

6. Based on the decision by the Council, the applicant shall be admitted by INN for registration as an INN-Accredited Certification Organization and INN should make a public statement announcing the applicant as being INN-registered. (Registration and Announcement Accreditation). To ensure strict adherence to the approval conditions, it is desirable that INN should exchange a contract with the applicant prior to conferring the Accreditation Certificate upon the applicant.

7. INN shall conduct surveillance on the certification organization in receipt of INN accreditation, in accordance with the specified rules. (Surveillance Service)

Accreditation Procedure for Certification Organization



ANNEX 5-3

JIS MARKING SYSTEM IN JAPAN

1. General Description of the Marking System

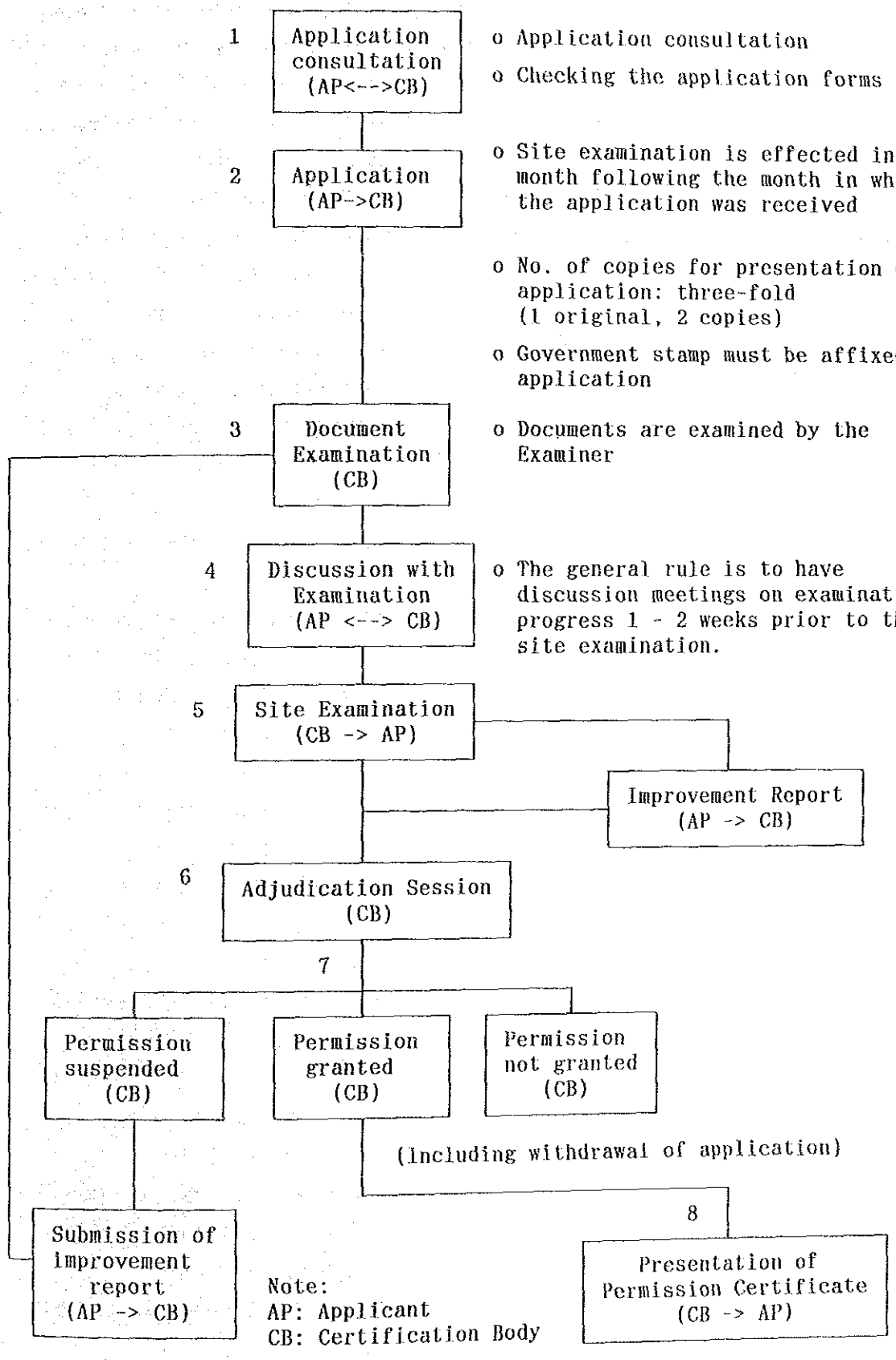
The JIS Marking System permits the display of the JIS mark on products subject to said products' meeting the JIS standards concerned and subject to the quality control system at the production factory manufacturing said products having been recognized on government inspection and examination as being in compliance with the government-specified factory examination conditions and examination standards. (The examination conditions consist of general conditions applicable to all products and of specific examination conditions varying from product to product.)

Compliance with the government-specified factory examination conditions and examination standards implies the continued ability to manufacture products meeting JIS standards, subject to the production of said products under the quality control system applicable thereto.

2. Procedures for Obtaining Permission

The chart below gives the flow for the grant of permission from the application stage to the grant of the Permission Certificate.

PERMISSION APPROVAL PROCEDURE FLOWCHART



3. Document Checking and Examination

Document checking and examination (3) implies that the documents presented by the applicant in accordance with 2 above are checked for conformity of the applicant factory's quality control system, quality control implementation and product to the standards concerned, and this on the basis of the documents presented by the applicant on the application forms specified by the Certification Body. Thus, in addition to checking all documents appended to the application form and the details contained therein, the document examination also includes the requirement that the information given must be sufficiently extensive to enable to appropriate assessment and judgement to be made. (It should be noted that the required entries and details are listed on the form.) The following are the main entries and details to be completed by the applicant.

(1) Location of factory, arrangement/layout plan, organization chart

(2) Production records for the product(s) concerned for the most recent six months

(3) Overview chart of company standards

(4) Process diagram for the manufacture of the product(s) concerned

(5) Method(s) of quality assurance for the main materials used for manufacture

(6) Implementation of quality control in the manufacturing process for the product(s) concerned

(7) Quality characteristics for the product(s) concerned

(8) Status of main production facilities, main testing and inspection equipment and status of quality control for the same

(9) Assignment of subcontract orders and control procedures for subcontracting orders

(10) Procedures for dealing with complaints

(11) Qualifications of officers responsible for the promotion of industrial standardization and quality control, practical experience with respect to industrial standardization and quality control, practical experience with respect to the technology required for the manufacture of the product(s) concerned.

4. Site Examination

In the event that the applicant has cleared the documentary examination procedures in accordance with 3) above, a site examination is carried out after discussion and consultation with the applicant about the manner in which the site examination shall take place.

(1) Site examination procedure

The site examination shall be carried out in order to establish whether or not the applicant's factory has, at the time of examination, the production capability for the manufacture of the specified product(s) and possesses the appropriate quality control system. In the event that the application is made for or by a JIS-certified factory, the site examination shall be designed to assess whether or not the applicant will be capable of maintaining and/or upgrading his quality control system in keeping with his status as a JIS-certified factory in the future. Based on the (general) examination items, examination standards, and specific examination items, the examination procedures shall, in general, be carried out as follows.

1) General items:

Outline of company, outline of factory, management (control) policy

Status of in-house standardization, quality control (quality assurance)

Examination of general specifications/regulations

Availability, keeping, amendment, general recognition of company standards
Organizational system, task division and assignment, task definition and demarcation
Committee system for quality
Education, training, etc.
Staff responsible for the promotion of industrial standardization and quality control
Quality assurance system (system for handling complaints, lot tracing)

2) Conformity to product standards and JIS standards

3) Factory examination (raw materials, process, equipment, inspection, products, etc.

4) On-the-spot (site) testing

5) Specific items:
Product
Material --- Checking for conformity to product standards and JIS standards
Production process --- Checking of standards, quality control conditions, records
Equipment (manufacture - testing)
Subcontract orders

(2) Details of site examination based on the specific examination items [Details given in parentheses ( ) shall be verified on site.]

1) Product standards and product quality

(1) Quality characteristics for products equivalent to JIS are specifically prescribed and the examination is to check whether their quality characteristics meet the JIS standards or not (product standards).

(2) Product checking/inspection standards, inspection conditions, inspection system (product inspection standards, inspection specifications, inspection records, practical implementation for inspection procedures, keeping and using of inspection records)

(3) Measures for dealing with down-grade products/lots (Product inspection standards, inspection records, precedents)

(4) Product storage conditions

2) Control of materials

(1) Standard for material purchases (Materials purchasing standards, acceptance records, criteria for selecting operators/forwarders for materials deliveries)

(2) Acceptance inspection conditions (Inspection standards, acceptance inspection records)

(3) Conditions for materials storage (Materials storage standards, material storage conditions, material shipment system)

(4) Measures for dealing with down-grade products/lots (Materials purchasing standards, acceptance records, precedents)

3) Control of production process

(1) Reasons for deciding the production conditions and verification records for same (Technical standards documents)

(2) State of standardization of production conditions, operating conditions (Process control standards, manufacturing standards, production records, state of

process control, status of operations, operating environment, conditions for improvement)

(3) Conformity of process to the control standards (production standards, operating standards, status of operation)

(4) Process inspection standards (Process inspection specifications, inspection standards, state of inspection procedures, inspection records, use of statistical methods and their practical utilization)

(5) Status of measures for dealing with down-grade products/lots (inspection records)

(6) Measures taken if abnormalities occur in the process, remedial measures and measures to prevent re-occurrence

4) Control of production equipment/plant and inspection facilities

(1) Standards for equipment/plant control (Specifications for equipment/plant control)

(2) Status of maintenance, inspection and service (Service/inspection records)

(3) Past records of service (Logbooks kept for service control)

5) Site testing

(1) Sampling

(2) Product quality testing, etc.

These shall generally be covered in the site examination carried out by a team of two examiners visiting the location (factory) for one day.

ANNEX 5-4

CONDITIONS FOR SETTING UP AN ACCREDITATION SYSTEM FOR TESTING AND INSPECTING ORGANIZATION

When setting up an accreditation system for testing and inspecting organizations for introduction of a unified certification system, the following conditions must be studied and fixed.

1. Conditions for accrediting testing and inspecting organizations (Criteria)
2. Duties of the testing and inspecting organizations
3. Qualification and registration of personnel responsible for implementation of testing and inspection

1. Conditions for accrediting testing and inspecting organizations (Criteria)

(1) Organizations

1) The legal position must have been established.

2) Partition of jobs among all related staff must have been clarified in documents.

3) The organizations must have been run systematically.

4) The organization must be able to insure that the staff will not be put under illegal pressure or incentives which may give influences over determination of the staff or results of their jobs.

5) To insure ownership and protection of secret information, the organization must have enough rules and means for security.

6) One representative of the organization, responsible for all quality control jobs, must be registered.

7) One representative of the organization, responsible for all technical jobs, must be registered.

8) Procedures for quality control must have been clearly defined, and the rules concerning the procedure must correctly reflect the latest circumstances in this field.

9) The organization must review their quality control activities periodically or according to the necessity to assure that effective operation of the organization can be maintained.

(2) Staff

1) The staff must have participated in education and training for their jobs, and have necessary knowledge and experience in the job field.

2) Education and training for staff must be provided to the staff appropriately.

3) The organization must have alternative staff so that, even if a responsible person is absent, no trouble will occur to operation of the organizations as a testing facility.

4) Information concerning training of staff and their experience must have been accumulated, maintained and controlled accurately.

(3) Profiles of objectives for testing and equipment used for testing

1) The organization must be able to clarify profiles of objectives for testing, requirements and rules for the testing.

2) The organization must be able to have equipment required for testing including software (called "Test equipment" hereinafter) and clarify procedures and rules for use of the test equipment.

(4) Identification of function of test equipment

1) When introducing any test equipment, it must be checked and identified that the test equipment has enough functions to correctly test the objectives for the testing.

2) The organization must check and identify, periodically or according to the necessity, that functions of the test equipment have been correctly maintained.

3) If it is determined that functions of the test equipment have not been maintained correctly, the organization must be able to improve the equipment.

4) Records concerning management of test equipment must be under correct management.

5) The organization must be able to carry out works for checking functions of the test equipment in inspection.

(5) Testing method and procedure

1) The organization must have instructions for a method for implementation of testing, procedure, a method for using the test equipment and preparation of reports on testing. At the same time, the instructions must be reviewed periodically and the contents must be communicated to staff thoroughly.

2) If a testing method or procedure not standardized yet is required to be employed, the contents must have been clearly described in documents.

3) In relation to addition of new objectives to be tested or policy for improvement, a long term plan for implementation of testing services must have been described as clearly as possible.

(6) Conditions and environment for works

1) The organization must prepare devices required for monitoring the environment.

2) Appropriate policies for improvement of the environment must have been established correctly.

3) Restrictions to inhibit access of outsides must have been clearly defined.

(7) Treatment of products to be tested and systems in which products to be tested are incorporated

1) Necessary records must have been maintained for object products to be tested in each testing item and products in which object products to be tested are incorporated (Called "Incorporated product").

2) The organization must carefully store and protect incorporated products. Also necessary measures must be taken so that the incorporated products will not be broken.

3) The organization must have clear rules for deposition and return of incorporated products, which the organization accepted for testing, after testing is performed.

(8) Records concerning implementation of testing

1) Restrictions for storing records of testing and others must be introduced, and the records must be stored for a specified period.

2) Secret of an client in relation to testing must be kept. The restrictions must include such items as that concerning disclosure of results of testing.

(9) Test Report

1) Results of testing performed and other related information must clearly be described in this report.

2. Duties of Accredited Testing/Inspecting Organizations

(1) When testing or inspection is requested, the organization can not refuse the request within any reasonable reason, and must start the testing or inspection as soon as possible.

(2) When carrying out the testing or inspection, the organization must use testing equipment and other facilities satisfying the conditions for the above-described accreditation, and at the same time the testing or inspection must be carried out by personnel having the qualification as described above.

(3) If it is necessary to change a site of the facility where the testing or inspection is conducted, or if the organization hopes to change the site, a notification must be made to INN by 2 weeks before the change is actually made.

(4) Job rules for testing must be decided, and the rules must be authorized by INN.

(5) Items related to job rules are decided by INN (according to a decree by the Ministry of Economy)

(6) All or a portion of jobs for testing must not be abolished or halted without acquiring authorization by INN.

(7) A program of activities and a budget must be prepared in even fiscal year before the program is started.

(8) A work report and a balance sheet must be prepared and presented to INN every year within 3 months after the end of a fiscal year.

(9) Any appointment or dismissal of executives without authorization by INN is invalid.

(10) Notes must be prepared to write in data concerning items for testing and inspection specified by INN (a decree by the Ministry of Economy). Also the notes must be stored as specified by INN (a decree by the Ministry of Economy).

3. Qualification and Conditions of Personnel Responsible for Implementation of Testing and Inspection and their Registration

(1) The organization must employ personnel having full qualification and conditions for testing and inspection. Of them, a specified number of staff must have ever participated in training for quality control and other practical jobs for testing and inspection. One or more executives must be designated to control the inspecting organization when the technical manager is absent.

(2) Executive staff responsible for the original recommendations in relation to authorization of a quality control system in a manufacturer of a specific product must satisfy the following conditions.

1) The staff must have a qualification in the field.

2) The staff must have practical experience in the fields of quality control, inspection technique and production method for at least 2 year.

(3) If executive staff controlled by the above staff and responsible for monitoring quality control in manufacturers are not qualified as specialists, nor have any scientific and technological knowledge in the related fields, the staff must be put under control by the above-described executive staff, and the conditions described in (2) above must be satisfied by the staff. The ration of the above executive staff and qualified staff should be in a range where any consigned job can be carried out smoothly.

(4) All of the executive staff must be well aware of their responsibility and its limit.

ANNEX 5-5

POLICIES FOR ENHANCEMENT AND PROMOTION OF TESTING CAPABILITY OF TESTING/INSPECTION ORGANIZATIONS

1. General

The current situation of and problems concerning the testing/inspection organization are described in 3.5, it is necessary to enhance and promote testing/inspection organizations' capability for testing and inspection.

It is recommended to implement the following policies for enhancement and promotion of capability of testing/inspection organizations.

(A) To set up an organization for education and training, prepare a program for educational courses, employ, educate and train engineers for testing and inspection in special fields periodically and systematically.

(B) To periodically update equipment and facilities for testing and inspection in the existing private testing/inspection organizations and those in universities and introduce new equipment and facilities which can satisfy new technological demands, standards and requirements. Note that these equipment and facilities must be calibrated periodically to make higher the reliability of results of testing and inspection.

(C) To update equipment and facilities for testing and inspection, or in other words to update equipment and facilities to the latest ones and improve them qualitatively and in terms of their application fields.

