3.6.5 Organizations Responsible for Maintenance of Measurement Standards

(1) General

There is no organization dedicated to maintenance and control of measurement standards. CESMEC is spontaneously making efforts to control and maintain the secondary standard for weight which was supplied from UNIDO in place of the government. For time, however, the Space Laboratory of Chile University own 3 units of time standards based on a cesium 133 watch system, and makes mutual calibration between the units, and at the same time compares the standard units to those in NASA in the United States. For this reason, it is possible that the standard units are national standard and the facilities are asked to take charge for control and maintenance of these time standard devices. Technological level of this laboratory is enough for that purpose.

(2) Relations with international measurement standard organizations

In 1875 when BIPM was established, also Chile participated in the international organization, but has not participated in any practical activity. INMETRO in Brazil is now a central organization for measurement in South America, and this organization has been authorized as a calibrating organization for measurement systems in Chile, so that CESMEC and universities in Chile ask INMETRO to calibrate their equipment and devices according to the necessity.

CHAPTER 4 MAIN PROBLEMS AND OBJECTIVES TO BE ACHIEVED FOR IMPROVEMENTS OF INDUSTRIAL STANDARDIZATION

4.1 General

As described in Chapter 2, Chilean economy, supported by traditional industries such as mining, agriculture, forestry and fishery, has recently been in exceptionally good shape compared to other South American nations. The reason why Chilean economy is heavily dependent on natural resources is that because the Government has been pursuing the open-market policy based on the market principle with minimum intervention in the market and has not adopted the policy to positively promote any specific industrial sectors or fields, naturally those industries which have a comparative advantage are of greater importance. Since the open-market policy has been so far effective and thus contributed to the good economic conditions, the Government is very likely to continue to adopt this policy with minor changes for the foreseeable future. Also, taking into account the fact that the policy is by and large supported by domestic manufacturers and that Government officials are seemingly confident in the policy, it is expected that there will be no substantial change in Chilean industrial structure; i.e. Chilean economy will continue to depend strongly on mining and other primary industries.

However, it is recommended that Chile make efforts to produce higher value-added products based on primary industry, in other words, highly processed primary products. The Government also seems to have an intention to do so. In order to achieve this goal, to improve the product quality is quite important and so is to promote industrial standardization. With standardized high-quality products, Chile will be able to substitute them for currently imported products and even to export them after gaining enough international competitiveness in its products. Smooth transition from import substitution to export promotion might be relatively easy because Chile's tariff rates are rather low in the first place.

Development in high value-added industries will lead to not only an increase in national income but a decrease in external debts through obtaining foreign currency by export. Thus, as industrial standardization program could be one of keys for economic development, the program should be given a high priority for implementation.

Various action programs will be necessary to promote standardization.

4.2 Main Problems and Objectives to Be Achieved for Establishment and Improvement of Industrial Standards

National standards in Chile (NCh Standards) are under control by INN, and this area is where activities of INN are most successful. The NCh standards should be a basis for the unified certification system to be established in the future, and the common standards including the testing/inspecting methods and product specifications will be essential for diffusion of quality control activities. For this reason, consolidation of NCh standards is regarded as a starting point for establishment of policies for standardization. Thus, it may be said that establishment of NCh standards is a first objective for INN to wrestle with as soon as possible.

Problems relating to preparation of standards were described in 3.2, and the items are as follows.

(1) Establishment of policies for an industrial standard system

Adjusting the contents of the national standard to international standard is a big problem for every country. Officials working in an organization responsible for administration of a national standard system have to collect information concerning movement of foreign countries and be familiar with trends in industries in their own country. Their activities to present policies required for introduction of any specific industrial standard to the government and lead people concerned for realization of the system should be based on a wide range of information thus collected by them. From this viewpoint, the policies now being implemented in republic of Chile seem to be too passive. Fortunately, INN now occupies a position suited to promote a more aggressive policy for introduction of a full scale industrial standardization both internationally and domestically.

(2) Maintenance for NCh standards

Periodic review of the standards is necessary. This is required not only to prevent getting technologically behind, but also to improve reliability in the standards and promote their distribution. It is recommended to review the standards once every 5 years according to the ISO standard, but it is necessary to review quickly about 500 standards which have been implemented for 20 years without any modification since their introduction.

(3) Introduction of necessary Annexes to description of each standard

For users of a standard, some of the important problems are a process of introduction of the standard, disputed points during investigation, and relations with related compulsory laws and regulations are not clear or are very difficult to understand. To solve this problem, it is recommended to introduce annexes to the text of a standard. This would also be useful for diffusion of the standard.

In case of JIS, introduction of annexes to a text has proved to be very successful.

(4) Policies for distribution for industrial standards

Public relations activities are indispensable for promotion of industrial standards. In this point, INN is not so aggressive. It is recommended for INN to issue its own publication for promotion of PR activities. Also INN should make use of other related organizations.

(5) Activities for international industrial standardization

INN has participated in various influential international and local organizations for industrial standardization including ISO. However, there is no domestic official organization responsible for investigation and activities to adjust the national industrial standards internationally. It is recommended to set up a

committee making use of some of the current 22 standards technical committees. They would become more sensitive and responsive to trends in foreign countries, and introduction of new industrial standards into the NCh standards would be promoted.

The improvements pointed above can easily be achieved because the current staff of INN are very excellent. The database NORDAT clearly indicates the current state of each standard. It is also advantageous that INN always traces trends in international standards and is familiar with contents of discussion in the standards technical committees and means for publicity.

Consolidation of technical standards is performed not only for realization of a unified certification system, but when viewed from its aspect as a certification system, if a certification is introduced without consolidating relevant standards, the defect is fatal for maintaining reliability and prestige of the certification system.

An important point is timing for implementing the improved certification system, and that consolidation of standards is complete is a prerequisite for it. In this sense, consolidation of standards must be complete before start of implementation of other plans including consolidation of a certification system.

However, it is extremely difficult to improve and consolidate around 2,000 standards within a short period. So, priority is assigned to each standard, and the work should be carried out according to the introduced priority order. At first, common standards must be reviewed and updated to the latest version. Then standards for products in tangible and important industries should be reviewed and updated. Thus, establishment of an adequate standard development system is the urgent objective for running a certification system.

4.3 Main Objectives for Establishment of Unified Certification System and Objectives to be Achieved

4.3.1 Basic Concept for Unified Certification System

In section 3.3 "Certification System", the actual situation of certification systems in the country was investigated, and several problems were pointed out and the direction for solution of the problems were suggested depending on results of the analysis. However, the problems pointed out in this section relate mainly to improvement of the current situation, and suggest a relatively short-term measures for the current certification systems. For this reason, it is necessary to discuss anew what type of unified certification system should be established in the future.

So, the basic concept for unified certification system is taken up and discussed here. Apart from individual problems, it should be noted that some certification systems, especially voluntary certification systems are not working now in Chile. The basic reason why of this is that there are few incentives for manufacturers. In other words, "even if a company gets a certification, consolidates a production system and produces products according to the conditions upon which the certification has been given, the company cannot feel or expect that they can obtain the merits and advantages as listed below".

(1) Improvement of product quality
(2) Reduction of rejection ratio
(3) Improvement of productivity
(4) Reduction of production cost
(5) Increase of sales
(6) Increase of profit

These merits and advantages would not be realized without introducing quality control and a unified certification system which are internationally accepted. Even if a product is shipped only to the domestic market, maintenance of an international quality level is indispensable for survival of the company in a framework of free trade. For these reasons, the basic concept for the unified certification

system would be as described below.