(D) To Acquire the capabilities for repairing equipment and facilities of testing and inspection and for insuring high precision.

(E) To carry out calibration of measurement equipment and establish a traceability system.

(F) To establish organizations for calibration of measurement equipment and consolidate a network of the organizations.

(G) To utilize private testing/inspection organizations such as CESMEC and testing organizations of universities such as DICTUC and IDIEM

(H) To set up a central testing center for implementation of testing for certification and standards conformity.

By carrying out this program, it can be expected to solve such problems as piling up of works for evaluation, shortage and aging of equipment and facilities for testing, inconsistency between contents of required testing and capacity of equipment and facilities for testing, low precision an accuracy of equipment and facilities for testing, poor service of equipment and facilities for testing, shortage of technical documents, poor maintenance, management and calibration of equipment and facilities for testing, and shortage of testing engineers and researchers.

Even if capability of private testing/inspection organization and those in universities for testing and inspection are enhanced according to the proposals (A) and (B) above, each organization has not way but to run their jobs putting a highest priority in their own roles and assignments, and they can not easy respond to needs of testing and inspection based on the unified certification system, and for this reason it is desired that a central testing center for carrying out testing for certification and standards conformity proposed in (H).

Also consolidation of a central organization for calibrating measurement equipment proposed in (E) and (F) is very important in Chile to improve the technological level, and it is recommended that a priority should be placed on this objective. This problem is described more detailedly later in the section concerning a metrological system.

In addition, as an effect of carrying out the programs (G) and (H), it can be expected that installing expensive equipment and facilities for testing and inspection or specific ones not used so frequently at a specific site is advantageous to raise their availability. It will improve the economical effect, and uniformed and uneven results in testing and inspection due to difference of equipment and inspection as well as of capability of technical engineers between organizations for testing and inspection will be reduced, and at the same time reproducibility of results of testing and accurate control by grasping progress of testing jobs can be maintained.

If a function to bring up engineers for testing and measurement is added to the organizations described in (F) and (H), bringing up engineers for testing and measurement now short in Chile can be performed systematically, taking into considerations the demand.

2. Required Equipment and Facilities for Testing

The main types of industry falling within the scope of the Unified Certification System are believed to include the following sectors: agriculture, pasture-farming/cattle-raising, fisheries, processing of agricultural, fisheries, and cattle-farming produce, forestry/timber production, processed wood products, ores and mining output, gas, water supply, building equipment and materials, processed metal products, machinery, electric power, electronics, chemistry, textile fiber, leather, the environmental and testing equipment calibration. Needless to add that the testing equipment required for certification will need to be determined in strict compliance with the appropriate national standards (NCh). The present level to which NCh standards have been established for the above types of industry is as described below. Since many of the national standards have been drawn up on the basis of, or by citing, the corresponding international and/or foreign standards, we have here also presented these standards for reference.

Products in mining:

NCh 122, 1389 - 1397. etc.

Cited standard: ISO, JIS, ASTM

Gas, water supply:

NCh 74, 75, 76, 77, 409, 411, 1620, etc.

Cites standard: ANSI/ASTM, ISO, AWWA, DIN

Construction equipment:

NCh 162, 164, 167, 1019, etc.

Cited standard: ASTM, COPANT, ISO

Metal manufacturing:

NCh 197, 198, 199, 233, etc.

Cited standard: ISO, COPANT

Machine :

NCh 461, 766, 1515 - 1515, etc.

Cited standard: ISO, COPANT, MIL, ASTM, UL

Electric, electronic:

NCh 910 - 919, 1558, 2008, 2019, etc.

Cited standard: ISO, NF, IEC, VDE

Chemicals:

NCh 147, 531, 1224, 1238, etc.

Cited standard: ISO, COPANT, ITINTEC, IS

Textile, leather:

NCh 138, 139, 315, 317, 325, 553, 622 - 629, 1167, 1197, etc.

Cited standard: ASTM, ISO, COPANT, BS, NF, UNE

Environment:

Not consolidated yet as NCh. Foreign standards should be introduced into the current certification system

Calibration of measurement equipment:

Not consolidated yet as NCh. Foreign standards should be introduced into the current certification system

NCh standards now being used for certification in each field are based on international standards such as IEC and ISO or national standards such as ANSI/ASTM. Survey on contents of the standards shows that equipment and facilities for testing in several organizations including CESMEC are still inappropriate. What types of equipment for testing are required, where they should be installed, and how many testing staff are required are described below depending on estimations of required works for certification.

The certification field is largely divided to the 3 fields; chemical, electric/electronic and machine, and equipment and facilities required for testing and inspection in each field are described below.

(1) Chemical

As for chemical, as described in 3.5, such organizations as CESMEC,INTEC,IDIEM, SGS, and FUNDACION-CHILE has most advanced equipment and facilities for analysis and testing, and these organizations can provide services for segregation and quantitative analysis of known elements of organic or inorgnaic compounds, and furthermore the organizations can perform qualitative analysis of organic compounds, and qualitative/quantitative analysis by means of structural analysis and mass analysis. For this reason, equipment and facilities for testing in these organizations are fully available for analysis and testing of agricultural/stock farming products, marine products, processed agricultural/stock farming and marine (food) products, gas, and water.

For this reason, when considering a consolidation plan program for new testing and analysis equipment in the field of chemical field, the necessity to improving or updating the equipment and facilities in these organizations can not be recognized.

It cannot be said that equipment for analysis of air pollution and water pollution are enough, but Japanese expert is performing technological transfer in CIMM, and appropriate equipment will be installed there as accompanied equipment for expert in the latter half of 1991.

(2) Electric and electronic fields

In electric and electronic fields, such organizations as CESMEC, IDIEM, DICTUC and IDIC can carry out a portion of performance test, endurance/life test, weathering test and safety test, which are some of items required in certification, but the organizations do not have equipment and facilities for testing to certify conformity to national standards such as IEC standards.

Representative equipment and facilities not installed yet in these organizations are as described below. Note that measuring equipment such as testers to measure basic factors such as voltage and current and common facilities such as a constant voltage power supply are omitted here.

Performance test

Capacity measuring tester	Wind rate meter/tester, heat efficiency tester, etc.
Noise tester	Acoustic room, noise level meter
Acoustic tester	Shield room etc.
r.p.m tester	Tacho meter, stroboscope, etc.
Transmission meter/tester	Optical bench, etc.
All light beam meter/tester	Spheroidal light beam meter (integrated sphere), standard electric lamp, etc.

Safety test

Insulation tester	Insulation resister, Dielectric withstand tester, etc.
Overload tester	Thermal shock test device, short circuit test device, etc.
Temperature increase tester	Recording thermometer, contact resistance tester
Arc tester	Arc tracking resistance tester, arc resistance tester, etc.
Burning tester	Burning tester, etc.

Endurance/life tester

Temperature/humidity condition setter/tester	Low temperature constant temperature/constant humidity bath, etc.
Life tester	Cord bending tester, vibration tester, etc.

Weather resistance tester

Heat resistance/humidity resistance tester	Constant temperature bath, water bath, oil bath, etc.
Thermal expansion tester	Constant temperature/constant humidity bath, etc.
Water-proof capability tester	Rainfall tester, etc.
Acid resistance tester	Salt water spray tester, etc.

Ozone resistance tester	Ozone resistance tester, etc.

(3) In machine field

In the field of machine, such private organizations as CESMEC, IDIEM, Engineering department of Chile University, and other universities and Army have equipment and facilities for testing respectively, but generally they are rather obsolete. Most of the equipment and facilities are for testing strength of materials for construction such as steel bars and concrete blocks, and there are few testing equipment for precision machines.

Basic test

Measurement equipment	Three-dimensional meters
Strength tester	Hardness tester, versatile precision tester

Performance/safety test

Spring characteristics tester	Automatic spring tester, leaf spring tester etc.
Non-destructive tester	Radiation transmission testing device, ultra-sonic flaw detector/ tester
Noise tester	Noise level meter etc.
Leakage tester	High pressure pump, pressure resistance tester
Shock absorbance tester	Shock absorbance tester, head rest shock tester, etc.

Penetration resistance tester	Penetration resistance testing machine, Human head model set, etc.
Tyre strength tester	Bead unseating testing device, etc.
Destruction/pressure resistance tester	Cylinder expansion testing device, high pressure pump
Endurance/wear resistance test	
Bending tester	Vibration tester, etc.
Endurance tester	Head rest resistance tester, etc.
High speed endurance tester	Tyre endurance tester, etc.
Wear resistance tester	Constant wearing characteristics tester, etc.
Weather resistance tester	
Heat resistance/humidity resistance tester	Constant temperature bath, water bath, oil bath, electric furnace, etc.
Thermal expansion tester	Constant temperature/constant humidity bath, etc.
Water-proof capability tester	Rainfall tester, etc.
Acid resistance tester	Salt water spray tester, etc.
Ozone resistance tester	Ozone resistance tester, etc.

The measurement law as a national law has not been introduced, nor a traceability system has not been consolidated in Chile, so that

calibration of measurement equipment are still not enough. Problems concerning measurement were described in a section on a plan to consolidate a framework for measurement system, so description on it is not made here.

It is indispensable, however, to prepare equipment for calibration of measurement equipment which can insure higher precision than that of equipment in the testing facility, and maintenance and management of the equipment are very important.

3. Plan and Organization for Implementation

Outline of cost required for equipment and facilities, and a site for construction of a testing center which plays a central role are described below.

(1) It is recommended to set up a testing center having a series of equipment for testing in Santiago city, which accredits private organizations in each certification field so that private testing organizations such as CESMEC and INTEC and those in universities including Chile University can efficiently be utilized.

(2) Also it is recommended to set up a testing center having a series of testing equipment in Concepcion city, which accredits private testing organizations including Concepcion university in each certification field to satisfy the needs.

Probably around 1.5 billion yen will be required only to procure necessary equipment and facilities. It is desired that the capability of each organization for testing and inspection is enhanced step by step, but in the initial stage the recognition on the necessity of a new unified certification system to be introduced according to the proposals as described above must be diffused through PR activities, and the needs can be covered by only supplementing the current shortage of required equipment and facilities in private testing organizations.

This initial period will continue for 3 years.

In the latter half of this initial stage, efforts to bring up engineers for testing must be made to respond to growth of industries in the country, a program for education and training must be introduced for that purpose. 2 years will be required for this. For these reasons, the second stage will start in 5 years after start of the initial stage.

It is expected that a quantity of works will rapidly in this stage, but if it can be assumed that the growth rate of works for testing will be within 3% a year, the growing demands can be satisfied by expanding a range for enhancement of testing equipment in the private testing organizations a little.

However, if the growth rate is more than 5% a year, it would be necessary to set up testing centers in Santiago and Concepcion as described above.

ANNEX 5-6

CERTIFICATION PROCEDURES

1. Preparations Prior to the Filing of an Application for the Grant of Product or Quality System Certification

(1) Prior meetings and discussions

Before lodging a formal application for certification by the certification organization, the applicant should first arrange for preliminary discussions so that the certification body can obtain a clear idea of the conditions and realities (including the status of implementation of quality control at the applicant's factory/factories) of the company intending to file the application. For the applicant, in turn, such prior discussions serve to gather all relevant information concerning the conditions and formalities required for obtaining certification permission.

(2) Carrying out of a preliminary investigation

When the applicant has decided to file the application after the above consultation meetings, the applicant concerned will be sent a Provisional Inquiry Form (Questionnaire) by the Certification Body with the request to complete the relevant items the Accreditation Body may refer to for the purposes of the subsequent certification Assessment and to return the form to the Certification Body. Upon request, the Certification Auditor(s) may conduct a preliminary site investigation and specify any areas which may require improvement.

2. Submission of Application for the Grant of Certification Approval and Examination/Scrutiny and Evaluation by the Certification Body of the Documents Submitted by the Applicant.

The application for certification shall be submitted to the Certification Body by suppliers desiring to obtain certification approval. The following shall be considered an example of the documentary formalities required for this purpose.

(1) Certification approval application

1) Name and address of supplier
2) Name of officer to be contacted and his/her position in the company
3) Location of factory
4) Name of person to be contacted at the factory and his/her position in the company

(2) Nature (types) of products for which certification is sought, manufacturing and finishing process(es) or nature of services

(3) Documents relating to quality (control) system and quality manual (written statement explaining the quality control system in operation at the factory under application and giving the extent to which the practical status of implementation can be inspected).

(4) Statement by the applicant pledging strict observance to the rules and standards laid down for the certification system and/or conditions and a formal undertaking to make payment of the costs and fees laid down for the certification procedures.

(5) Applicant's signature and date of application

Upon receipt of the application documentation, the certification body will scrutinize the documents concerned to assess whether they are acceptable or not.

3. Carrying out of a Site Examination

If the Certification Body, having examined the application documents under 2. above, feels that the applicant meets the conditions required for certification approval, it will make the following arrangement for a site examination visit.

(1) Fixing the schedule for the site investigation (on the basis of mutual consultation with the applicant).

(2) The Certification Body will appoints a site investigation team composed of members capable of making a sound assessment of the status of implementation of quality control at the applicant's factory.

(3) At the same time, a checklist shall be prepared for use in the site examination.

(4) Execution of the site examination. For the examination, arrangements shall be made by the applicant to appoint a member of his factory staff to witness the examination.

The site examination shall be carried out by checking against the entries made in the application form.

(5) The site examination team shall draw up a document specifying the items checked and verified during the site examination and hold a confirmatory meeting with the applicant's appointed factory examination witness to agree on the findings as part of the examination schedule.

(6) The site examination team shall prepare an examination report of the site examination. The form and format of this report shall be in accordance with the report document specified by the Certification Body.

(7) The site examination team shall explain to the factory representatives the details of said report (6) and invite comments for the records.

(8) The site examination report document shall be submitted to an assessment and evaluation committee.

The Certification Body will need to lay down specific examination items or criteria and establish examination and inspection specifications including these. This will be essential to eliminate the risk of personal bias on the part of the examiners.

It is deemed desirable that for the execution of the examination procedures carried out by the certification body on behalf of the Applicant notably for the auditing of quality systems, said procedures should be based on, or comply with, the Guidelines for auditing quality systems laid down in ISO 10011.

4. Evaluation by the Evaluation Committee

The Evaluation Committee shall carefully assess:

(1) The test and inspection reports relating to the conformity of the applicant's products to the standards and specification concerned in case of product certification

(2) The site examination report referred to above 3.

The decision to grant certification permission approval will made, if the Committee is satisfied that the products concerned have been found, by model or sample testing, to meet the standards and the applicant has been recognized as having a steady manufacturing capability to produce the products concerned to a standard meeting the specification requirements of the factory concerned as stated in(2) above.

5. Exchange of Certification Certificate

When the decision to grant certification approval has been made subject to the provisions of 4. above, and

(1) An agreement has been concluded by the applicant (grantee) with the certification body (grantor) in which the grantee pledges strict adherence to the certification conditions required by the certification body.

(2) The grantee has made payment of all relevant charges and fees in connection with the certification and the registration,

certification permission will be granted to the applicant so that the applicant can register the certified factory/factories, or product(s). It may also be desirable to adopt a certification approval system in which the use of the certification body's mark (symbol) or logo is approved.

6. Surveillance Inspections by the Certification Body after Certification Approval

After certification approval has been granted, it will be desirable to adopt suitable measures to monitor the certified supplier's adherence to the approval conditions. For this purpose, the following provisions may be made:

(1) Compulsory submission by the certified supplier of regular reports on the state of quality system maintenance and control

(2) Compulsory submission by the certified supplier of an application form for modification(s) in the event that the quality system is to be modified or changed.

(3) Compulsory submission by the certified supplier of a report document on modification(s) in the event that the quality system has been modified or changed.

(4) Implementation of witnessed inspection visits to the certified factory by the certification body.

(5) Carrying out of tests and inspections on the products manufactured at the certified factory.

7. Miscellaneous

Procedures should also be defined for the following:

(1) Compilation and official publication of documents such as a list of the registered factories and a product list.

(2) Secrecy pledge undertaken by the certification body

(3) Implementation of countermeasures against the misuse of registration by the supplier

(4) Suspension/discontinuation of registration

(5) Corrections and amendments

(6) Cancellation of registration

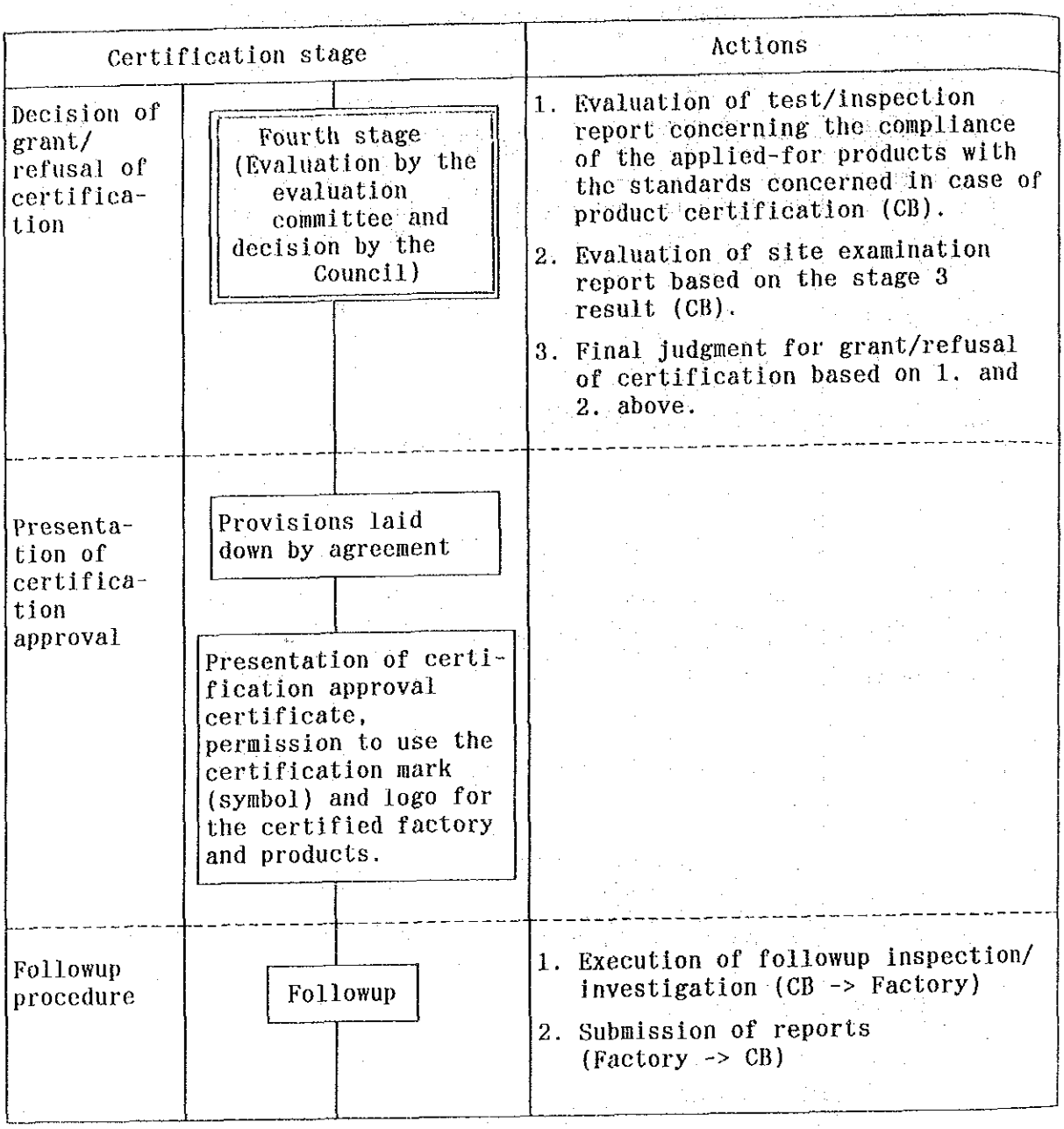
(7) Measures to be taken when the certification system is modified

(8) Provisions for dealing with disputes and rules of appeal

For details relating to quality systems, reference should be made to ANNEX 5-7 "Auditing of Quality Systems."

CERTIFICATION PROCEDURE FLOWCHART

Certification stage		Actions
Preliminary phase	Preliminary meeting	1. Assessment of actual conditions at the factory under application (CB -> Factory)
	First stage (Preliminary Examination)	1. Sending of provisional questionnaire (CB -> Factory) 2. Response from factory (Factory -> CB) 3. Carrying out of a preliminary site examination on request (CB -> Factory)
Formal certification application	Second stage (Document scrutiny)	1. Submission of application document (with attached reference documentation on quality system, quality manuals etc.) (Factory -> CB) 2. Document examination and evaluation by the certification body (CB)
	Third stage (Site examination)	1. Drawing up of schedules (CB - Company) 2. Appointing the examination team 3. Preparation of check list for site examination (CB) 4. Site examination (Confirmation on site) (CB) 5. Confirmatory meeting about actual conditions with factory representatives (CB - Factory) 6. Preparation of report by the examination team (CB) 7. Inquiry meeting to invite comments from factory representatives on the above (report) (Factory - CB)



* Note: CB is short for Certification Body.

ANNEX 5-7

AUDITING OF QUALITY SYSTEMS (EXAMPLE)

Certification bodies, too, have witnessed a growing demand for the auditing of quality systems. It is self-evident that while great importance has widely been attached to the evaluation of quality systems as part of the certification systems operated by the various nations of the world, there is no uniformity in the manner in which quality systems are evaluated as the inspection (auditing) and/or evaluation specifications differ from system to system. With the worldwide expansion of trade, however, there is a greater need for establishing common criteria and a unified certification system. At the same time, the quality assurance requirements for products and services have intensified. In view of this, international standards are being prepared for quality assurance. In an attempt to unify the implementation of these standards, international standards have already been made public concerning the quality system auditing methods, qualification requirements for auditors and the control of assessment programs. In addition to these existing standards, some proposals for international standards have been made.

Based on these current conditions, the following suggestions will be made.

1. Inspection Items and Circumstances for Auditing Quality Systems

Auditing procedures may generally be carried out on the basis of the aspects listed in ISO 9001 and 9002. These standards give the following items:

(1) Management responsibility
   1) Quality policies
   2) Organization
   3) Management review

(2) Quality system

(3) Confirmation of contract clauses (in case of contract)

(4) Design control

1) General
2) Design & development plans
3) Inputs for design
4) Outputs from design
5) Confirmation of design
6) Design modification

(5) Document control

1) Approval and issue of document
2) Modification and amendment of document

(6) Purchasing

1) General
2) Evaluation of sub contractors
3) Purchasing data
4) Confirmation of purchased products

(7) Purchaser supplied product

(8) Product identification and traceability (only where applicable)

(9) Process control

1) General
2) Special processes

(10) Inspection and testing

1) Acceptable inspection and testing
2) In-process inspection and testing
3) Final inspection and testing
4) Inspection and testing records

(11) Inspection, measuring, and test equipment

(12) Inspection and test status

(13) Control of non-conforming products

1) Non-conformity review and disposition

(14) Corrective action

(15) Handling, storage, packaging, and delivery

1) General
2) Handling
3) Storage
4) Packaging
5) Delivery

(16) Quality records

(17) Internal quality audits

(18) Training

(19) Servicing

(20) Statistical techniques

The above items have been presented for the case that ISO 9001 is used. Since the specifications are given in the case of product certification, the itemization may be according to ISO 9002, which is the equivalent with item 4 [Design Control] having been left out. For actual audit, however, it is necessary to have a suitable degree of flexibility so as to make ad-hoc adaptations in the itemization to suit the type and nature of the industry concerned.

2. Quality System Auditing Methods

After presentation of the application to the certification body, the certification body may proceed with the auditing in the following manner.

(1) Prior to the commencement of the auditing, a meeting shall be organized with the applicant to agree the necessary arrangements.

(2) After the consent of the applicant, a preliminary visit to the site shall be arranged to gather the information necessary for the full-scale site examination. Such information may include data on the scale/size of the factory under application, production conditions, type of technology, etc.

(3) The applicant will be required to submit the documentation necessary for quality system evaluation of the factory concerned. This documentation shall be examined prior to the full-scale site auditing and the applicant may be requested to amend the documents if and where required.

The following documents will be required for submission:

1) Documentation specifying the quality system(s) for the factory under applications (including quality manual)

2) Documentation specifying the current status of implementation of the quality system(s).

(4) The site auditing team shall be appointed. The auditors shall possess the qualifications entitling them for registration with the registration authorities. The team should best consist of two or more than two members. One member should act as the Lead Auditor to guide and control the auditing.

(5) Before the site examination is started at the location, the auditing team shall hold a meeting with the managers of the

applicant concerned,

1) to reach a mutual understanding about the execution procedure for the examination

2) to establish the communication channels.

3) to reach a prior understanding, wherever possible, about matters involving secrecy and similar problems.

(6) The site auditing shall be carried out on the basis of the previously prepared checklist and the quality system documentation and quality manual submitted by the applicant to permit a detailed evaluation of the actual facilities and conditions provided for the quality system at the factory under application. For this purpose, it will be necessary to verify the practical existence of the details presented in the document so as to prove the truthfulness of the applicant's statements.

(7) On completion of the site auditing, the auditing team shall sum up the findings and confer on the results.

(8) The auditing team shall present the findings to the managers and/or representatives of the applicant. The Lead Auditor on the team shall give a verbal resume of the audit results.

(9) If improvement is considered necessary, the certification body shall serve notice thereof upon the applicant by stating the time limit (deadline) to be observed.

(10) If the applicant has presented a reply indicating that he has made the appropriate improvement, the certification body shall, if required.

1) re-conduct a complete, full-scale site auditing.

2) and/or conduct a partial repeat auditing concerning only the improvement areas

3) and/or confirm the improvement in the course of the followup audits.

(11) The certification body shall make its decision on the approval of certification based on the advice of the auditing team and serve notice thereof upon the applicant so that the latter may arrange for the registration of the factory concerned. For the final adjudication, it is best to appoint an evaluation committee and have it examine the matter most carefully.

It is also advisable to arrange for an agreement to be signed between the certification body and the grantee at the time of presentation of the certification approval certificate to the applicant, so as to ensure that the certified items are really implemented.

ANNEX 5-8

GUIDELINE FOR THE ACCREDITATION BODY IN CONDUCTING ACCREDITATION OF AUDITORS FOR QUALITY SYSTEM CERTIFICATION (EXAMPLE)

It would be desirable that an accreditation body for accreditation of auditors is established satisfying the following conditions. In addition, it should have a sound financial basis and be operated fairly impartially.

1. Creation of a Management Structure

(1) Establishment of a council

(2) Appointment of high-level managerial staff assigned to the council

2. Clear Definition of the Power of the council

(1) Establishing management/operating plans for the Accreditation Body

(2) Monitoring the practical implementation of the above policies

(3) Monitoring the financial situation

(4) Establishment of committees as necessary

3. Establishment of Organizational Structure

(1) Organizational chart (with clear indication of responsibilities, reporting hierarchy, and assessment/accreditation functions)

(2) Drawing up of financial resource measures

(3) Statement of principle concerning the accreditation system, including rules and procedures for accreditation

(4) Establishment of legal status

4. Accreditation Officers

(1) Qualification requirements

(2) Training and experience

(3) Responsibilities and authority

(4) Conditions for subcontracting accreditation tasks

5. Document and Control

(1) Document allocation

(2) Arrangements for modifications and amendments

(3) Arrangement of old documents

(4) Notification of accreditation approval and changes for the appropriate accreditation scheme users

6. Records

(1) Record maintenance system

(2) Accreditation procedures

(3) Keeping of records

7. Accreditation and Surveillance Procedures

(1) Facilities required for personnel accreditation and documentation procedures

(2) Regular surveillance for persons having been granted accreditation permission

8. Facilities Required for Accreditation and Surveillance

(1) Facilities required from the viewpoint of the accreditation officers and facilities required for accreditation for applicants (including subcontracting of accreditation tasks)

(2) Conditions for subcontracting external organizations to act on behalf of the accreditation body in conducting inspection audits and surveillance and cooperation with proxy organization

9. Quality Manual

Preparation of quality manual and documented procedures, including at least the following:

(1) Quality policy statement

(2) Legal status of the accreditation body

(3) Accreditation body's organization statement, including the council and its composition, authorities and powers of the board members, and operation statutes

(4) Names of senior managers in charge of the affairs of the council and of accreditation officers, their qualifications, experience and authorities (including outside equivalents)

(5) Training for accreditation officers

(6) Organizational chart showing the command hierarchy from the senior managers in charge of the affairs of the council, the distribution and division of responsibilities and functions

(7) Documented procedures for inspecting/auditing of applicants

(8) Documented procedures for surveillance carried out to monitor accreditees.

(9) Documented procedures for checking and monitoring the subcontractors' lists and the subcontractors' functions

(10) Appeal procedures

10. Obligation of Secrecy

11. Public Announcement

(1) List of accreditees and scope of accreditation

(2) Accreditation system

12. Appeal Procedures

13. Internal Audit and Periodic Review

14. Measures against the Misuse of Certificates of Competence

15. Dealing with Complaints

16. Withdrawal of Accreditation Certificates

ANNEX 5-9

AUDITORS TRAINING PROGRAM FOR QUALITY SYSTEM CERTIFICATION (EXAMPLE)

1. In Case of a Five-day Course:

First day

1) Explanations concerning quality assurance and quality assurance standards

2) Explanations concerning the historical background of the ISO 9000 Series and requirements

3) Case studies and statement of results

Second day

1) Practical methods for conducting auditing and assessment

2) Questioning procedures for auditors

3) Case studies and statement of results

Third day

1) Explanation concerning the ways in preparations should be made for auditing

2) Method of drawing up documents

3) Methods of communication

4) Case studies and statement of results

Fourth day

1) Nature of quality assurance contracts

2) Methods for preparing quality plans

3) Approach to conducting discussions/meetings

4) Case studies and presentation of results

5) Examination (held in the form of questions and submitting of reports)

Fifth day

1) Case studies and critical evaluation

2) Summing up

2. In Case of a Four-day Course:

First day

1) General points such as the purpose of training course and the background of quality assurance

2) Principles and practice of quality assurance

Second day

1) Introduction to auditing

2) Audit planning and preparation

3) Workshop for audit planning

4) Methods for carrying out audit tasks

5) Workshop for audit implementation

6) Methods of audit reporting and followup

7) Training and qualification requirements for auditors

8) Case studies

Third day

1) Quality assurance standards

2) Case studies

3) Workshop

4) Audit meeting role-play

Fourth day

1) Repeating the main points

2) Audit role-play

3) Audit meeting role-play

4) Graduation examination

ANNEX 5-10

TEACHING MATERIALS USED FOR THE TRAINING OF AUDITORS FOR QUALITY SYSTEM CERTIFICATION

Teaching materials should be compiled including the following aspects.

Title	Main Contents
1. Purpose of the Training Course	1) Conveying the basic knowledge about auditing 2) Explaining the various types and methods for auditing 3) Clear statement that the purpose of the training is to acquire the skills needed for audit planning, implementation, reporting and followup.
2. Background of Quality Assurance	1) Correct understanding of quality assurance 2) Customer-supplier relations so far 3) Objective verification of quality 4) Required means 5) Inclusion of text pointing to the need for audit and review
3. Principle and Practice of Quality Assurance	1) Principle of quality assurance 2) Practice of quality assurance 3) Quality system standards 4) Inclusion of text referring to implementation standards and measurement
4. The Organization of Quality	1) Mechanisms 2) Responsibility 3) Role of quality assurance functions 4) Inclusion of text explaining the positioning of quality assurance functions
5. Economics of Quality Assurance	1) Development costs 2) Operating costs 3) Inclusion of text referring to matters such as benefits
6. Quality Auditing and Assessment	1) Meaning of auditing 2) Reason for auditing 3) Extent of auditing 4) Scope of auditing 5) Types of auditing 6) Procedures for auditing 7) Quality auditing and quality assessment 8) Qualification requirements for auditors 9) Characteristics of auditors 10) Auditing site

Title	Main Contents
	11) Tools available to the auditors 12) Inclusion of text referring to the conduct of auditors
7. Improvement Requests	1) The instruction material shall include information about the way in which auditors should point out that certain items have been found unsatisfactory in an audit and that these points need improving.
8. Quality Manual for the Company (Example)	1) Company policy (1) Statement of policy (2) Authority and responsibility 2) Outline of system elements (1) Contract review (2) Design control (3) Change control (4) Identification and followup control (5) Document control (6) Control of purchased product (7) Control of special processes (8) Control of non-conformity products (9) Corrective action (10) Testing and inspection status (11) Inspection, measurement and testing equipment control (12) Handling and storing (13) Storing, packaging, and delivery (14) Acceptance testing and inspection (15) In-process testing and inspection (16) Final testing and inspection (17) Quality records (18) Internal quality audit (19) Training (20) Servicing (21) Statistical techniques 3. Indices of procedures etc. should be prepared so that they can serve the company as reference in preparing its quality manual.
9. Check list for Quality Assurance Auditing	Preparation of checklist to suit ISO 9001, 9002, and 9003, respectively. These shall be prepared on the basis of the items given in 8 above.