(1) In addition to maintenance and improvement of consumers' health and sound environment, the unified certification system must contribute to improvement of industrial technology in Chile, improvement of production efficiency, reduction of production cost, and improvement of quality of industrial products and services.

(2) The unified certification system must be accepted not only in Chile, but internationally.

(3) The unified certification system must be consistent with trends in international certification systems.

(4) It is required that standards for quality assurance and various guideline employed in international organizations for standardization such as ISO/IEC can be used in the framework of the unified certification system as much as possible.

(5) The unified certification system will be a voluntary one in the initial stage, but it must be able to contribute to integration and improvement of other compulsory or voluntary certification systems being implemented at present in Chile.

(6) Certification made under the unified certification system must generally accompany a certificate of conformity to NCh standards.

Comparison of this basic concept to the objectives proposed in Section 3.3 shows that all of the objectives are based on this basic concept. Also a plan for introduction of a new unified certification system will be made up based on this basic concept.

4.3.2 Improvement of Current Certification System

Improvement of the current certification systems in Chile will be useful to smoothly introduce a unified certification system in the

future. Although there are many certification systems and certifying organizations in Chile, most of them are compulsory ones by governmental or public institutions or voluntary ones employed by sellers and buyers for convenience of their business transaction. The former type of systems and organizations are continuous, while the latter type ones are temporary and not continuous. When viewed from a viewpoint of certification form, the cases of lot certification (ISO/7 type) are overwhelmingly many, while certifications based a examination of the product quality system and accompanying a conformity mark (ISO/5 type) are rare cases.

The objectives proposed in Section 3.3 are as shown below.

(1) Consolidation of certifying organizations and definition of a scope of certification each organization should take charge of

(2) Arrangement and rationalization of NCh standards used for certification

(3) Setting up criteria for qualification

(4) Differentiation of certification bodies from testing and inspection bodies

(5) Traceability of products

(6) Improvement of conformity marks

(7) Documentation of procedure for certification

(8) Measurement system

(9) Units used for certification

(10) Quick processing for certification

The basis concept is for a voluntary system based on the NCh standards which is internationally accepted. To be accepted

internationally, the unified certification system must reflect trends in international certification systems for quality assurance. For this reason, it is inevitable that lot certifications, which share most of the current certification systems, will be shifted to a conformity mark certification system including examination of the product quality system. Also transparency of the unified certification system is indispensable for the system to be accepted all over the world. For this reason, the following 5 items of those listed above should be reviewed in relation to the problems raised in 3.3.

(1) Consolidation of certifying organizations and definition of a scope of certification each organization should take charge of

(3) Setting up criteria for qualification

(4) Differentiation of certification bodies from testing and inspection bodies

(7) Documentation of procedure for certification

(8) Measurement system

The item (8) "Measurement system" is discussed later, so that no discussion is made here for this problem.

As for the item (1), a government institution in control of each certification system independently specifies certification bodies and the scope of certification, so that it is difficult for outsiders to have correct understanding on this problem. To solve this problem, it is recommended to set up a single or a few accreditation bodies and prepare documents clearly stating a purpose, required procedures, criteria for examination, criteria for maintenance and financial aspect of each body to establish transparency of each body.

Now only INN takes charge of authorization concerning voluntary certification, but following up after authorization is inadequate in some aspects. Taking into considerations an international position of INN, it will be better to centralize the certifying organizations for

both voluntary and compulsory certifications into INN.

International standards or ISO/IEC guidelines are available for reference in relation to any of (3) "Setting up criteria for qualification", (4) "Differentiation of certification bodies from testing and inspection bodies" and (7) "Documentation of procedure for certification". Therefore, practical rules reflecting the international standards and guidelines should be introduced. The ISO standards and ISO/IEC guidelines relating to certification are as follows.

ISO 9000,9001,9002,9003,9004
ISO 10011 PT 1,2,3
ISO/IEC guidelines
7,16,22,23,25,27,28,38,39,40,42,43,44,45,46,48,49,53,54,55
ILAC documents (International Laboratory Accreditation Conference)

As for (2) for improving NCh standards to be used for certification, a general direction for discussion is described in 3.2.6 "Problems in Preparation of Standards". Also several remarks were given for consolidation of NCh standards used for certification described in 3.3.3-(2). For this reason, it is emphasized here only that improvement of NCh standards is a prerequisite for introduction of a unified certification system and the task for it should be started as soon as possible.

To carry out the item (5) "Traceability of products" and item (6) "Improvement of conformity marks", necessary measures should be taken in plants (sites) where works for certification are made. It is necessary to clearly define a degree of demand for traceability of each product, taking into account such factors as weight, form and size of each product, and to standardize a practical method for recognition and criteria for processing. Additionally, a method of checking up a certificate with its actual products should clearly be defined as part of the procedure for certification.

A certification mark indicating the certification system itself should be used in place of that indicating the certification bodies, because the latter one is not desirable to defuse the certification system in the future.

The item (9) "Units used for certification" should be carried out in parallel with the item (2) "Arrangement and rationalization of NCh standards used for certification". As this problem is closely connected to designing and testing in fields, so that many problems such as introduction of design standards, modification of scale of modified testing units should be solved at the same time. For this reason, measures at a national level are required to wrestle with this problem.

As for the item (10) "Quick processing for certification", it should be noted that all of state-run companies, non-profit organizations and private companies are now working under the same certification system. It is recommended that this current situation should be reviewed from the viewpoint of whether it is desirable for quick processing of works for certification or not.

The above-described proposals are based on analysis of the current situation and relate to urgent objectives. It should be emphasized that these problems must be solved for consolidation of a unified certification system which will be accepted internationally. The objectives to be achieved for that purpose are described in 4.3.3.

4.3.3 Objectives to be Achieved for Realization of Unified Certification System

The goal of the unified certification system is naturally to diffuse the certification system in Chile and improve quality of services and products in the country for the purpose to contribute to further development of industries, and the following conditions must be taken into considerations to establish a effective certification system.

(1) Establishment of legal base

Even though a certification is either voluntary or compulsory, the system must be run fairly, consistently and systematically. For that purpose, it is necessary to consolidate comprehensive laws and restriction which will give a base for the unified certification system. At least provisions on the following items should be provided in the laws and restrictions.

- Purpose of the certification
- Definition of the certification
- Body or bodies in control of the certification system
- Advisory committee and special committee concerning administration of the certification system
- Roles of and conditions for accreditation body
- Roles of and conditions for a certification body
- Qualification required to auditors of certification
- Roles of and conditions for testing and inspection body
- Certification fee
- Correction and treatment of claims
- Penalty

At present, the DOC-70-200 "SISTEMA NACIONAL DE CERTIFICACION DE CONFORMIDAD OCTUBRE 1988" and the DOC-70-128 supplementing the former are in effect, but these rules do not have a power for legal restriction, nor cover all of the items described above.

(2) The frame work of the unified certification system

Although there are still several problems in relation to a framework of the unified certification system and other changeable elements, taking into consideration the recent trends in international certification systems and the current situation around INN which is a national organization responsible for introduction of a unified certification system, the following framework is recommended.

1) Government (or a government institution) in charge of a unified certification system should set up an organization (which accredits certification body) to insure that the certification bodies organizations have legal power required for certification. In this case, it is not necessary to set up a new accreditation body, and INN should take charge of the job. Also it is necessary to set up an organization to accredit testing and inspection bodies and measuring organizations which will participate in the unified certification system.

2) A certifying organization which hopes to do certification jobs based on the unified certification system presents an application to the accreditation body described above. In other words, only accredited organizations can do jobs for certification based on the unified certification system.