Title	Main Contents
10. Qualifications and Registration of Auditors and Lead Auditors	1) Qualifications and experience of auditors 2) Qualifications and experience of lead auditors 3) Score point system for assessing qualifications and experience of auditors and lead auditors 4) Registration procedures 5) Registration of auditors and lead auditors 6) Certificate 7) Text referring to the code of practice of auditors and lead auditors

ANNEX 5-11

THE INTERPRETATION OF ISO 9002

-QUALITY SYSTEM IMPLEMENTATION GUIDE-

4.1.1 Quality Policy

(A) Does the supplier' management define and document its policy and objectives for, and commitment to, quality?

See an example of "Quality Policy Statement".

Quality Policy Statement

One of the important concerns of corporate management is to produce good quality products through the quality management.

I, as a managing director of this company, have established and implemented the quality system program, for the quality management, which refers to latest revision of ISO 9002, as set out in this Quality System Manual.

I have made continued effort to maintain/improve the quality systems through sincere taking of corrective actions whenever nonconformity to the quality systems occurs.

I have placed the personnel/organization in charge of the quality management activities such as quality assurance, product designing, production scheduling, production, in-process quality control, quality cost control, inspection/test, maintenance of production facilities, calibration, nonconformity control and corrective actions, and others stated in this Quality System Manual.

The personnel said above is required to fully implement their assigned duties as described in this Quality System Manual.

I take the responsibility for all matters relating to implementation of the quality systems and corrective actions whenever nonconformity to the quality systems occurs, and authorized the Quality Assurance Manager to carry out the matters.

On the basis of this, I hereby address this Quality Policy Statement and that products/services fully in compliance with all the applicable specifications/standards are produced at this company.

Signature

Title

The important matters should be stated in the quality policy statement are that what adequate measures are there to achieve the policy, objectives for, and commitment to quality from view point of "customers", not from "suppliers", and these are as follows;

(a) The "quality" shall be one of the most important concerns of the supplier from the view point of customer.

Quality cost reduction and raising productivity made by the suppliers are not so attractive selling point to the customers as far as they do not bring merit to the customers.

(b) That the Quality Systems Manual is not self-conceited but referred to ISO 9002 should be clearly stated.

(c) The responsibility of top management for the control of nonconformities to the quality systems and its corrective actions should be clearly stated.

(d) Disposition of personnel in charge of the activities stated in the Quality Systems Manual should be clearly stated.

(e) The Quality Assurance Manager who is authorized to take an initiative to perform the Quality Systems Manual by top management should be clearly stated.

(B) Does the supplier ensure that this policy is understood at all levels in the organization?

See 4.17 Training.

(C) Does the supplier ensure that this policy is implemented and maintained at all levels in the organization?

See 4.1.3 Management review.

4.1.2.1 Responsibility and Authority

(A) Are the responsibility, authority and the interrelation of all personnel who manage, perform and verify the work stated in a) - e) affecting quality defined?

See an example of Functional Chart.

The important matter in making the functional chart such as the example is that it should be made from view point of the jobs which affect quality, not from view point of the organization or the personnel allocation in present.

(B) (Continued from question above), and particularly for personnel who need the organizational freedom and authority to perform the a) - e)?

See an example of Organization Chart.

The organization chart should say that to whom the respective organization shall report.

In this example of organization chart says Inspection Sec., Quality Assurance Sec. and Manufacturing Depts. are in organizational freedom to each other and authority to perform a) - e) above, and these activities are monitored by QA personnel.

Different configuration of organization chart may exist according

Quality Systems Functional Chart

– (refered to the requirements of 4.1.2.1 of ISO 9002) –

Key Jobs on quality systems implementation	RESPONSIBLE SECTION									
Items in group 1. which refer to processing respective order from order entry to shipping and certified material test report issuance.	Managing Director	Mr.QA	General Affair Sect.	Sales Sect.	Purchasing Sect.	Quality Assurance Sect.	Manufacturing Sect.	R&D, In-Process Tech. Control Sect.	Inspection and Test Sect.	Ref. No. of ISO QS rules (9002)
(1) Receipt and review of customer's order/ spec.				◎		○				4.3
(2) Quality design and documentation of production/inspection procedure for customer		○		○		◎	○		○	4.3
(3) Production scheduling and its following up				◎	○		○		○	4.8.1
(4) Production instruction				◎	○		○		○	4.8.1
(5) Acceptance test, identification and stock control of purchased material and supplied material by the customr, and operational record documentation for above					◎		○			4.5.4 4.6 4.9.1
(6) Statistical control of purchased material		○			◎	○	○	○	○	4.5.3 4.15
(7) Production and identification of material in production line, and operational record documentation for above					○		◎		○	4.15 4.7
(8) Statistical process control on production		○				○	○	◎	○	4.18
(9) Inprocess inspection and identification of inprocess-inspected product, and operational record documentation for above				○		○	◎		○	4.9.2
(10) Statistical control on in-process inspection		○				○	○	◎	○	4.18

◎: Key section ○: Supporting section

Quality Systems Functional Chart

– (refered to the requirements of 4.1.2.1 of ISO 9002) –

Key Jobs on quality systems implementation	RESPONSIBLE SECTION									
Items in group 1. (continued) which refer to processing respective order from order entry to shipping and certified material test report issuance.	Managing Director	Mr.QA	General Affair Sect.	Sales Sect.	Purchasing Sect.	Quality Assurance Sect.	Manufacturing Sect.	R&D, In-Process Tech. Control Sect.	Inspection and Test Sect.	Ref. No. of ISO QS rules (9002)
(11) Disposition of nonconformity and customer complaints, and its acknowledgment to sections concerned	○d	a ◎ d		○b		○e	○b	○c	○b	4.1.2.1 4.9.2 4.12 4.12.1
(12) Inspection and identification on final product, and operational record documentation for above				○		○	○		◎	4.9.3 4.9.4
(13) Statistical control on final product inspection		○				○	○	◎	◔	4.18
(14) Storage and delivery control of product				◎		○	○		○	4.14
(15) Certified material test report issuance		○		○		◎	○		○	4.11

◎: Key section ○: Supporting section

Quality Systems Functional Chart

– (refered to the requirements of 4.1.2.1 of ISO 9002) –

Key Jobs on quality systems implementation	RESPONSIBLE SECTION									
Items in group 2. which refer to QA/QC systems implementation that supports smooth performance of the key jobs stated in group 1.	Managing Director	Mr.QA	General Affair Sect.	Sales Sect.	Purchasing Sect.	Quality Assurance Sect.	Manufacturing Sect.	R&D, In-Process Tech. Control Sect.	Inspection and Test Sect.	Ref. No. of ISO QS rules (9002)
(16) Quality policy by management	◎	○	○	○	○	○	○	○	○	4.1.1
(17) Quality systems program and its documentation(QS manual)	○	○	○	○	○	◎	○	○	○	4.2
(18) Production procedure chart		○		○	○	○	○	◎	○	4.8.1
(19) Enactment of quality-related incompany standard, such as product specification, technical standard and work standard for production/inspection activity etc. and these indoctrinations		○				◎	○	○	○	4.8.1
(20) Purchasing management(purchasing specification enactment and vendor control etc.)		○			◎	○	○			4.5
(21) Before/after technical advice, after-sales service		○		○		◎	○		○	N/A
(22) Corrective action for nonconformity and customer's complaints	○d	a ◎ b		○b		○e	○b	○c	○b	4.1.2.1 4.12 4.12.1 4.13
(23) Enactment of incompany standard except for that stated in (19) (20) and these indoctrinations	○	○	◎	○	○	○	○	○	○	4.4
(24) Company-wide standardization activity and document control	○	○	◎	○	○	○	○	○	○	4.4
(25) Coordination activity by Mr. QA on standardization and QA/QC performance	○	◎	○	○	○	○	○	○	○	4.1.2.3

◎ : Key section ○ : Supporting section

Quality Systems Functional Chart

– (refered to the requirements of 4.1.2.1 of ISO 9002) –

Key Jobs on quality systems implementation	RESPONSIBLE SECTION									
Items in group 2. (continued) which refer to QA/QC systems implementation that supports smooth performance of the key jobs stated in group 1.	Managing Director	Mr.QA	General Affair Sect.	Sales Sect.	Purchasing Sect.	Quality Assurance Sect.	Manufacturing Sect.	R&D, In-Process Tech. Control Sect.	Inspection and Test Sect.	Ref. No. of ISO QS rules (9002)
(26) Monitoring on QA/QC performance by Mr. QA and his assistant		◎		○	○		○		○	4.1.2.1 4.1.2.3
(27) Maintenance of production/inspection facilities	○	○				○	◎	○		4.10
(28) Calibration	○	○			○	○	○	◎	○	4.10
(29) Personnel allocation	◎	○	○	○	○	○	○	○	○	4.1.2
(30) Indoctrination of QA/QC	○	○				◎				4.17
(31) Personnel qualification	○	○				◎				4.8.2
(32) QA/QC incompany audit	◎	◎	○	○	○	◎	○	○	○	4.16
(33) QC(Quality Commitment) Circle & "Suggestion" activity	○	○	◎	○	○	○	○	○	○	N/A
(34) Environmental management	○		◎		○		○		○	N/A
(35) Housekeeping	○		◎		○		○		○	N/A

◎ : Key section ○ : Supporting section

Subjects	Check Items	Appraisal						Remarks
		Grade					N/A	
		5	4	3	2	1		
13. Training and qualification of personnel	1) Are the training on quality policy, quality systems manual and in-house standards concerned executed? 2) Are personnel in charge of quality assurance, inspection/test, in-process control and quality system audit qualified? 3) Are training records maintained? 4) Are qualification records maintained? 5) Are re-training and re-certify executed?							
14. Internal quality audit	1) Does internal audit cover all elements provided in the quality system manual? 2) Are the audit made on present personnel (managerial, staff and engineer, operator), material (product, raw material and etc.) and document using check list? 3) Are audit records sent to directing manager for his reviewing? 4) Are auditors qualified? 5) Are all the items found unsatisfactory as a result of the audit subjected to corrective actions and re-audit?							

to the enterprise's size, but functions stated in functional chart should be clearly identified.

4.1.2.2 Verification Resources and Personnel

(A) Does the supplier identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities?

See an example of Quality Assurance Flow Diagram.

(B) Does the verification activities include inspection, test and monitoring of production and installation process and/or product?

See an example of Quality Assurance Flow Diagram.

Different types of quality assurance flow diagram may exist except for this, the important thing is that they should show clearly how "vertical" and "horizontal" aspects of quality assurance such as shown below are implemented in the diagram.

The "vertical" one shows the aspect from order entry to shipping on respective transaction, and "horizontal" one shows the aspect of quality systems which support good implementation of the "vertical" aspects of quality assurance.

The quality assurance flow diagram-shall identifies in-house verification requirements such as;

* Establishment of Production Standard,
* In-Process Quality Control,
* Inspection and Test Control,
* Nonconformity Control,
* Quality System Audit

(C) Does supplier provide training system for personnel for verification activities?

See 4.17 Training.

(D) Are audits of quality systems, process and/or product carried out by personnel independent of those having direct responsibility for the work being performed?

See the example of Organization Chart and Quality Assurance Flow Diagram.

As the above chart/diagram said, audits of quality system, process and/or product shall be carried out by QA sec./QA personnel, which are independent of those having direct responsibility for the work being audited.

4.1.2.3 Management Representative

(A) Does the supplier appoint a management representatives who, irrespective of other responsibility, shall have defined authority and responsibility for ensuring that the requirements of this International Standard are implemented and maintained?

See 4.1.1 Quality Policy, 4.1.2.1 Responsibility and authority, Organization Chart, 4.16 Internal Quality Audits.

4.1.3 Management Review

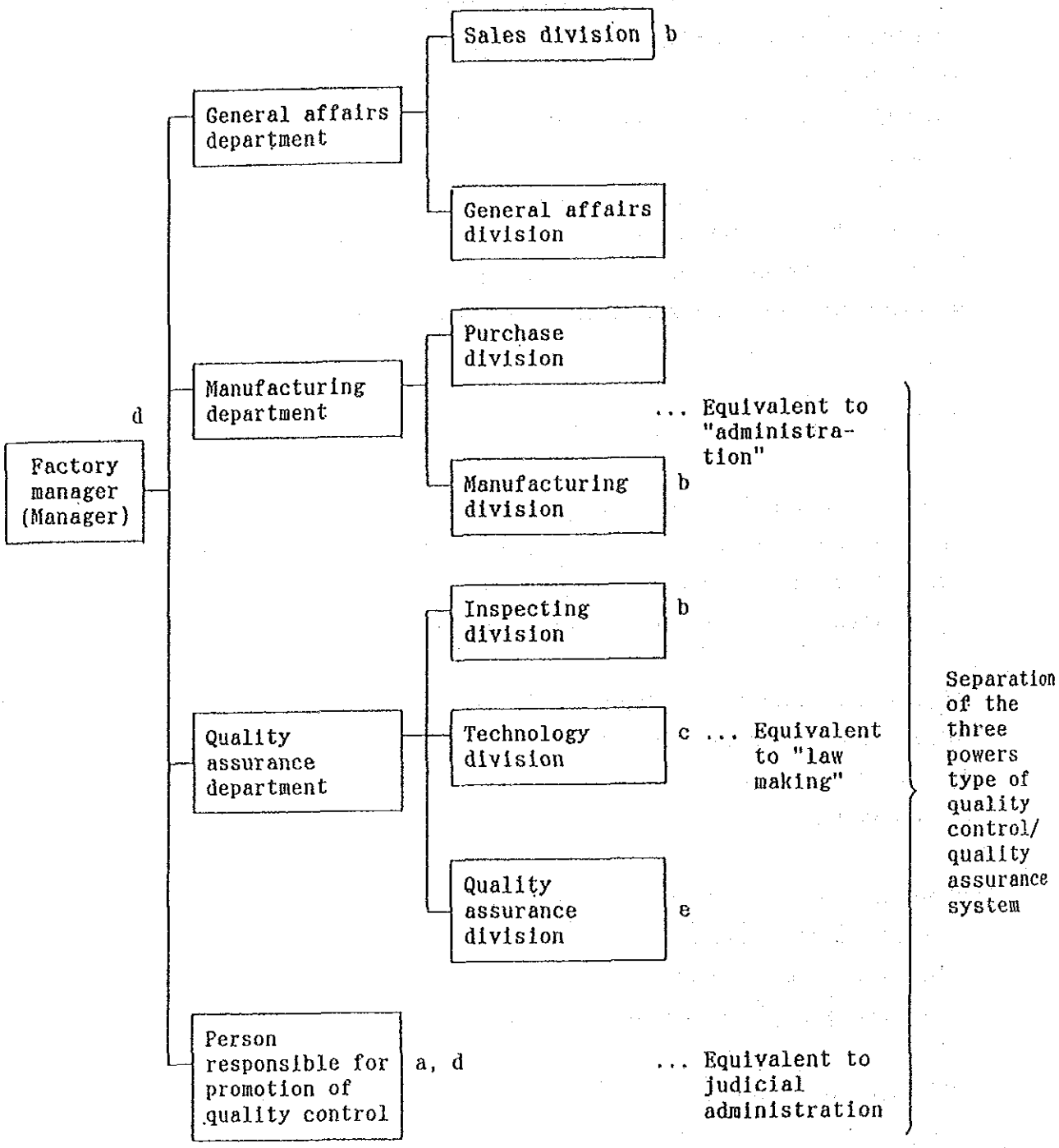
(A) Are the quality system adopted to satisfy the requirements of this International Standard reviewed at appropriate interval by the supplier's management to ensure its continuing suitability and effectiveness?

See 4.16 Internal Quality Audits.

(B) Are record of such reviews maintained?