3) Certification bodies not having their own equipment and facilities for testing and inspection must request jobs for testing and inspection to testing and inspection bodies accredited according to conditions introduced separately.

4) Equipment in the accredited testing and inspection bodies must be calibrated periodically according to the conditions decided for each equipment by the accredited measurement body.

5) Industries hoping to get a certification that their products and services conform to a particular standard must present an application to the certification body and receive an examination. The same principle is applied also to certification of a quality system.

6) Only auditors registered in the registering organization can make an examination of an application for certification. The registering organization specifies various conditions required to become the auditor and introduces a qualification system in which only persons satisfying the conditions can be registered.

In Chile, most of the certification bodies also function as testing and inspection bodies, and it is necessary to define roles of each organization clearly and in detail.

It is necessary to set up 4 types of accreditation bodies; a measuring body, a testing and inspection body, a certification body and a body for registration of auditors, which will accredit organizations having the corresponding functions. As for auditors, education and training will be provided by organizations for education and training, and their qualifications will be accredited and registered in the registration body. When these organizations are established and effective standards are prepared, the certification system will become completely transparent and fair. Also, only when the criteria of operation of the certification system are consistent with international standards or guidelines, the system will be accepted internationally.

(3) Consolidation of administrative organizations

1) Accreditation body

Organizations which accredit certification bodies and testing/inspection bodies must satisfy the following conditions to fairly carry out the duties.

(a) The government must assist the organizations. Especially strong assistance will be required until the unified certification system becomes a permanent fixture with the society.

(b) An administrative structure must be established.

- The accreditation body must have an advisory committee in it.

- The financial base must be stable.

- The accreditation body must have a necessary number of competent auditors to examine certification bodies and testing/inspection bodies. (All of the auditors need not always be regular (full time) staff.

- The organization must be neutral in its social position and contribute to public benefit.

- The organization must have competent office staff.

2) Certification body

A certification body must review and consolidate its organizational aspect from the following viewpoint, so that the organization can fairly and effectively carry out the purpose.

(a) The financial base must be stable.

(b) The control system must have been established.

- The organization must have an advisory committee in it.

- The organization must have facilities and administrative functions enough to achieve jobs for testing and inspection. However, if the jobs are assigned to an external organization, the external organization must satisfy the requirement.

- The organization must have a necessary number of auditors who have enough experience and knowledge.

- The jobs must be carried out fairly and neutrally from a social point of view.

(4) National standard (NCh standard) enacting organization

As products and services certified in a national certification system show quality level of the products and services of the country, so that standards used in the certification system must be national ones. In this case, it is important that the national standards reflect not only technical level of the country but also recent trends in international standards and standards in influential countries. National standards must be prepared, implemented and maintained so that the standards will not get behind industrial development in the country.

National standards must be prepared for all items required for certification jobs at least in important fields. The contents must be appropriate for purposes of the certification system.

To achieve the purpose, the current functions of INN must be utilized effectively.

(5) Clarification of a certification scheme (guideline for implementation and requirements for implementation)

It is extremely important to prepare documents clearly and concretely describing the guideline for implementation or requirements for implementation, so that the unified certification system in Chile will be transparent to both inside and outside of the country. A transparent certification system is indispensable for the unified certification system in Chile to be accepted internationally.

Also, a transparent system is necessary for diffusion of the unified certification system in the country.

A certification scheme defined clearly and concretely is effective to industries and plants which make an application for certification in the following points.

- The probability for auditors to make an uneven determination is reduced.

- The probability for auditors to overlook an important item or items related to examination is reduced.

- The documents are useful for an industry or a plant hoping to making an application for certification to prepare for it.

(6) Registration body and educational organization for auditor

Whether a certification system is successful or not depends on quality of human resources. In other words, it is necessary to obtain staff who have expertise in the field of managerial engineering including quality control. Furthermore, repeated education and training are indispensable so that the staff can catch up with the changes in and trends of international standards for certification.

Also, fairness and high moral of the auditors for examination of certifications are required.

Because of the reasons as described above, it will be necessary to introduce a special qualification system (for instance, official or registered auditor system).

(7) Testing and inspection body

Relations between certification bodies and testing/inspection bodies can be defined as described below.

- Certification bodies have their own equipment and facilities for testing and inspection, and carry out testing and inspection for themselves.

- Certification bodies do not have their own equipment and facilities for testing and inspection, and jobs for testing and inspection are consigned to external organizations for testing

and inspection. In this case, the external organization for testing and inspection may be either those officially accredited or those the organizations select for themselves.

In either case, testing and inspection must be performed by staff of an organization having appropriate equipment and facilities for testing and inspection according to certain standards. From this point of view, it is required for public institutions in control of the unified certification system to prepare guidelines which clearly show requirements for testing/inspection bodies, which can participate in activities based on the national certification system, and accredit (or register) testing/inspection bodies. Also it is desirable to monitor how the testing/inspection bodies carry out their assigned jobs. (It is not always necessary that INN becomes an organization for accrediting testing/inspection bodies, but close communications between the accreditation body and INN is indispensable.)

(8) Measurement body

Consolidation of a measurement system is indispensable not only for implementation of a unified certification system, but also for maintenance of international trade and improvement of quality in products and services.

However, as consolidation and maintenance of a measurement system require a vast amount of cost, and also as citizens in Chile are not so strongly aware of the necessity of a national measurement system, it is necessary to point out here that the measurement system in the country still has many points to be improved.

It is necessary to select standards to be introduced, taking into industrial policies of the government in Chile and the current situation of industries in the country, so that the standards introduced will be accepted by international community smoothly.

Pre-requisites for consolidation of an administrative system for the unified certification system, when viewed from systematization

of the system is described above. What can be said as a conclusion is that there is no difference between conclusions obtained through practical measures and those obtained through theoretical planning. For this reason, it must be emphasized here that basic (logical) preparations must be made in parallel with works to make up practical plans.

What was described above is based on investigation made a viewpoint of those who run the unified certification system. In order for a certification system to be successful, also the system must be attractive for manufacturers and consumers. Unless manufacturers practically feel merits provided by the certification system and consumers reply upon the certification mark, any certification system can not be successful.

For that purpose, it is recommended to apply the new certification system to industries now having competitiveness in the international market or having the potentials for it first. The reason why the voluntary certification system for raw fish and refrigerated fish introduced by APSTC has achieved a great success is its big merits to producers.

Secondly, it is necessary to make citizens in Chile feel that, among industrial products which citizens usually see and touch in their daily life, especially products with a conformity mark are excellent in their quality and price. In order to achieve these objectives, however, it is necessary to introduce necessary measures including those for bringing up industries relating to particular products. At the same time, nation-wide campaigns such as utilization of CCV which is an organ of SERNAC are effective.

Thirdly, it is necessary to recommend products with conformity mark in relation to products purchased by Government and public organizations in large quantities. Although it seems that this method can easily be introduced, it will never be successful unless it gives merits to purchasers.

Fourthly, it is necessary that manufacturers, who introduced quality control and succeeded in improvement of product quality, actually obtain profits by producing and selling products with a conformity mark. Purchasers, who once felt reliability to products with the conformity mark, remark the mark from next time on. As a result, it will contribute to increase of sales and profits. Success in quality control will provide merits when all employees of a manufacturing company participate in the activities for quality control and the company return profits realized by the activities to the participants (employees).

4.4 Main Objectives for Diffusion of TQC and In-house Standards and Goals

4.4.1 Main Objectives

The main objectives to solve the problems found out through our survey concerning the current situation of industrial standardization and quality control by means of inquiries and visit to industries are as follows.

(1) To diffuse correct understandings on quality control and TQC among industries in Chile, taking into account international trends in the field of quality control and TQC.

(2) To diffuse among industries in Chile the recognition that quality control/TQC activities are for optimization of quality elements taking into account all factors relating to quality control.

(3) To diffuse among top executives of industries in Chile the recognition that they should take initiatives in quality control/TQC activities.

(4) To establish the quality system as shown in 3.4.1, which is a base for quality control/TQC activities in Chile.

(5) To radically improve curriculum of education for quality control/

TQC, which is an important means for achieving the above objectives.

(6) In updating of the educational curriculum, the "cultural" items shown in 3.4.9-(4) which are important for diffusion of quality control/TQC activities should be taken into consideration.

(7) To practically carry out updating of systems for education on quality control and TQC in Chile described in (5) and (6) above, it is necessary to set up a technical committee (including a preparatory committee for setting up the technical committee) consisting of representatives from industrial, academic and educational circles in Chile.

4.4.2 Main Goals in Achieving Main Objectives

The goals as described below should be set up to achieve the aforesaid main objectives.

(1) Innovation of educational systems for quality control and TQC in Chile

To train up staff who can deal with the main objectives (1), (2), (3) and (4) in 4.4.1, educational systems for quality control and TQC in Chile should be innovated. Contents of the innovation should be as follows.

1) Setting up a technical committee and sub-committees for it to innovate systems for education and diffusion of quality control and TQC

A purpose and members of the technical committee should be as described in 5.2.2.

2) Preparation of a program for updating of systems for education and diffusion of quality control and TQC in Chile by the technical committee

A. Outline of the program, configuration of the program and purposes of education according to the program are described in Section 5.2.3.

B. Study of texts and a curriculum for education according to the program

Contents of the texts are described in 5.2.4.

C. Study of measures for acquiring excellent lectures for education based on the program

Outline of the measures is described in 5.2.5.

D. Summarization as a new educational curriculum

E. Study of a program for diffusion of or assistance to quality control and TQC systems including measures for financial assistance to small and medium scale industries

F. Decision and authorization of a program for innovating education and diffusion systems of quality control and TQC

3) Recruiting lectures for the new educational curriculum according to the program

4) Education for recruited lecturers based on the new educational curriculum.

(2) Start of education based on the new educational curriculum

(3) Establishment of a quality system in industries in Chile by graduators from courses based on the new educational curriculum

It is expected that each industry will make efforts to train up his staffs by self-help according to the new educational curriculum and at the same time introduce a quality system based on ISO 9002.

The goals for achievements in this plan are as follows.

(1) Large-scale industries should introduce a quality system based on ISO 9002 and establish the quality system within 2 years.

It is desirable that, after introduction of a quality system, large-scale industries make efforts to diffuse their quality system among their raw material suppliers and contractors utilizing their quality system functions to control supplies and contractors.

The industries, which have established the quality system based on this ISO 9002 are desired to carry out positive quality activities to develop the system into a more comprehensive system for quality control and TQC.

(2) It is difficult for small and medium scale industries to introduce a quality system based on ISO 9002 system into them from the initial stage, so that they should aim at establishing a system for nonconformity control (including a related system for in-house standardization and so forth).

The reason why, of the elements constituting a quality system based on ISO 9002, the system for nonconformity control was taken up is that it can be considered as the best means for establishing and upgrading the system for correct quality control and TQC because "Without correct nonconformity control, correct quality control/TQC can not be carried out". It is also desired that, after the above objective is achieved, each small and medium scale industry expand their quality system by and by according to their capability, finally to ISO 9002 and establish a complete system for TQC.

However, an important element that should be taken into account in this step is financial assistance to small and medium scale industries.

In order to small and medium scale industries to improve their systems by introducing the quality system as described above, it seems to be necessary that financial assistance is given to them.

Generally, large scale industries can employ people who devote themselves to the work to innovate their systems for quality control and TQC activities, while small and medium scale industries can not employ such specialists.

Especially, it is extremely difficult for small and medium scale industries to employ people who have a wide range of expertise and knowledge enough to wrestle with the work to innovate systems for quality control and TQC.

To supplement the shortage in human resources, it is necessary to retain external consultants for a fairly long period, and it can be considered that the government bears a portion of the cost, for instance, as of the assistance system for vocational education by SENCE described in 3.4.2.

As described above, it is desired for the technical committee for innovation of educational systems for quality control and TQC and its sub-committees to take up this problem.

4.5 Main Objectives for Consolidation of Framework for Measurement Standards and Calibration Systems and Goals to be achieved

4.5.1 Main objectives

The classical Measurement Law enacted in 1848 proclaimed employment of the metric system in the country, and then use of the metric system was made a duty of the country's citizens in 1869, but this Measurement Law include several problems to be a basis for correct administration for metrological systems in the country. For this reason, enactment of a modern measurement law is an origin for establishment of a modern metrological system, and it is necessary to urgently introduce a modern measurement law.

Generally in modern countries, registration systems for manufacturers, repair shops and marketers of measuring instruments related to measurable quantities, and compulsory legal restrictions based on legal metrology including a verification system for measuring instruments have been introduced for fair business transaction and protection of consumers. Also, in many countries, measurement calibration systems traceable to national measurement standards have been established as official services for industrial metrology.

The main objectives for that purpose are as described below.

1) Enactment of a modern measurement law
2) Establishment or accreditation of organizations responsible for legal metrology
3) Establishment of national standards, and setting up a national metrology laboratory for maintenance and control of the national standards
4) Establishment of a traceability system for industrial metrology and setting up or accreditation of organizations responsible for metrological calibration
5) Arrangement of measurement standards and equipment for calibration

4.5.2 Goal to be Achieved

It can be considered appropriate to achieve the goals, using the following methods, to solve the above problems and main objectives generated to relation to the problems.

(1) Enactment of a measurement law

It is desired to set up a committee for enactment of a measurement law and a technical special committee under control by MINECOM, provide a forum to hear opinions from people in the industrial world and consumers, and make a full investigation on this problem. In this case, high capability is required to office

staff responsible for preparation of the original plan, so it is recommended that CORFO or INN should take charge of it.

(2) Organization responsible for implementation of legal metrology

The most important objectives to be carried out first is establishment of an organization accrediting bodies for implementation of legal metrology, and it can be considered that INN and the national metrological laboratory to be established anew should take charge of this task. When convenience for manufacturers of measuring instruments and consumers is taken into consideration, it is desired that an organization responsible for implementation of legal metrology should be established in each economical unit area.

(3) Establishment of a national metrological laboratory

It is necessary to establish a national metrological laboratory, which take charge of establishment, maintenance and control of national standards and development and diffusion of metrological technologies. In this case, the laboratory may be established as an organization belonging to an appropriate public body, employing technicians and engineers from testing facilities of each university, CESMEC and INTEC-CHILE as staff of the laboratory.

(4) Establishment or accreditation of an organizations for calibration

It will be practical to accredit testing facilities belonging each university, CESMEC and INTEC-CHILE and other organizations as calibrating organizations for each measurement unit according to capability of each facility.

(5) Consolidation of hardware such as metrological standards and equipment for calibration

It is desirable to set up a committee consisting of engineers having technical knowledge concerning metrology and discuss the

problem under guidance by related institutions under control by MINECOM because the national budget is related to this problem.