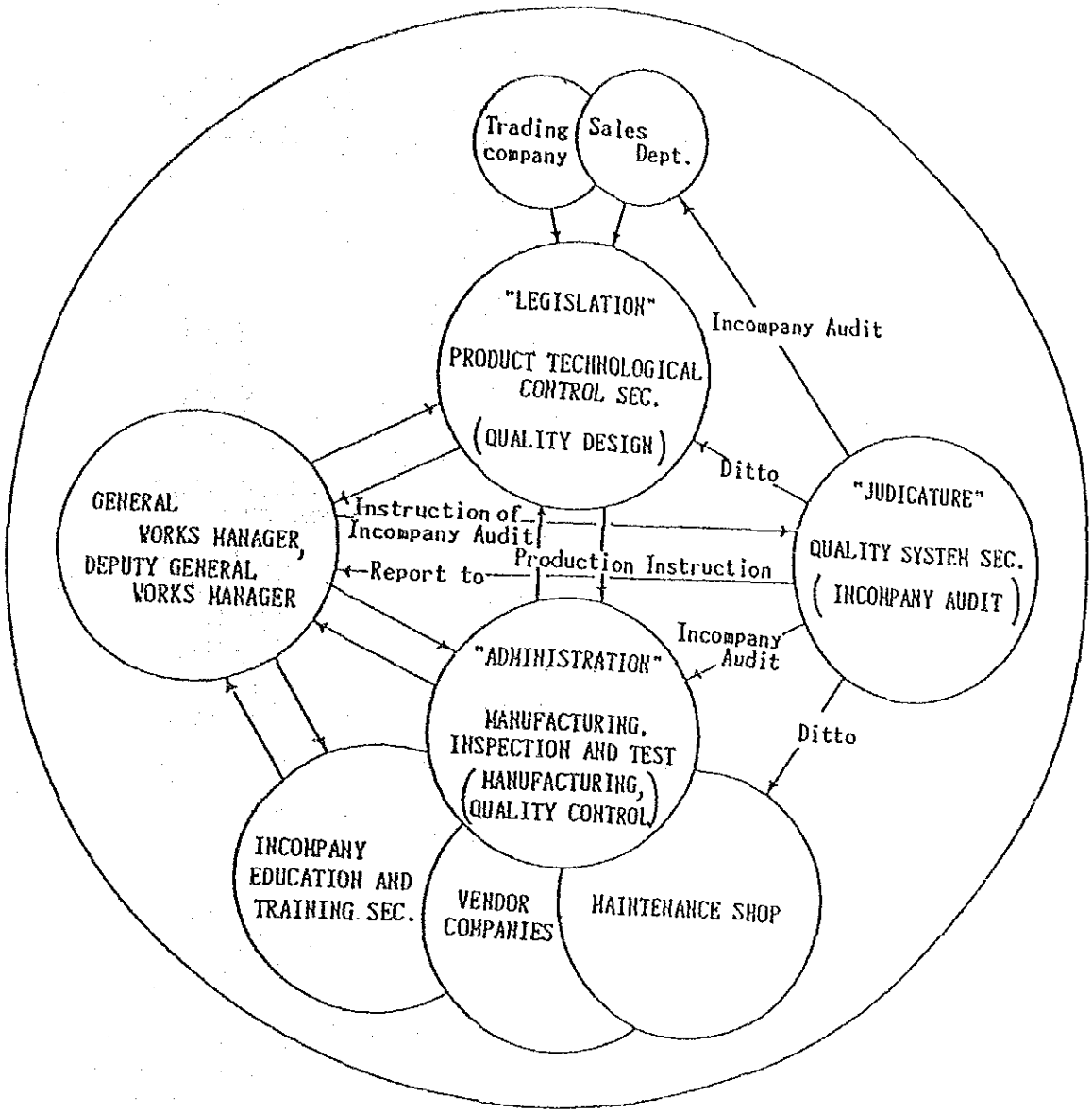
See 4.16 Internal Quality Audits.

[Note]: a,b,c and d in the figure below correspond to a), b),c) and d) in 4.1.2.1.



QUALITY ASSURANCE SYSTEM

This system looks like a system which has respective independence of three powers of "administration", "legislation" and "judicature".

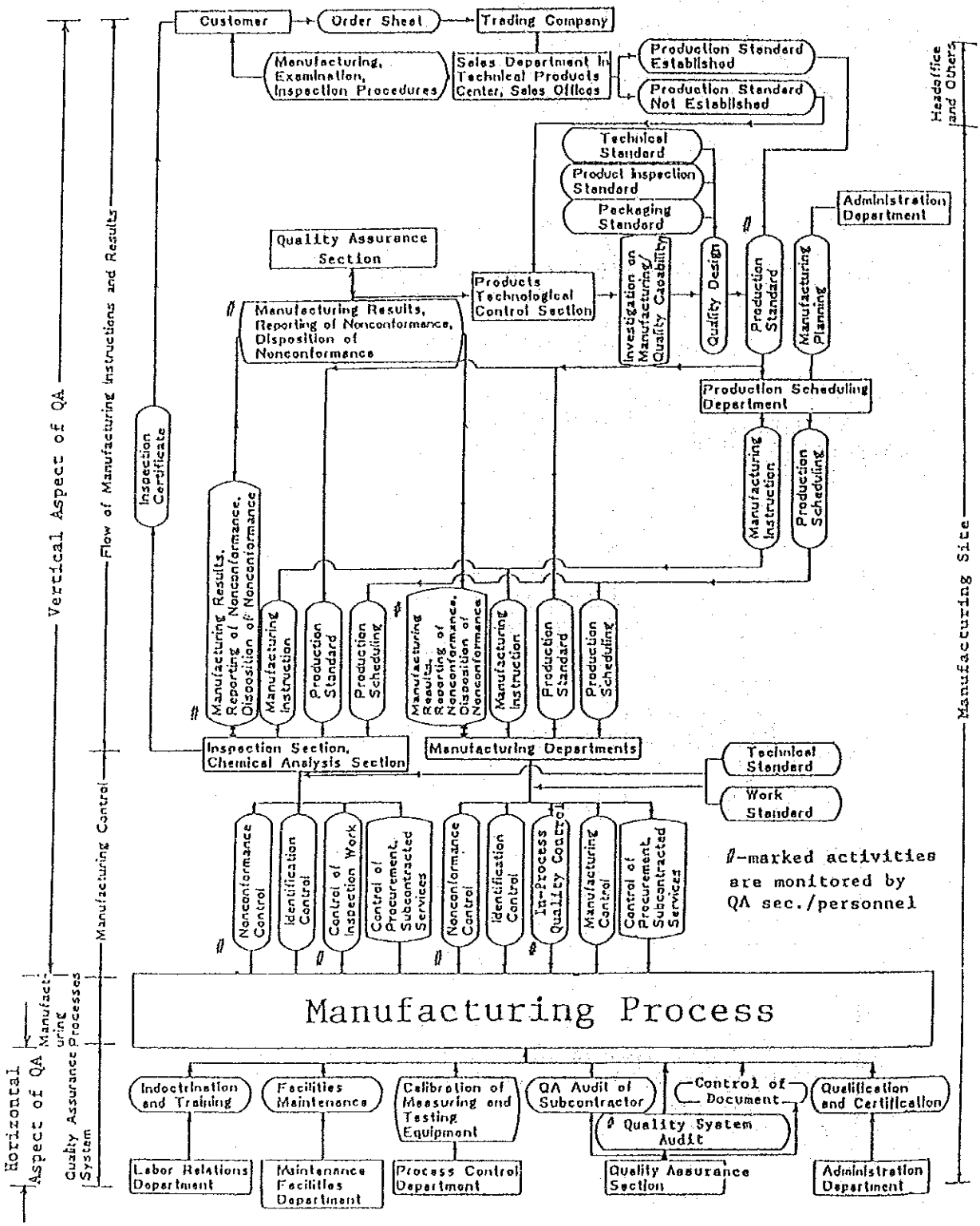


QUALITY SSURANCE SYSTEM

(This system is called as "Quality System" and is provided in the form of "Quality Assurance Program.")

(Example)

Quality Assurance Schematic Flow Diagram



4.2 Quality System

(A) Does the supplier establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements?

See an example of Quality System Manual Control Rule.

The Quality System Control Rule

The Quality System Manual describing the quality system program at the enterprise shall be established and controlled as follows;

(a) The Scope of the Manual

The Manual sets forth the requirements of the quality system program used for manufacturing of products at this company.

The Manual has a position of "Control Standard" in the in-company standard, numbered as QM-XXXX.

The Manual describes the quality system program which is necessary to thoroughly ensure the customer that the products manufactured are in complete conformance with the requirements of ISO 9002.

Unless otherwise specified by the customer, quality assurance activities at this company shall be based on the program as described in the Manual.

By carrying out the quality assurance program as described in the Manual, the quality design, reliability, manufacturing technique and manufacturing control for the products can be well balanced and maintained at this company.

The quality system program, as described in each section of

the Manual, consists of individual control systems relating to quality assurance, each requirement of which satisfies the requirements of ISO 9002.

The Manual shall become effective only when the Quality Assurance Manager of this company approves to release and only for copies of the Manual registered their distribution list by the Quality Assurance Department.

Other copies of the Manual are invalid.

(b) Positioning of the Quality System Manual

From a viewpoint of control system, the Quality System Manual is considered as an in-company standard describing basic requirements and control methods necessary for quality control and production control.

Therefore, the Manual is positioned as a Control Standard, thereby there shall not exist any in-company standards, specifications, or other provisions in contradiction to the provisions of the Quality System Manual.

(c) Contents of Quality System Manual

The following contents shall be included in the Quality System Manual.

* Policy statement by management
* Revision history sheet of the Manual
* Table of contents of the Manual
* Glossary
* Scope
* Control of the Manual
* Organization of the company
* Personnel qualification
* Document control
* Manufacturing control and statistical process control

* Identification control
* Control of inspection and testing, and its status
* Control of nonconformities/customers' complaints and corrective actions
* Handling, storage, packaging and delivery
* Production/quality records
* Calibration
* Control of manufacturing facilities
* Control of subcontracted services/purchasing
* In-company audits and corrective actions
* Indoctrination and training

The expressions of contents above may be changeable from the provision which stated in ISO 9002 to meet with respective enterprises' quality performances.

Control of manufacturing facilities should be included in the contents so that facilities used to manufacture products provide constant and uniform quality level of products even though ISO 9002 does not refer to that.

(d) Classification of Quality System Manual

The Quality System Manual shall be classified into two types by the Quality Assurance Section; i.e., "Controlled Copy" and "Uncontrolled Copy".

The "Controlled Copy" of the Manual shall be identified as such on the cover sheet, however, "Uncontrolled Copy" shall bear no identification.

Original copy of the Manual shall be retained by Quality Assurance Section.

(e) Controlled Manual

Copies of the controlled Manual shall be issued to the related sections within the company, customers and other

outside organizations, upon request, by Quality Assurance Section.

The controlled Manual shall be current at the time of issue, and shall be maintained up-to-date by issuing all revisions thereof to the holders of controlled copies.

The Quality Assurance Section shall document distribution thereof on the Manual Holders List of controlled copy.

(f) Uncontrolled Manual

Copies of uncontrolled Manual is current at the time of distribution thereof, however, shall not be maintained up-to-date thereafter.

The Quality Assurance Section shall document distribution thereof on the Manual Holders List of uncontrolled copy.

(g) Establishment and Revision of Quality System Manual

The Quality System Manual shall be established and become valid after approval of the Quality Assurance Section Manager.

Name change of the enterprises' organizations and expression change of sentences in the Manual are not the subjects of the Manual's revision control.

When revising the Quality System Manual occurs, the revision contents is summarized on the Revision History Sheet, and a triangular mark shall be identified in the left hand marginal place adjacent to the revised portion.

When an entire page is revised, a statement "entire page revised" is written on the right hand top of the applicable page in place of a triangular mark.

Only the latest revisions shall be identified either by the triangular mark or the statement.

When the whole Manual is revised, no revision marking shall be identified.

(h) Maintenance of Quality System Manual

The Quality Assurance Section shall periodically, usually in every November, review the Quality System Manual to see whether or not it is maintained up-to-date and satisfies current requirements of the rules etc. concerned.

(i) Training and Indoctrination of Quality Systems Manual

See 4.17 Training.

4.3 Contract Review

(A) Does the supplier establish and maintain procedures for contract review and for the coordination of these activities?

See an example of in-company rule "Order Entry".

Such in-company rule in charge of "Order Entry" as said under should be established.

In-Company Rules of Order Entry

Scope; This in-company rule covers the activities of order entry.

Order Entry Rule;

Upon receipt of an inquiry from a customer, Sales Sec. shall distribute it to Quality Design Sec., QA Sec. and the other sections in charge.

The Quality Design Sec. shall review the customer's spec. in consultation with Production Scheduling Sec., In-Process Production Control Sec., and Inspection/Test Sec., and determine acceptability for production.

Any items requiring clarification on the customer's spec., if any, shall be transmitted to the customer via Sales Sec.

When all the parties, i.e., the customer, the Sales Sec., Quality Design Sec. and so forth reach to a mutual agreement on all terms and conditions of the spec., Sales Sec. summarizes it into formal Products/Services Specification for approval of customer, then the customer's order shall be accepted by Sales Sec.

These documents concerned shall be added ID number and kept in accordance with in-company document control rule.

(B) Does the supplier review each contract to ensure the items shown in A) - C)?

See above (A).

(C) Are records of such contract reviews maintained?

See above (A).

4.4 Document Control

(A) Does the supplier establish and maintain procedures to control all documents and data that relate to the requirements of this International Standard?

Such in-company rule in charge of "Document Control" as stated under should be established.

In-Company Rule of Document Control

Scope; This rule provides that all the latest in-company standards and related documents are being properly used for production, inspection/test, calibration, quality assurance and all other activities related to the implementations of the quality system manual.

In-Company Standard Classification

Next table shows classification, contents and responsibility of the in-company standard (only quality-related ones are shown).

Making, Revision and Abolition of In-Company Standard

When a request for making of an in-company standard is made from a section, the responsible section as specified in the table said shall develop an initial in-company standard, and obtain approval of the section manager.

When a need is occurred to revise or abolish the in-company standard throughout a daily work, the section responsible for the standard shall proceed it.

In this case, the reasons of revision/abolition shall be clearly shown on the Notice of Standardization.

Additionally, the section responsible for preparation of in-company standards shall review all their in-company standards in every November and proceed to revise/abolish in-company standards, when deemed necessary.

The numbering system shall be followed as specified in the In-Company Standard Control Standard for identification of the in-company standard.

When Process Control Sheets, Manufacturing Procedures or

Inspection/Test Procedures, which are prepared in consultation with the customer and submitted to the customer, and which are required the customer's consent in any revision/abolitions thereof, the revision/abolition of the in-company standard identified on such documents also may be required the customer's consent.

Distribution and Retrieval of In-Company Standard

The Document Control Section shall immediately distribute new/revised in-company standard using the In-Company Standard Transmittal Sheet, to related organizations, and at the same time retrieve obsolete ones.

The Distribution List shall be documented and attached to the in-company standard to be distributed.

The section responsible for initiation of an in-company standard shall show on the In-Company Standard Transmittal Sheet the applicable in-company standard number, including revision number, and number of copies to be distributed and to be retrieved to ensure proper distribution and retrieval.

The recipient shall verify the information on the In-Company Standard Transmittal Sheet of the received in-company standard with sign-off and date, and return the In-Company Transmittal Sheet together with obsolete in-company standard, if any, to the Document Control Section.

Retrieved in-company standard shall be incinerated.

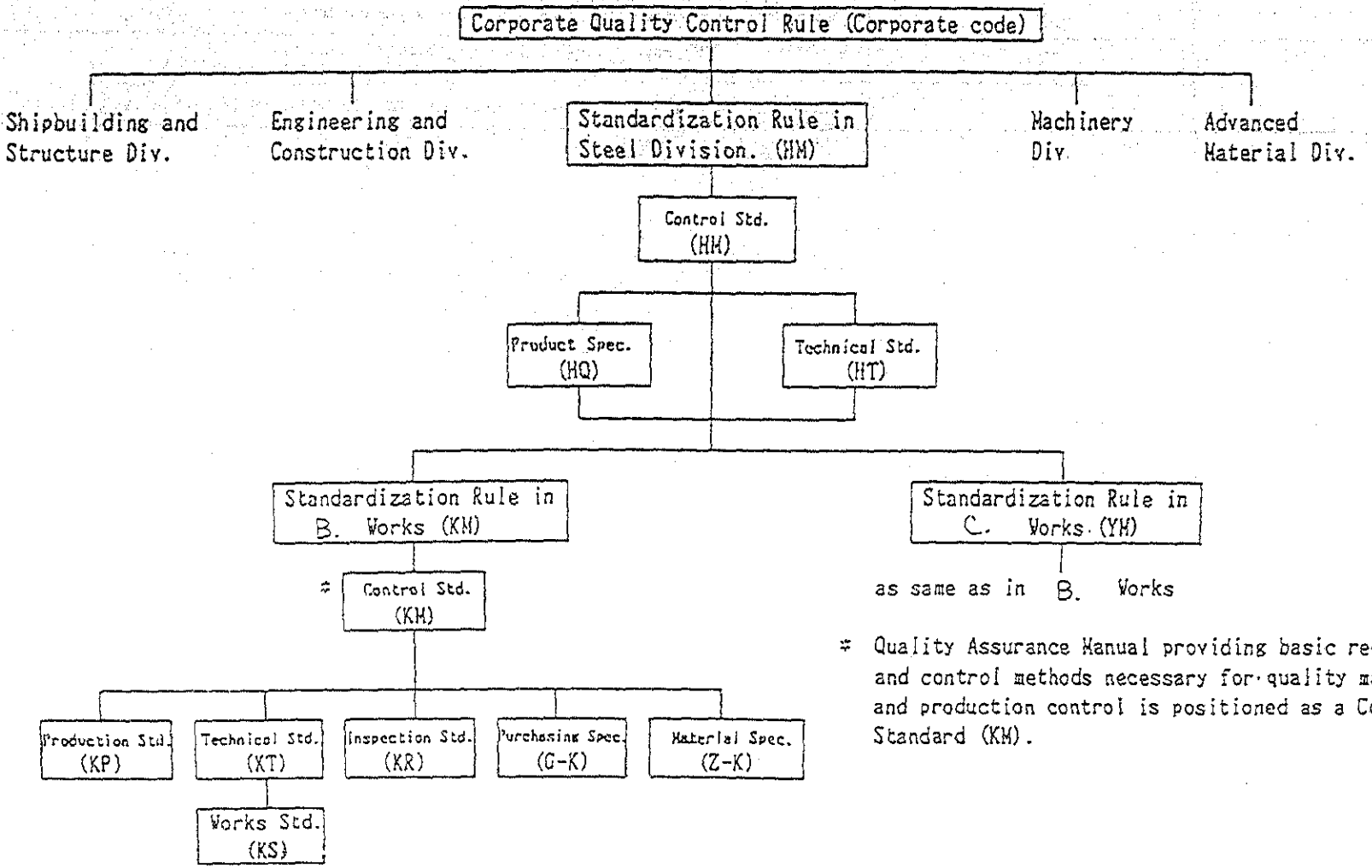
However, the section responsible for initiation of an in-company standard shall retain the original copies of obsolete ones for at least 10 years.

The table under summarizes establishment, revision, abolition, distribution and retrieval procedures of in-company standards.

Fig 2

Job-standardization system in A. Corp.

Hierarchical configuration of A. Corp.'s Standard system is as follows.



* Quality Assurance Manual providing basic requirements and control methods necessary for quality management and production control is positioned as a Control Standard (KM).

Classification, Contents and Responsibility of In-Company Standards (only quality related in-company standards are shown)

Name and Symbol	Contents	Prepared by	Approved by
PRODUCT STANDARD (XQ)	Defines quality criteria required for products. Supplement: Defines quality criteria (mechanical properties, dimensional allowances, chemical composition and so forth)		
PRODUCT INSPECTION STANDARD (XI)	Defines inspection methods, acceptance criteria, and dispositions which assures the final quality of products. Supplement: Criteria, dispositions and control methods of technical matter, and acceptance criteria and dispositions of semi-finished products are defined in XTA and XTP.		
PACKAGING STANDARD (XK)	a) Defines general packaging requirements including packaging style, shipping mark and packaging materials.		
	b) Defines packaging requirements for specific order, including packaging style, shipping mark and packaging materials.		
CONTROL STANDARD (XM) Quality/ Manufacturing Control Standard (XMA)	Defines basic requirements and control methods required to administer quality, manufacturing and others. Supplement: Defines quality assurance program, internal audits, operation planning, quality information reporting, and calculations of standard values for budget.		
Computer Systems Control Standard (XMB)	Defines general requirements and control methods of Computer System. Supplement: Defines establishment, revision, and abolition of Computer Master Table and Code Table.		
Facilities Control Standard (XMC)	Defines general requirements and control methods of facilities. Supplement: Items to satisfy legal rules and regulations and associated requirements, and items to affect quality yield ratio.		
	Defines general requirements and control methods of electronic computers and their terminal units, and automatic controllers.		

Continued

Name and Symbol	Contents	Prepared by	Approved by
Subcontracting Control Standard (XMH)	Defines general requirements and methods to control subcontractors. Supplement: Unit price list, cost estimation, and etc.		
Raw Materials Control Standard (XMJ)	Defines general requirements and control methods of raw materials. Supplement: Receiving inspection criteria, inventory of raw materials, sampling check method, etc..		
Standardization/ QC Circle Suggestions Control Standard (XMK)	Defines general requirements and control methods of acquiring manufacturing approvals, QC circle suggestions, standardization and patents. Supplement: Control criteria for acquiring approvals from outside organizations/bodies, control criteria of incompany standards, and evaluation criteria for QC circle suggestions etc..		
PRODUCTION STANDARD (XP)	a) Defines standard manufacturing methods to satisfy each product specification. b) Defines manufacturing methods for repeated orders. c) Defines manufacturing methods for a specific specification. d) Defines manufacturing methods for a spot order.		
TECHNICAL STANDARD (XT) General Technical Standard (XTA)	XTA defines general requirements concerning manufacturing, production scheduling, inspections, and products.		
	a) Defines general technical criteria for product quality of final and semi-finished products.		
	b) Defines general technical criteria for manufacturing and inspection, and control methods and dispositions thereof.		
	c) Defines general requirements and control methods for production scheduling, dispositions thereof.		
	d) Defines requirements and control methods for clerical work of inspection and analysis. Example: witnessing, processing of mill sheets.		

Continued

Name and Symbol	Contents		Prepared by	Approved by
Operational Technical Standard (XTO)	Defines requirements for operations, and handling, control and disposition of materials within one process.			
	a) Defines technical criteria, control methods and dispositions on plant operation, inspection/test, handling, storage and delivery. Example: Operational temperature · pressure · speed, inprocess inspection, inspection techniques, slinging techniques and way of protection of products after inspection/test and shipping.			
	b) Defines production scheduling criteria for plant operation and handling of in-process materials. Example: Process planning and manufacturing instruction, etc.			
Product Technical Standard (XTP)	Defines technical and operational criteria to design final product. General requirements relating to these items are defined in XTA.			
	1	Product Design Standard	Technical requirements of product design. Ex.: Applicable standards for order specification, and assignment of raw material grade etc.	
	2	Inspection Standard	Design criteria of visual appearance, shape, mechanical test values, and chemical composition in consideration of order specification, application, and user's requirements.	
	3	Process Scheduling Standard	Technical criteria of processing and shipment scheduling. Ex.: Use of left-over materials and semi-finished products etc.	
	4	Order Entry Standard	Order entry processing procedures, such as instruction methods of SPS specifications.	
Facilities Maintenance Technical Standard (XTC)	Defines maintenance requirements of facilities, equipment, and computer systems. Supplement: Maintenance criteria of the ones said above to maintain uniform manufacturing capacity, quality and yield level, calibration procedures etc..			
WORK STANDARD (XS)	Supplements workers' technical skills in consideration of work control, based on the Technical Standard. Defines criteria for operation and checking to be performed by workers for each shop, process or shift, and handling of computer terminal units etc.			

Continued

Name and Symbol	Contents		Prepared by	Approved by
SPECIFICATIONS Raw Materials Specification (XR)	a) Defines procurement and receipt of raw materials.			
	b) Defines procurement and receipt of raw materials, and inspection criteria and inspection methods thereof.			
Material Specification (XPR) Supplement: No specification is prepared for (1) standardized products (2) commerical products (catalogue products)	a) Defines procurement of materials for products, production and operations. Supplement: Coating materials, paints, packaging and marking materials, rolling rolls, mandrel bars, molds, shear knives, plugs, guide shoes, lifting lugs, other special materials.			
	b) Defines specifications for procurement of facilities repair materials, repair and machining work. Supplement: Repair materials, lubricating oils and so forth.			
Subcontracting Specification (XSC)	a) Defines specifications of subcontracted services for completed and semi-finished products.	Quality-related		
		Receiving and handling of the materials		
	b) Defines specifications of subcontracted services for intermediate products.	Quality-related		
		Receiving and handling of the materials		
	c) Defines specifications of subcontracted work except for above.			
Product Specification (CS)	Defines specifications of products for customers.			

Maintenance of In-Company Standard at Each Section/Plant

Each section/plant shall establish the Technical Standard provided in-company standards handling procedure including duplicated ones, such as numbering, distribution and retrieval, filing, location of files, and training and implementation thereof within the section/plant.

Each section/plant shall assign and In-Company Standards Controller and a clerk to properly control the in-company standards within the section/plant.

A file of in-company standards shall be clearly identified as "In-Company Standards" on its back cover to segregate it from other document files.

Indoctrination and Training of In-Company Standards

Indoctrination and training of in-company standards which are distributed to the In-Company Standards Controller, associated with implementation of QS Manual, and strict adherence to the requirements of such in-company standards are of the responsibility of the In-Company Standard Controller.

The method to train to adhere strictly to the in-company standards include training seminars by internal lecturers, class-room type in-company standards reading meetings, and small scale of in-company standards discussion meetings.

Format of In-Company Standard

The formats used in in-company standard control are shown in next several pages.

4.4.2 Document Changes/Modification

(A) Are changes to documents reviewed and approved by the same functions/organizations that performed the original review and

approval unless specifically designated otherwise?

See an example of Incompany Document Control Rules.

(B) Does the designated organizations shall have access to pertinent background information upon which to base their review and approval?

See an example of Incompany Document Control Rules.

(C) Is the nature of the change, where practicable, identified in the document or the appropriate attachment?

See an example of Incompany Standard Notice Form of Incompany Document Control Rules.

(D) Is a master list or equivalent document control procedure established to identify the current revision of documents in order to preclude the use of non-applicable document?

See an example of current Incompany Standard List.

(E) Are documents re-issued after a practical number of changes have been made?

See an example of Incompany Document Control Rules.

4.5.1 General

(A) Does the supplier ensure that purchased product conforms to specified requirements?

See below and the rest.

4.5.2 Assessment of Sub-Contractors

(A) Does the supplier select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality

Confidential

Format No. XXXX

Classification No.

Incompany Standard ☐ Making ☐ Entire revision ☒ Partial revision ☐ Abolition Notice

Making/revised year

Approved	Reviewed	Prepared by

Classification

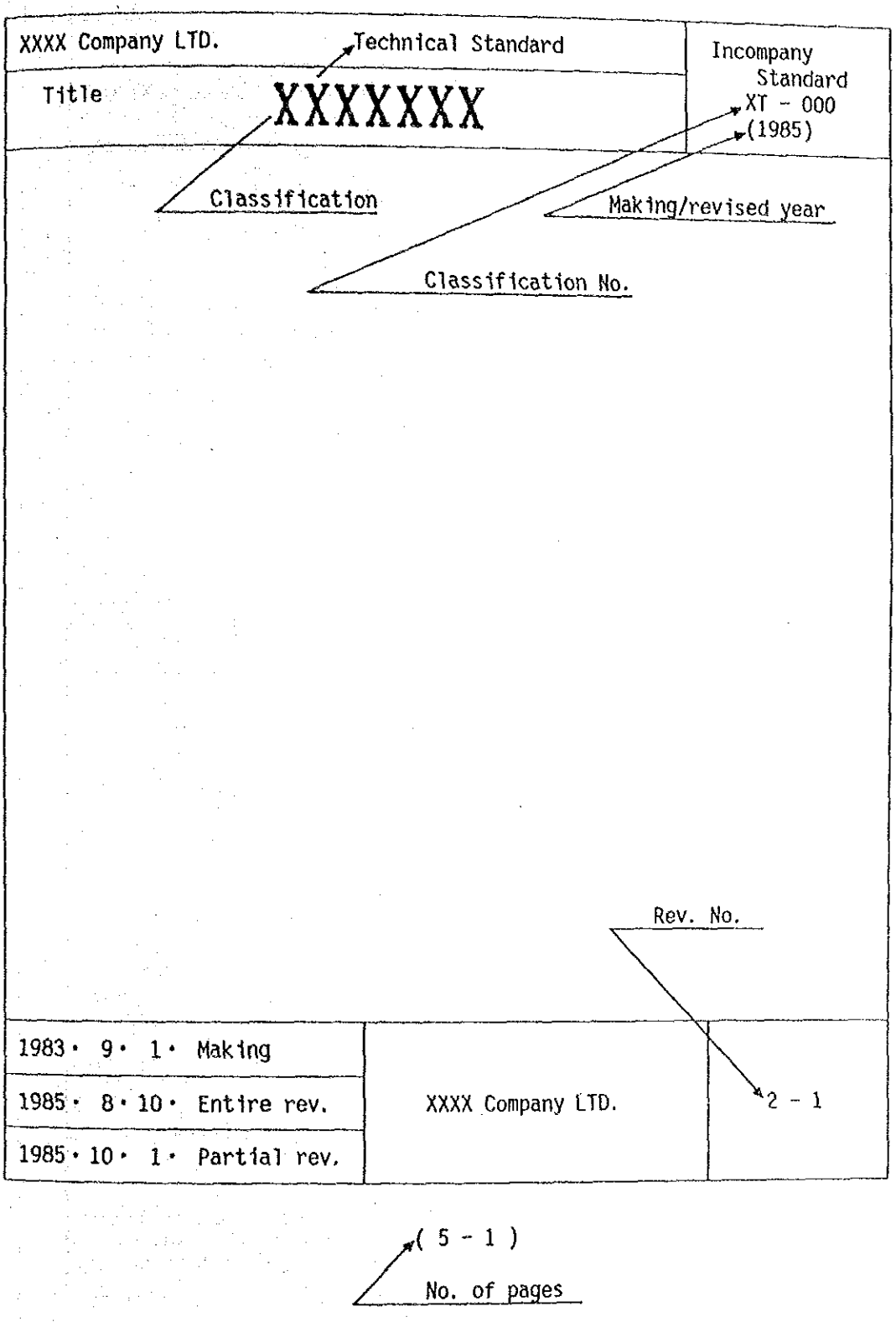
XXXX Company LTD. Technical Standard			Incompany Standard XT - 000 (1985)
Title XXXXXXX			
Making/Rev./ Abolition date	No. of pages to be revised	Rev. No. of pages to be revised.	New revision No.
1985・10・1	5 - 3	2 - 0	2 - 1
Reason of Making/Revision/Abolition;			Execution date
			1985・10・1

(1 - 1)

Page No. of the Notice

Format No. XXXX

Confidential



Confidential

Format No. XXXX

Incompany Standard XT-000

Classification No.

1983・ 9・ 1・Making	XXXX Company LTD.	2 - 1
1985・ 8・10・Entire rev.		
1985・10・ 1・Partial rev.		

(5 - 2)

No. of pages

Rev. No.

Format No. XXXX

8 August, 1989
XXXX Company LTD.
DOC. Control Sec.

To; _____

Incompany Standards Transmittal Slip

We distribute the incompany standards listed below to you. Please send this Transmittal Slip together with the obsolete standards back to the above sec. with the signature of recipient within 7 days.

List of Incompany Standards

Incompany Standards Number	T i t l e	Distribution		Obsolete versions	
		Rev. No.	The number of copies	Yes	No.
Remarks;					

Recipient Signature

NOTE If there is a shortage in the number of obsolete version(s) to be replaced, you are requested to write the reason and trace the missing one(s).

Format No. XXXX

Distribution List

Title	Standard No.		Rev.No.		The Total of Copies	
					Maker of list	
					Distributer	

Distribute to	The number of copies	Return Check	Distribute to	The number of copies	Return Check	Distribute to	The number of copies	Return Check

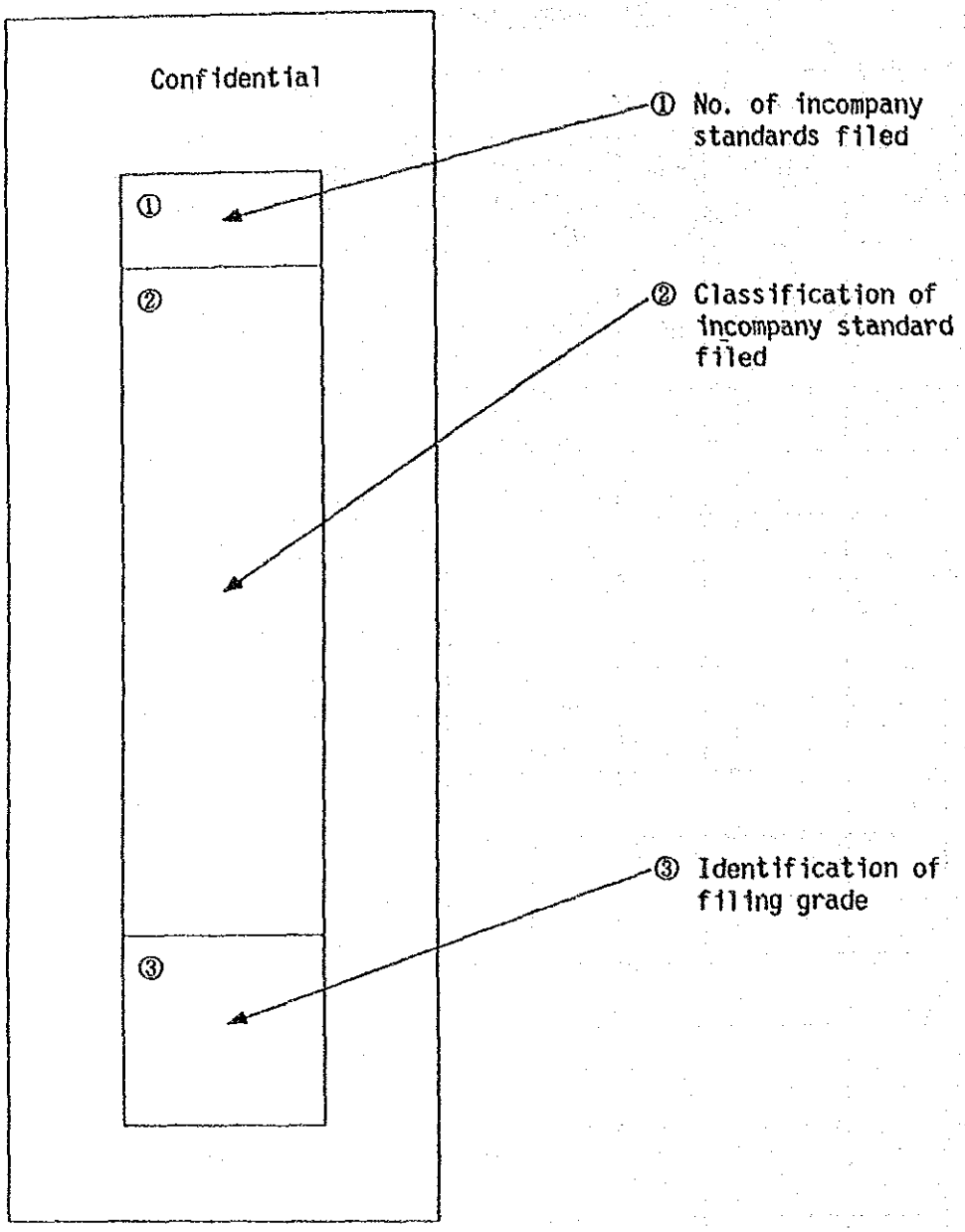
Format No. XXXX

Current Incompany Standards List

checked date . .