CHAPTER 5 PROGRAMS OF THE INDUSTRIAL STANDARDIZATION SYSTEM DEVELOPMENT

5.1 Plans for the Introduction and Diffusion of a Unified Certification System

There are various types in certification systems. However, for the reasons presented in Chapter 4, this Report will consider a certification system which comprises two parts, namely, assessment and certification of quality system based upon ISO 9000 Series and verification of compliance of the product manufactured in the factory whose quality system has been certified with an applicable standard or specification.

In line with the above consideration, the following six programs will be proposed.

(1) Program for establishing a legal and regulations associated with the unified certification system.

(2) Program for establishing accreditation system for certification bodies.

(3) Program for establishing certification system.

(4) Program for establishing a registration system for qualified auditors who conduct assessment of quality system under the Unified Certification System.

(5) Program for establishing training system for qualified auditors.

(6) Program for the diffusion of the unified certification system.

Fig. 5.1-1 sums the above programs. (The topic of metrology will be dealt with under a separate heading.)

Since the establishment of international standards on quality assurance, or ISO 9000 Series, there is a growing worldwide tendency toward establishing a certification system for quality system based upon ISO 9000 Series in more and more countries. And some countries have adopted preferential procurement policy for government use for

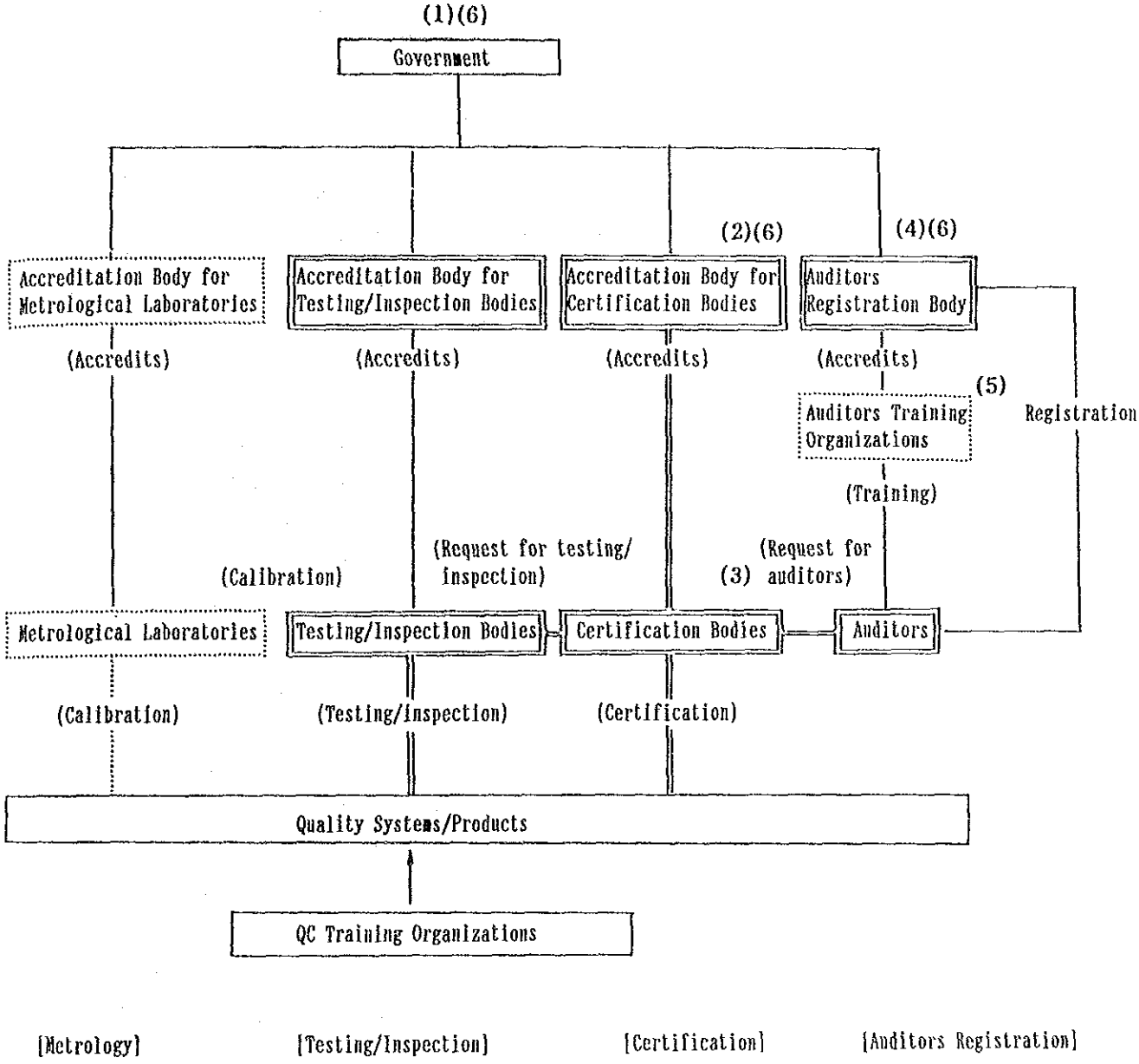
products produced in those factories whose quality systems have been certified by authorized third-party certification bodies. Even in business among private companies, purchasers tend to ask suppliers that their factories be certified by third-party certification bodies based upon ISO 9000 Series. These trends will be more intensified in the near future. In view of these circumstances, it will be an urgent task for Chile to establish a new certification system for quality system in order to comply with the worldwide trends and to further promote her exports.

Taking such an urgent need into consideration, the programs proposed in this Report are formulated in such way as to be fully utilized for the establishment of QS certification based upon ISO 9000 Series. In this case verification of compliance of a specific product with an applicable standard or specification will not be needed and relevant parts of the proposed programs can be set aside. However, please note that QS certification has its own advantage and disadvantage as follows;

Advantage : The capability of the manufacturer is approved or authorized and can be used by him in claiming general manufacturing competence for a specific range of end products.

Disadvantage: The end product cannot be certified by the certification body as complying with the specification, and therefore, certification mark cannot be attached on each product.

Note: QS certification may alternatively be called QS assessment and registration in some countries. However, words QS certification is used throughout this Report. There is no difference between QS certification and QS assessment and registration.



Note:

: Present organizations (and systems) to be strengthened
: Organizations (and systems) to be established
: Works directly related to certification
: Works though not directly related to certification but necessary for supporting certification
: Works desirable for supporting certification

Fig. 5.1-1 Interrelation between Accreditation Body

The creation of a Unified Certification System will necessitate major efforts and will prove to be a formidable task as will be described later. It will also be essential to introduce such a system in an organized manner to ensure consistency and the absence of mutual contradictions within the system. For this purpose, it would, therefore, appear to be desirable for INN to proceed with the operations in accordance with the following approach.

(1) Reinforcement of the administration office

INN should establish a Standby Section preparing for the establishment of the Unified Certification System and should assign specific responsibilities for the tasks to a plural number of staff members so as to ensure an Administrative Preparation Service with capability pending the establishment of the Unified Certification System.

(2) Establishment of Standby Committee in preparation for the creation of the unified certification system

A Standby Committee will be created consisting of a membership. INN will make the first step in inviting and actively soliciting participation. The scope of solicitation should include the government ministries concerned, the certification organizations, the testing and inspection organizations, the quality control education and training organizations, the technical experts, the legal experts, the industrial sectors, the exporting business/industry sectors, and the representatives of the consumers. It is of importance that the Committee should be composed in such a manner as to ensure neutrality and impartiality and to avoid bias in terms of any over-representation of a particular group or particular sectors.

The tasks of the Standby Committee will be as follows:

A. Exchange of views in general about the nature and form the unified certification system should have.

B. Provision of advice on preferable organizations and persons to become the members of the Preparation Committee for the unified certification system. After receiving the advice of the Standby Committee, it is desirable to proceed to the next step at the earliest possible time.