Incompany Standard No.	Title	Rev. No.	Making/ revision date	Rev. No.	Revision date	Rev. No.	Revision date

Identification of Incompany Standard File



requirements?

See an example of in-company rule of "Control of Sub-Contractors" under.

In-Company Rule of Control of Sub-Contractors

Scope; This rule provides that control of purchasing and sub-contracted services when part of manufacturing processes is sub-contracted.

Qualification of Sub-Contractors

Prior to contract of purchasing/sub-contracted services, the Quality Assurance Sec. shall determine the control method to the sub-contractor on the basis of direct control or indirect control.

Control of Sub-Contractor which is directly controlled by our company.

For the control of sub-contractor which is directly controlled by our company, QA Sec. shall witness the performance concerned in the sub-contractor, if necessary, and shall assure the well implementation of production, identification and calibration etc. in accordance with purchasing/sub-contracted survive specification.

Control of Sub-Contractor which is indirectly controlled by our company.

For the control of sub-contractor which is indirectly controlled by our company, QA Sec. shall get quality system manual of the sub-contractor as specified under and review whether it is satisfactory or not.

The Sub-Contractor's Quality System Manual

The sub-contractor's quality system manual preferably includes the following items.

* Management policy statement concerning quality assurance
* Quality assurance organization
* Standardization and document control
* Manufacturing control
* Identification control
* Control of examination, inspection and test
* Nonconformance control
* Calibration
* Maintenance of manufacturing facilities
* Personnel qualification
* Control of his sub-contractors
* Quality audits
* Indoctrination and training

Survey and Audit of Sub-Contractors

The QA manager shall survey the implementation of the sub-contractor's quality system manual before its qualification.

After the qualification, the qualified sub-contractor shall be audited at least periodically once in a year and additionally as needed to maintain and improve their quality system.

The survey and audit shall be carried out using the check list shown in next page as an example.

The check list to be used to survey and audit sub-contractor's quality system program shall cover all the items of the quality system manual submitted by the sub-contractor.

Survey and Audit Method

(1) Survey and Audit Team

The survey and audit team consists of QA manager as team leader, and following members.

* Product Design Sec. manager or his chief staff
* Inspection/Test Sec. manager or his chief staff

After survey/audit, the team has a meeting to get a result by the team members basing the member's observations and make a result report using the form shown in next page. Items found unsatisfactory on survey/audit and items required to take corrective actions are subjected to re-audit.

(2) Corrective Actions and Re-Audit

The Quality Assurance Sec. Manager/Product Design Sec. Manager shall require the sub-contractor to take appropriate corrective actions for the items found unsatisfactory at the audit or other items found unsatisfactory in daily manufacturing activities.

When such request is made, the sub-contractor's quality assurance manager shall decide corrective actions to be taken and report to the Quality Assurance Sec. Manager for his approval.

Re-audit shall be made to verify the implementation of these proposed corrective action.

(B) Are the selection of sub-contractors, and the type and extent of control exercised by supplier dependent upon the type of product and, where appropriate, on records of sub-contractors' previously demonstrated capability and performance?

See the answer for (B) above.

(C) Does supplier ensure that quality system controls are effective?

See the answer for (B) above.

VENDOR AUDIT CHECKLIST

Date: October 24, 1985

Vendor's Name B. Corp.
Audit Date September 18-19, 1985
Subject Premium Threading Operations

I. General Comment (opinions, required corrective actions)

Findings through the audit by A. Corp. dated at September 18 - 19, 1985 are as follows;

1. QA Manual

(1) Following new procedure manuals are needed to add into the existing manual file.

(a) In-company education & training system and administration system for QC (QA) personnel
(b) Maintenance of manufacturing & inspection facilities
(c) Control of vendor & subcontractor
    i. Purchasing of chaser, phosphating material and thread protector
    ii. Zinc plating

(2) Following forms are needed to add into the existing manual file.

i. Form (QC 100, 101, 102, 103, 104)
ii. All other documents and forms stated in the manual

(3) Job descriptions are needed to add into the organization chart in the existing manual in the form of functional chart.

2. In-Company Audit

In-company audits for QA system implementation by QA section are requested.

QA manager is requested to conduct in-depth internal audit to assure further effective implementation of the QA manuals which might not be appraised by the short time survey conducted by A. Corp.

Those findings are requested to be corrected on or before October 31, 1985.

II. Appraisal

Appraisal Grade
Grade 5 ... Very good
4 ... Good, higher level
3 ... Fair, normal level
2 ... Further improvements needed
1 ... Radical reform needed
N/A ... Not applicable

1. Control of QA Manuals

(1) Do the QA manuals describe the control system for quality assurance of products appropriately and adequately? (4)

See the comments 1-(1), -(2), -(3) on the General Comment above-mentioned.

(2) Are the QA manuals reviewed and approved by personnel in charge? (3)

The existing QA manuals are only approved by Plant Manager, and those will be approved by QA Manager and the other personnel in charge hereafter.

(3) Is the distribution of the QA manuals to the related organizations controlled? (4)

Para. VII-3, Sec. I. 11. 0 of the QA manuals says that the Log of all holders of the QA manuals is kept to provide control of QA procedure, and the Log was reviewed by the NKK audit team.

(4) Are the indoctrination and training of the QA manuals performed? (3)

No records are kept.

2. Organization

(1) Is the job assignment clearly defined, and are the responsibility and authority of QA section established? (4)

The job assignment of personnel in charge are shown in each section of the QA manuals.

(2) Is the QA personnel able to negotiate with the top management directly? (4)

The organization chart in the QA manuals says that the QA Manager reports to V.P. Operations.

(3) Is the organizational chart provided? (4)

The job descriptions are needed to add into the organization chart in the existing manuals in the form of functional chart.

3. Document Control

(1) Are there Incompany Standards or Work Instructions for production and examination and test? (5)

"Product Inspection Requirements Form (QC 103)" is issued.

(2) Does the QA section check the customer's specifications? (3)

The customer's specifications are usually checked by Inventory Control Personnel except for new specifications which shall be checked by QA section.

(3) Is the distribution of Incompany Standards controlled? (3)

The distribution of Incompany Standards documented in the form of QA manuals are controlled in accordance with the provision of Para. VII-3, Sec. I. 10. 0 of the QA manuals.

(4) Is there a provision for document custody? (4)

Sec. I. 14. 0 "Quality Assurance Record Procedure" is issued and its implementation was checked by NKK audit team and it was well implemented as far as production record.

(5) Is the system established that the documents required for processes are checked by the QA section? (3)

The documents are checked by production personnel, not by QA.

4. Control of Production Processes

(1) Do the Work Instructions specify the criteria and specifications applicable to the processes? (5)

"Product Inspection Requirements Form (QC 103)" is issued

and it specifies the criteria and specifications applicable to the processes.

(2) Is there the established rule for revision of the instructions? (4)

Sec. I. 11. 0 "Quality Assurance Revision Procedure" of the QA manuals is established for above.

(3) Do they use a table sheet in order to control processes? (N/A)
Does the table contain enough information? (N/A)

The table sheet is not used.

(4) Is there the established rule for shipment? (5)

Filling out the document of "Completion Notice" for all good pipe is performed before shipment and its implementation was reviewed by audit team.

(5) Are the manufacturing equipment properly maintained? (3)

See the comment 1-(1)-(b) on the General Comment above-mentioned.

5. Control of Examinations and Tests

(1) Is the system established that the documents required for examinations and tests are properly transmitted to the personnel in charge? (5)

The Sections from I-1-0 to I-8-0 of the QA manuals provide the systems above-mentioned and their implementation were checked by audit team.

(2) Are the examinations and tests performed by qualified personnel? (3)

There are no documented "Personnel Qualification Systems".

(3) Are there the recording form for examinations and tests? (3)

Some of the recording forms for examinations and tests are established and others of them are not.

(4) Is the system established to cover properly customer's specifications? (3)

The customer's specifications are not always checked by QA.

(5) Is there a provision for custody of examination and test records? (5)

Sec. I.14.0 "Inspection-Quality Assurance Record Procedure" of the QA manuals is provided for above and its implementation was checked by audit team.

(6) Are the examinations and tests results technically compiled and analyzed by the vendor? (3)

Those were made case by case but there were no records for above.

6. Identification Control

(1) Is the identification control properly made on each piece or lot of products? (4)

Serial number for identification are painted on middle of the pipe body.

(2) Is the traceability among the product and its Work Instructions and its Daily Work Record verified? Is it documented? (5)

The filled "Product Inspection Requirements Form (QC 103)", "Completion Notice Form" and "Scraps and Rejections Form" are arranged for every Requisition Number and filed.

(3) Are the identification methods adequate so as to prevent being erased? (4)

Stenciled Marking, Red Tag and "Mean Streak Marker" Marking are applied.

(4) Is there the Standard for identification control? (4)

The provisions for identification for products and for nonconformances are stated in Sec. I-1-0 - Sec. I-8-0 of QA manuals.

7. Control of Nonconformances

(1) Are there established provisions for disposition of nonconforming material? (5)

The provisions for disposition of nonconforming material are clearly defined in each section, from Sec. I.1.0. to Sec. I.8.0. of the QA manuals.

(2) Are the nonconformances, if necessary, notified to A. Corp? (4)

Product Engineer or Inventory Control Engineer will contact with A. Corp.

(3) Are the nonconforming materials identified? (4)

The identifications of nonconforming material are made by "Red Tag", "Mean Streak Marker" and "Grease Pencil" etc., and these are provided in each section, from Sec. I.1.0 to Sec. I.8.0 of the QA Manuals.

(4) Are appropriate control methods taken for prevention of recurrence of nonconformances? (3)

No records of them are kept.

8. Control of Measuring and Test Equipment

(1) Is there the Standard for measuring and test equipment control? (5)

Page 3 and 4 of Sec. 1.4.0 of the QA manuals defines the provisions for gauge calibration.

(2) Is the calibration frequency appropriate? (4)

The gauges are calibrated at the every start-up of customer's order and the calibrated gauges are given to operator with issuance of the "Product Inspection Requirements Form (QC 103)".

(3) Are the measuring and test equipment identified, such as by label showing validity of calibration? (3)

The gauges have no label showing validity of calibration because of calibration at the every start-up of customer's order.

(4) Is there a control ledger to show the history of calibrations? (3)

No control ledger shows the adequate history of calibrations.

(5) Are the master gauges, if used, properly controlled and calibrated? (5)

Block gauges used as the master gauges are sent to the National Bureau of Standards for recertification once yearly.

9. Control of Subcontractors

The new procedure manuals for control of subcontractors are needed to add into the existing manual file (See the comments 1-(1)-(c) on the General Comment above-mentioned.).

(1) Are subcontractors properly selected? (N/A)

(2) Is the system established that the manufacturing specifications and instructions are properly transmitted to the subcontractor? (N/A)

(3) Is the system established that the receiving inspection after subcontract work is properly performed? Is it documented? (N/A)

(4) Is there the established provision that any adverse to conditions are immediately reported to your company? (N/A)

(5) Is the system established to control the processes subcontracted by your company? (N/A)

10. Marking, Storage and Shipment

(1) Is there the Standard concerning storage of completed products? (2)

No standard is provided for above.

(2) Are the products stored in a manner to prevent deterioration? (2)

No standard is provided for above.

(3) Is the system established to check the marking on the product is properly performed or not? (4)

Instruction for stencil is approved by QA.

(4) Is there the Procedure (Work Standard) providing the protection of product during transportation? (N/A)

D. Corp. is responsible for above.

(5) Is it rechecked that the product satisfies the customer's specifications or not at the time of shipment? (4)

It is rechecked through documentation of the "Completion Notice" which is stated in Para. VII-C, Sec. I.10.0 of the QA manuals.

(6) Does the QA personnel approve the Shipping Permit? (4)

It is checked by Inventory Control Personnel.

11. In-Company Quality Assurance Audits

See the comments 2. (In-Company Audit) on the General Comment above-mentioned.

(1) Is there provision of in-company quality assurance audits? (4)

Sec. I.12.0 and Sec. I.13.0 of the QA manuals define the provisions for in-company quality assurance audit.

(2) Do the audits cover all part of quality assurance program? (2)

The in-company audits are not implemented.

(3) Are the results of audit reviewed by management? (2)

The in-company audits are not implemented.

A. Corp. Audit Team
Headed By

S.S.
Quality Systems Manager, A. Corp.

Format No. xxxx

Issue No.

Subcontractor QA Audit Report

Team Leader
" Member
" "

Name of Subcontractor;

Subject;

Location;
Audit Date;

Audit Result

A		Very good
B	1	Good, higher level
	2	Fair, normal level
	3	Further improvements needed
C		Disqualified

Auditor;

Auditee;

Comments;

Corrective Actions

☐ Requested,

☐ Not Requested,

See attached sheet

Sent to;

Format No. xxxx

To

Issue No.

Issued Date

Corrective Action Request

Issued by (QA sec.)

Subject:

Date Corrective Action to be taken;

Finding:

Causes, Corrective Actions:

Attached Doc. No.

Signature of Auditee

☐ Satisfactory

☐ Unsatisfactory

Comments:

Attached Doc. No.

Closed Date

Approved By (QA sec.)

Verified by

4.5.3 Purchasing Data

(A) Does purchasing documents contain data clearly describing the product ordered, including, where applicable, above a) - c)?

See the answer for 4.3 Contract Review and 4.4 Document Control especially the diagram and the table shown in A-118.

As the Diagram says, when part of manufacturing processes is sub-contracted, the Sub-Contraction Spec. is prepared in accordance with the Production Standard by which manufacturing instructions are given to the sub-contractor.

When procure raw materials for manufacture of products, and other working materials, the Material Spec. is issued to the vendor.

Instruction of procurement and receiving inspection are made based on the Material Spec. by respective responsible organization; i.e., the Quality Control Sec. for raw materials, and applicable section/plant for the working materials.

When procured materials are officially standardized or when the vendor satisfies the requirement of the Quality System Manual presented by the vendor, no receiving inspection is conducted on the material procured unless otherwise specified.

4.5.4 Verification of Purchased Products

(A) Where specified in the contract, are the purchaser or his representative afford the right to verify at source or upon receipt that purchased product conforms to specified requirements?

See the diagram said as an example in A-118.

(B) Does verification by the purchaser not absolve the supplier of his responsibility to provide acceptable product nor preclude subsequent rejection?

See the diagram said as an example in A-118.

(C) When the purchaser or his representative elects to carry out verification at the sub-contractor's plant, are such verification not used by the supplier as evidence of effective control of quality by the sub-contractor?

See the diagram said as an example in A-118.

4.6 Purchaser Supplied Material

(A) Does the supplier established and maintain procedures for verification, storage and maintenance of purchaser supplied product provided for incorporation into the suppliers?

These are very ordinary question! For answer them, the provisions said above shall be stated in the in-company standard concerned (XM, XT and XS), if necessary.