(3) Establishment of Preparation Committee for the unified certification system and deliberation of fundamental aspects of its creation. The Preparation Committee will consist of a Committee proper and Subcommittees (see Fig. 5.1-2). The Committee proper will deliberates on the basic policy directions concerning the unified certification system and authorize in the final instance the adjustments made between the subcommittees and/or the conclusions presented by the subcommittees. The Subcommittees will attend to the preparation and drafting of practical proposals on the specific themes outlined below.

A. Subcommittee for planning and coordination

The task of this Subcommittee will be to examine the basic frame for the unified certification system and will adjust and harmonize all inter-subcommittee matters.

B. Subcommittee for legal affairs

The task of this Subcommittee will be to examine all matters pertaining to the legislative provisions and regulations concerning the unified certification system. This Subcommittee is thus the equivalent of the Deliberation Committee for Industrial Standardization Law referred to in 5.1.1. under "Program for establishing the legal and regulative basis associated with the unified certification system."

C. Subcommittee for accreditation

The task of this Subcommittee will be to examine establishment of an accreditation body and the accreditation procedures.

This Subcommittee is thus the equivalent of the Preparation Committee for the Establishment of the Accreditation System, referred to in 5.1.2-(2).

D. Subcommittee for registration of qualified auditors

The task of this Subcommittee will be to deliberate on the organizations concerned with training for candidates of auditors, as well as the education and training programs and curricula, and the registration system to ensure that personnel who conduct assessment of quality system meet the qualification requirements of the qualified auditors. This Subcommittee is thus the equivalent of the Committee for the Establishment of Registration System for Qualified Auditors referred to in 5.1.4-2 (1).

E. Subcommittee for the diffusion of certification

The task of this Subcommittee will be to develop plans for the diffusion and dissemination of the unified certification system. More specifically, this Subcommittee should concentrate its attention on the topics presented in 5.1.6-(2).

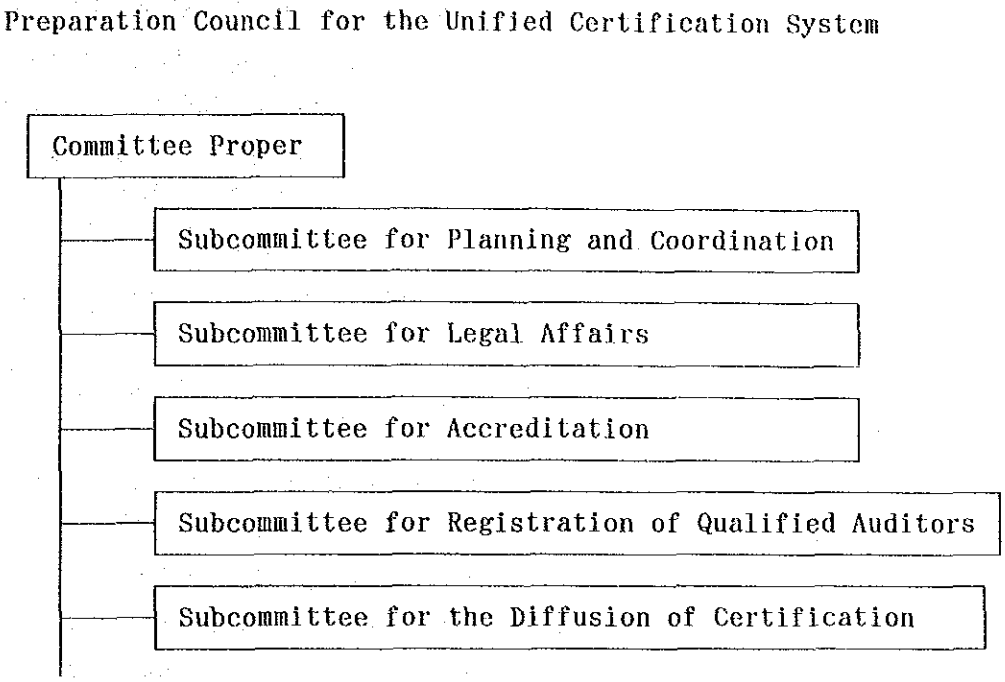


Fig. 5.1-2 Composition of the Preparation Council for the Unified Certification System

5.1.1 Program for Establishing a Legal and Regulations Associated with the Unified Certification System

In recognition of the fact that industrial standardization is an essential condition for the Republic of Chile to achieve economic development and public prosperity, it will be of vital importance to create the legislative basis for industrial standardization, including the certification system as part of the system of national laws of the Republic of Chile, and to establish the specific bye-laws and enforcement regulations based on these legislative measures.

(1) Entity to assume responsibility: This will be the MINECOM. In essence, this will imply that INN will seek to coordinate with all entities and authorities concerned and will act as a promoter in drafting the law and regulations.

(2) Details of the programs

1) Establishment of the Industrial Standardization Law INN should establish internally a Deliberation Committee for Industrial

Standardization Law. This internal Committee should preferably be composed of the representatives from the following organizations in order to ensure that this Committee will constitute a fair consensus of the nation's organizations and bodies concerned.

(a) Ministries and ministerial agencies concerned
(b) Industrial groups
(c) Universities
(d) Consumers
(e) Bodies and entities concerned with testing, inspection and certification

INN should appoint staff members (at least 2) with the appropriate capabilities and expertise so that the above Committees will be in a position to execute and fulfill their tasks. It would be desirable that a draft will be formulated in one year and sent to the Parliament for approval.

2) Items and details to be laid down in the Industrial Standardization Law
(While establishment of national standards is inseparable from the certification system, this Report will limit its scope to the certification system only.)

(a) Article concerning the objectives of the certification system

This Article will make it clear that the objectives associated with the implementation of the unified certification system based on national legislation are to raise the level of industry, achieve higher productivity, attain higher product quality, reduce costs, assure the health and safety of the general public, and protect natural environment.

(b) Article concerning the definition of certification

This Article will lay down clearly the objective of certification and its scope. As types of certification, this Article should specify also certification and registration of assessed quality systems reflecting recent international trends in addition to product certification.

(c) Article concerning the competent organization responsible for the certification system

This Article will specify the organization in which competence for the implementation of the certification system will be vested, and clearly define the extent of its authority and responsibility. While the competent organization should be neutral, impartial body in the public interest, this may not necessarily entail its being government body. It will be preferable, however, for the Government to assume ultimate authority so as to facilitate international recognition of the certification system.

(d) Article concerning the Advisory Committee and Special Committees for the operation of the certification system

For the certification system to be effective, it will be essential to ensure that the views of the officials concerned represent a fair consensus of opinion and that agreement is achieved among the officials concerned. Consequently, it will be of importance to have an Article which stipulates the creation of the Advisory Committee so that it will duly deliberate all important aspects pertaining to the certification system and advise the head of the competent organization in charge of the certification system.

While it will be necessary to specify the deliberation items for the Committee under the Article, they are likely

to cover important matters included in the following articles from (5) to (11).

(e) Article concerning the accreditation body for the certification bodies

While it is conceivable to create on the one hand a system in which the organization assuming competence for the certification system will itself act as accreditation body or establish a separate accreditation body on the other hand, a regulatory framework will be required in either case to outline the organizational structure, sphere of authority, the tasks and the accreditation scheme.

(f) Article concerning the certification bodies

This Article will lay down the conditions (organization structure, sphere of authority, and tasks) to be met by the certification organizations. In case of product certification relation between certification bodies and testing/inspection bodies should also be stipulated when the certification bodies request the testing/inspection bodies to conduct necessary testing/inspection on their behalf. (It may thus, for example, be made compulsory to place such testing/inspection requests with accredited testing and inspection organizations.)

Said Article will also provide a general outline of the certification scheme.

(g) Article concerning qualified auditors

The Article will specify:

a) Qualification and registration requirements for auditors
b) Obligations of auditing of registered auditors
c) Obligations of receiving training of registered

auditors

(h) Article concerning the testing and inspection bodies

In the event that a (separate) accreditation system for testing and inspection bodies be created within the unified certification system, it will be necessary to have an Article stipulating:

a) Accreditation conditions (criteria) for the testing and inspection organizations
b) Obligations of the accredited testing and inspection organizations
c) Qualification and registration requirements applicable to practitioners of the accredited testing and inspection organizations.

(i) Article concerning the fees for certification

This Article will lay down the charges and fees for the certification services on the principle that the examination and assessment costs for certification be recoverable. In this context, it is desirable, however, to provide for a maximum limit in the tariff so as to avoid an excessive burden being placed on applicants.

(j) Article concerning the procedures for dealing with complaints

The Article will provide for the procedures to deal with complaints and disputes unavoidably arising in connection with the actions and activities taken in the implementation of the certification system.

(k) Article concerning the imposition of penalty

The Article will define the penalty to deal with violations and infringements of the certification system

so as to ensure the proper execution of the certification service. Such penalty may take the form of:

a) Discontinuation or withdrawal of accreditation
b) Discontinuation or withdrawal of certification
c) Withdrawal of qualification status of registered auditors
d) Imposition of fines, etc.

3) Establishment of the necessary enforcement regulations for the execution of the Industrial Standardization Law

The Industrial standardization law will lay down the basic aspects of industrial standardization and the practical implementation and execution thereof will require the establishment of enforcement legislations to provide a legal basis for the execution thereof. In this context, INN should function as the core body to establish the appropriate Committees as defined in the previous paragraph (2)-1) in an attempt to ensure a fair representation of the opinions of all members concerned. The following of the execution regulations will be of particular importance.

(a) Provisions concerning the establishment and operation of the accreditation organization

(b) Provisions concerning the accreditation of the certification entities

(c) Provisions concerning the establishment and operation of registration entity for the qualified auditors

(d) Provisions concerning the approval of the training organizations for candidates of auditors

The specific contents of the enforcement regulations can be established by way of quoting the contents of the programs cited herein below.

5.1.2 Program for Establishing Accreditation System for Certification Bodies

(1) Organization in charge: INN

INN should function as Accreditation Body.

(2) Contents of program

1) Procedure for the establishment of the accreditation system

INN will establish system and procedures by which it will assess and accredit certification organizations capable of executing the certification of products (goods) and quality system of factories within the unified certification system. INN should also provide for system and procedures for monitoring the performance of the certification bodies concerned after accreditation by INN.

In the creation of the system and procedures, INN should establish a Preparation Subcommittee for the establishment of accreditation system consisting of representatives of the following:

(a) Ministries and ministerial agencies concerned
(b) Industrial groups (including organizations/ associations of exporters)
(c) Scientific and technological organizations (especially in connection with certification)
(d) Consumers
(e) Organizations carrying out testing, inspection, and certification

In this context, it is desirable that INN should proceed in consultation with the committee members on all important issues. It may also be worth considering the possibility of adding specialists from organizations with a proven

performance record for the certification service (both private and public) currently being implemented in the Republic of Chile.

2) Structure of Accreditation Body

INN will establish such structure as meeting the following conditions as Accreditation Body.

(a) Authorization

INN should be authorized in some form to other to indicate that it has the authority to accredit certification bodies. Generally, the obligations will be defined in connection with the authority vested in INN by virtue of legal statute (Industrial Standardization Law etc. described before.)

(b) Provision of an organizational structure

The Accreditation Body should possess full legal status and will need to have a clear instruction structure and definition of the responsibilities of the each section and staff.

As shown below, officers will be required for dealing with the office and administrative work, in addition to a senior executive with full responsibility for the operation of the Council. Some of the officers should have knowledge on quality control and quality assurance. These officers should also have experience in respect of certification. At least 3 officers will be necessary in addition to a senior executive.

(c) Council of INN

This Board should act as the Supreme Decision-Making Organ within the Accreditation Body. The Council will have the

authority to decide in the final instance on the accreditation of certification bodies based on the report submitted by Evaluation Committee.

(d) Establishment of an Evaluation Committee

This Committee should consist of members selected by the Council and qualified auditors employed by the Accreditation Body.

The Evaluation Committee will compile a report and submit it to the Council for its final decision on accreditation of the applicant certification body. Accordingly, it should include sufficient informations so that the Council can adequately reach a conclusion whether the application is acceptable or not.

The report compiled by the Evaluation Committee should be composed of the result of auditing made by the auditing team on the applicant body and other relevant informations.

(e) Securing auditors who assess certification bodies for accreditation

Auditors should be recruited by the Accreditation Body in the required number who comply with the conditions laid down in "Qualification criteria for auditors" of ISO/10011-2. It is desirable that some auditors have capabilities and qualifications or experience equal to or better than those specified for lead auditors in the above ISO standard.

Auditors may not necessarily be permanent employee of INN. Annex 5-1 gives an idea for the "Organizational Structure of INN as the Accreditation Body for Certification Bodies".

3) Establishment and official announcement of the Accreditation Scheme for Certification Bodies

The rules and procedures for carrying out accreditation should be clearly established and officially announced in an effort to ensure transparency for those concerned. In concrete terms, the following items should be defined.

(a) Application procedures for receiving accreditation (Application forms and entries)

(b) Quality manual of certification bodies

(c) Assessment of quality system and its operation, testing and inspection facilities etc. of an applicant certification body.

(d) Approval of accreditation and its conditions

(e) Period of validity of accreditation

(f) Surveillance

(g) Corrective action and complaints dealing

As it will be unavoidable for correction to be made in some cases to the accreditation activities or for complaints and/or disputes to arise, the details of the procedures to deal with this should be defined in writing.

(h) Accreditation fees

Tariffs should be fixed for the charging of adequate fees to recover the direct and indirect expenses associated with the accreditation works. Examination cost for application, assessment costs, surveillance costs and other costs will be taken into consideration.

(i) Obligation of accredited certification bodies for reporting to the accreditation body

To ensure proper follow-up supervision on the accredited certification bodies after accreditation, it will be necessary to insist on the obligation to report on important changes such as the status of certification activities and changes in the conditions for the grant of accreditation. The former should be subject to reporting on a regular basis, the latter generally to prior reporting. If necessary, reassessment should be conducted based on the report.

(j) Penalty

To ensure that the system concerned is executed in a fair and strict manner, it will be necessary to impose penalties to accord with the severity of the transgressions.

(k) Miscellaneous

Details should be defined concerning the registration, document control, and confidentiality.

It will be essential to lay down accreditation criteria for determining whether applicant certification bodies have required capabilities or not. Examination items, manuals and check list which are used for assessing them should also be prepared.

Annex 5-2 gives an example of "Procedures for Accreditation of Certification Bodies". For reference purpose, Annex 5-3 gives an example of "JIS Marking System in Japan."

5.1.3 Program for Establishing Certification System

(1) Organizations in charge

Certification bodies seeking accreditation by INN in the Unified Certification System. INN should establish transparent accreditation criteria and promulgate them in order to conduct fair assessment and surveillance. On the basis of this policy stance of INN's, the certification bodies should establish a system capable of meeting the INN guidelines and rulings in a fair and appropriate manner and operate the certification services and activities.