(B) Are any such product that is lost, damaged or is otherwise unsuitable for use recorded or reported?

See the answer said in (A).

(C) Does verification by the supplier not absolve the purchaser of the responsibility to provide acceptable product?

See the answer said in (A).

4.7 Product Identification and Traceability

(A) Where appropriate, does the supplier establish and maintain procedures for identifying the product from applicable drawing, specifications or other documents, during all stages of production, delivery and installation?

See The Inspection/Test Status Control Sheet and Traveller Sheet.

The Inspection/Test Status Control Sheet and Traveller Sheet shown in following pages are meet with this requirement.

(B) Where, and to the extent that, traceability is specified requirement, do individual product or batches have a unique identification?

See above (A).

(C) Is this identification recorded?

See above (A).

The Lot Traceability

The reasons why lot traceability of product is needed are,

1. To dispose the lot from which samples are taken. So, there is no idea of "inspection/test lot" when 100% of product are inspected/tested.

2. To avoid mis-use of the other products in the same lot from which the samples of nonconformity to criteria are taken.

The lots should be traceable to the products, if necessary, are as follows;

* Raw material lot identified by raw material test number
* Production lot identified by production number generated in each process such as rolling, heat-treatment, plating etc.
* Daily/shift lot, if necessary, identified by date/shift
* Inspection/test lot identified by inspection/test number
* Rework lot identified by rework number
* Return lot identification by return lot number

Traveller Sheet

Ref. Std. Operational Procedure XP _____

Customer's Name _____ Date of Issue _____

Customer's Order No. _____ Issued by _____

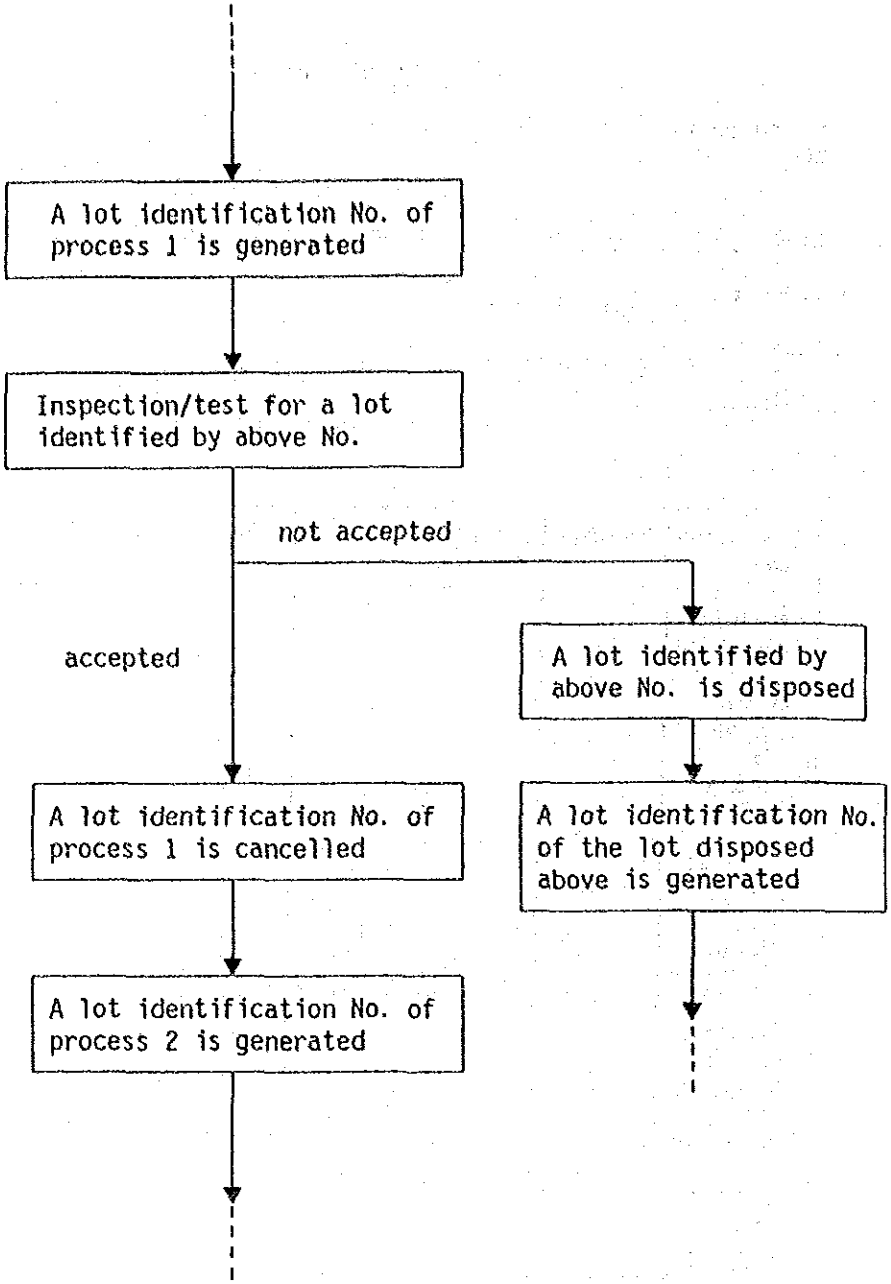
Customer's Spec. No. _____

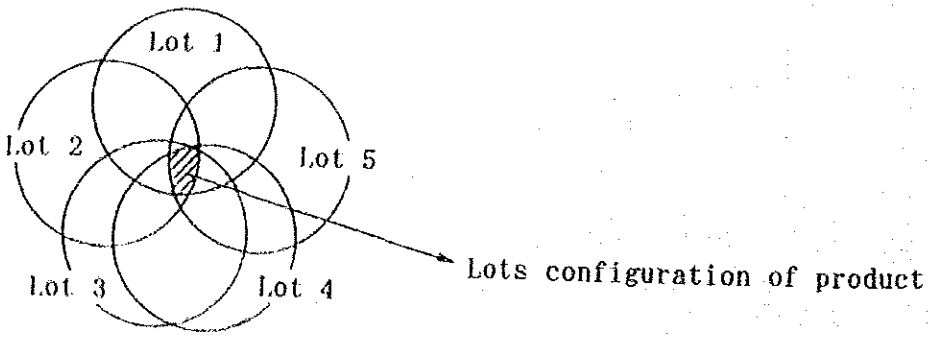
Production Instruction No. _____

Delivery Time _____

Page 1 of

Process No.	Production Steps	Operator	Accepted/ rejected	Time	Responsible person	Remarks
1.	Receiving inspection EG plate Lot No. Size Package condition S. Steel Lot No. Size Package condition P. Steel Lot No. Size Package condition					
2.	Shearing Size tolerance, camber, bur					
3.	Punching Size tolerance, camber, bur					
4.	Notching - - -					


A lot identification No. of process 1 is generated
Inspection/test for a lot identified by above No.
not accepted
accepted
A lot identified by above No. is disposed
A lot identification No. of process 1 is cancelled
A lot identification No. of the lot disposed above is generated
A lot identification No. of process 2 is generated


Lot 1
Lot 2
Lot 5
Lot 3
Lot 4
Lots configuration of product

* Calibration lot, if necessary, identified by ID number of gauge used

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etc.

In generally the traceability of product through the all process is very difficult and costly as shown under.

So, unless otherwise specified by the customer, a traceability for a lot identification is not needed after inspection/test result for the lot are found satisfactory to the criteria as shown in next diagram.

For some important use products, such as nuclear use and aircraft use etc., the suppliers are requested to present the traceability records of product ranging from raw material lot, melting lot, heat-treatment lot, sampling lot and so forth by the customer.

In this case, the supplier should request additional cost for preparation of the traceability records to the customer.

In case of commercial grade product, the supplier need not to prepare the traceability records said above, unless otherwise specified.

4.8 Process Control

4.8.1 General

(A) Does the supplier identify and plan the production and, where applicable, installation process which directly affect quality?

See an example of "Standard Operational Procedure".

The Standard Operational Procedure shown in next page, as an example, shall be established.

The Standard Operational Procedure shall be referred to incompany technical standard, work standard and so forth concerned.

(B) Are these process carried out under controlled conditions which include a) - d) above?

See above (A).

4.8.2 Special Process

(A) Are the Special Processes defined as the definition in 4.8.2 above?

See an example of the Special Process Control Rule.

The supplier shall establish a rule for special process as follows;

Special Process Control Rule

1. Definition of Special Process

The Special Processes are the processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use.

Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met.

Usually heat-treatment, non-destructive testing and so forth are defined as special process.

2. Control of Special Process

Prior to performance of a special process, the responsible organization shall prepare the in-company standards concerned such as Production Standards, Technical Standards, Work Standards in charge containing control procedures, control items, operational records and control of facilities for special process use.

Special process shall be carried out in accordance with the Production Standard (XP) prepared by Products Design Section referring to in-company standards concerned.

The personnel in charge of the special processes shall be qualified.

Any nonconformities occurred in the special processes shall be controlled as specified in the in-company rule "Nonconformity Control and Corrective Action" based on the requirement of 4.12 Control of Nonconforming Product and 4.13 Corrective-Action.

Calibration of the equipment used at the special process shall be controlled as specified in the in-company standard "Control, Calibration and Maintenance of Inspection, Measuring and Test Equipment" based on the requirement of 4.10 Inspection, Measuring and Test Equipment.

Audit of the special process shall be performed as specified in the in-company standard "Internal Quality Audit" based on the requirement of 4.16 Internal Quality Audit.

When sub-contract the special process, it shall be handled as specified in the in-company standard "Control of Sub-Contractors" based on the requirement of 4.5 Purchasing.

(B) Are the Special Processes qualified and do these also comply with the requirement of 4.8.1 General (4.8 Process Control)?

See above (A).

4.9 Inspection and Testing

4.9.1 Receiving Inspection and Testing

(A) Does the supplier ensure that incoming product is not used or proceed (except in the circumstances described in 4.9.1.2) until it has been inspected or otherwise verified as conforming to specified requirement?

See 4.5 Purchasing.

(B) Is verification in accordance with the quality plan or documented procedures?

See 4.5 Purchasing.

(C) Where incoming product is released for urgent production purpose, is it positively identified and recorded (See 4.15 Quality Records) in order to permit immediate recall and replacement in the event of nonconformance to specified requirements?

See 4.5 Purchasing.

4.9.2 In-process Inspection and Testing

(A) Does supplier inspect, test and identify product as required by the quality plan or documented procedures?

See the "Flow Diagram of Information on Order Entry--Shipping" and "Process Control, Inspection and Testing Status Control Sheet".

(B) Does supplier establish product conformance to specified requirements by use of process monitoring and control methods?

See above.

(C) Does the supplier hold product until the required inspections and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (See 4.9.1 Receiving Inspection)?

See above, especially the "Process Control, Inspection and Testing Status Control Sheet".

(D) Does not the release under positive recall procedures preclude the activities outlined in 4.9.2 a)?

See above (C).

(E) Does the supplier identify nonconforming product?

See 4.12 Control of Nonconforming Product.

4.9.3 Final Inspection and Test

(A) Do the quality plan or documented procedures for final inspection and testing require that all specified inspection and test, including those specified either on receipt of product or inprocess, have been carried out and that the data meets specified requirement?

See following "Flow Diagram of Information on Order Entry--Shipping" and "Process Control, Inspection and Testing Status Control Sheet".

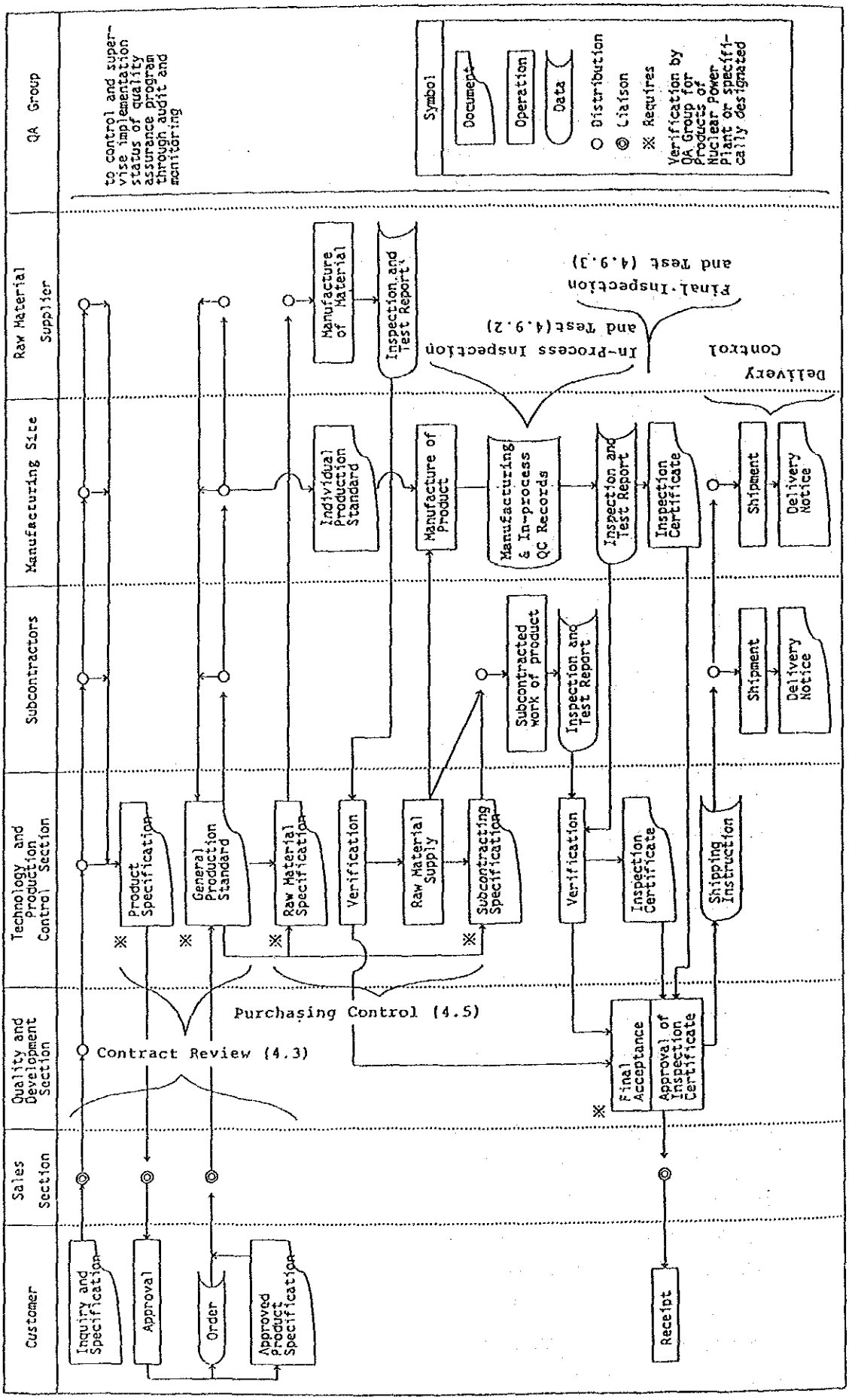
4.9.4 Inspection and Test Records

(A) Does the supplier establish and maintain records which give evidence that the product has passed inspection and/or test with defined acceptance criteria (See 4.15 Quality Records)?

See above "Process Control, Inspection and Testing Status Control Sheet".

(Example)

Flow Diagram of Manufacturing Control System



Reference Std.
Operation Procedure
XP XXXX

Process Control, Inspection and Testing Status Control Sheet

Customer's Name ⊤

Date of Issue 1 June, 1989

Customer's Order No. 123-001

Issued by Product Design Sec.

Customer's Spec. No. AB-123

Production Instruction No. 890601

Delivery Time 30 July, 1989

Process No.	Production Steps	Acceptance Criteria etc.	Reference Std.	Instrument Used (ID. Number)	Insp./ Test Times	Lot Number	Accepted/ Rejected (Causes)	Disposition	Operator	Responsible person	Remarks, Notice (nonconformities in past)
1	Receiving inspection EG plate Stain-less steel Perforated steel	See Production Instruction Lot No. Size, Number, Package condition	Purchasing Spec. No.xxxx		1/lot	Lot No. xxxx	Accepted		Mr. a	Mr. A	Watch for heavy rust, and heavy oily surface
2	Shearing	See Production Instruction Machine setting Size tolerance, Camber, bur	Shearing work std. No.xxxx	measuring tape: (No.xx)	1/ every start, 1/ every end		Rejected (bur)	Segregated and reworked (ground off bur)	Mr. b	Mr. B	Shearing work std. shall be revised as to shear edge adjustment.
	Marking	Model & Part No.			every piece						
3	Punching	See Production Instruction Size tolerance, bur	Punching work std. No.xxxx								