(2) Contents of program

1) Creation of a system capable of functioning as certification bodies

In order for a certification body to establish a firm certification system capable of getting accreditation of INN, it is desirable to have an Advisory Committee consisting of the following representatives.

The certification body should proceed in consultation with the Committee on all important issues.

(a) The ministries and ministerial agencies concerned

(b) INN

(c) Scientific and technological organization (Notably, with the addition of specialists on quality control and certification)

(d) Industrial organizations (Notably, organizations handling products covered by the Unified Certification System)

(e) Consumers

INN's representation should be provided for by the presence of INN members capable of giving valid comments on the new certification system.

2) Organization as a Certification Body

A certification body should have a system capable of meeting the following conditions in order to qualify for accreditation.

(a) Administrative structure

a) Establishment of a Council

This Council should be appointed for purposes, including the followings;

i. Drawing up a policy for operating the certification body
ii. Follow-up on the implementation status for the above certification policy
iii. Checking of the financial status of the certification body
iv. Setting up of an Evaluation Committee and Subcommittees

It will be important to select the members of the Council in order to avoid bias toward any persons with vested interests. A senior executive responsible for the Council should be appointed. Some permanent officers should be allocated to him to attend to the daily office and administration work. These officers should not have any personal vested interests in regard of the products falling within the direct scope of the quality system or with the products under certification.

b) Establishment of Evaluation Committee and Subcommittees

These Committee/Subcommittees should assess whether or not products and/or quality system are eligible for certification and registration on the basis of a site assessment by auditors, a written test and inspection report certifying the compliance of the products with the standards concerned, and of any other statements or reports that may be required or applicable.

This therefore imposes upon the members of the Evaluation Committee the need that they should be thoroughly familiar with quality control, quality assurance, quality system, and product certification. As a minimum requirement, they should meet the conditions for registered auditors laid down in 5.1.4.

(b) Organization structure

a) Keeping registered auditors

Qualified auditors registered under the registration criteria of INN should be appointed in the required number and their names should be listed. (These auditors may not necessarily be required to service as permanent officers.)

b) An organizational chart should be prepared showing the responsibility and reporting structure.

c) Establishing the regulations governing financial policy matters.

d) A written document codifying the certification system including the rules and procedures for obtaining certification permission should be prepared. (This document should best be drawn up making reference to

ISO/IEC guide 28.)

e) Establishing legal status

It will be necessary to ensure that presentation of the above be made to any person concerned including INN officials upon request.

(c) Clear definition of the staff instruction

A hierarchical instruction structures should be established for the duties and responsibilities of the officials. Staff instruction should be available to the officials.

(d) Document control

A system should be established for keeping/ controlling all documents concerned with the certification system to ensure that the items below are properly implemented.

a) Documents should be kept so that the necessary documents are visible in the necessary location.

b) Amendments or changes to the documents should be made subject to specific authorization and processed directly and speedily at the effective point.

c) Old texts should be quickly withdrawn from the certification body and from the bodies acting on behalf of them.

d) All changes and/or amendments should be notified to persons having received certification permission and to any other certification scheme users and/or participants.

(e) Records

Protocol documents should be prepared covering the certification procedures followed in each particular instance of certification. Attached to such protocols or records should be a test and inspection report. These notes should be kept for a specific time so that persons admitted as having the right to view the protocols may read them.

(f) Testing and inspection organization

When the certification bodies conduct the testing and inspection operations themselves, they should meet the requirements laid down in ISO/IEC guides 38 and 39. If the certification bodies order other (external) organizations to conduct the testing/inspection operations, the subcontractor organizations should be checked to ensure that they meet the requirements laid down in ISO/IEC guides 38 and 39.

As for an accreditation system for testing and inspection bodies, see Annex 5-4 and as for policies for enhancement and promotion of testing capability of testing and inspection bodies, see Annex 5-5.

(g) Confidentiality

All activities and services rendered in connection with certification and all activities of the testing and inspection bodies acting as subcontractors in connection with certification should be obliged to strict confidentiality.

(h) Publications

A directory should be drawn up giving the certified products and/or quality systems (or factories) for public

announcement. The products and quality systems listed in the directory should preferable be issued with an appended namelist of the recipients of certification or registration permissions. The printing and publications of certification system are also important.

3) Establishment and public announcement of the certification scheme

The rules and procedures concerning the implementation of the certification system should be made clear and published to ensure transparency and lucidity. In concrete terms, the following items should best be made clear:

(a) Application procedures for certification
(b) Assessment of quality system and quality manual
(c) For product certification, verification of compliance with the standards applicable to the product
(d) Certification permission
(e) Period of validity of the certification
(f) Surveillance
(g) Use of conformity mark and method of marking
(h) Public relations by the recipients
(i) Measures to prevent abuse of the conformity mark and certificate
(j) Suspension/withdrawal of permission
(k) Dealing with complaints and corrective actions
(l) Measures when the relevant standards are amended
(m) Certification fees

Tariffs should be fixed for the charging of adequate fees to recover direct and indirect expenses associated with the certification and registration. These should include inspection/examination costs, factory inspection costs, product testing and surveillance costs, etc. The certification bodies should determine the costs on an individual basis for each applicant upon consultation with him.

With respect to (3) above, it will be essential to appoint testing and inspection officials with the required qualifications and to have recourse to testing and inspection facilities meeting the appropriate requirements. (If the testing and inspection tasks are assigned to outsiders acting as subcontractors, it will be necessary to define the terms of the subcontracting agreement.) Annex 5-6 gives an example of the "Certification Procedures". Annex 5-7 gives an example of "Auditing of Quality Systems".

5.1.4 Program for Establishing a Registration System for Qualified Auditors Who Conduct Assessment of Quality System under the Unified Certification System

The Registration Body for qualified auditors will approve the training organizations for the training of qualified auditors under the unified certification system and endorse the training program(s) (including the curriculum) for the courses given by these organizations. To check that graduates who have completed the course do in fact possess the abilities required for assessment, the Registration Body will approve the examination methods and the details of the examinations held by the training organizations. The Registration Body will register only such persons as have passed the above examination and meet the given requirements in terms of personality and experience, and will publish their names.

(1) Organization in charge

INN will function as the Registration Body for qualified auditors.

(2) Contents of program

1) Creating a Registration System for qualified auditors

This should be established in line with, 5.1.2-(2)-1). It is important that the members of the Committee for Establishing

the Registration System for qualified auditors should include some specialists on QC and certification and some representatives of the QC training organizations.

2) Structure and function of a registration body for qualified auditors

INN should create a system meeting the following requirements to function as a Registration Body.

(a) Organization

b) Administrative structure

i. Council of INN

. This Council will examine and adjudicate all important matter pertaining to the operation of the Registration Body.

ii. Establishment of a Specialist Committee and an Evaluation Committee for qualified auditors

. These Committees will attend to the training bodies and training programs
. These Committees will attend to the qualification examinations, their methods and contents
. These Committees will attend to the qualifying conditions for registration of auditors and lead auditors
. These Committees will attend to the surveillance of performance of auditors and lead auditors
. These Committees will attend to the qualifying requirements for re-registration after the lapse of the period of validity of a registration.

The members of the Evaluation Committee should, therefore, preferably include some specialists in

the necessary special fields, in addition to members who are thoroughly familiar with the training of auditors and product certification and quality system registration as well as quality control, quality assurance, and quality system. Members may also be appointed on a non-regular basis.

b) Strengthening of administration office

The Registration Body should appoint staff for the handling of the registration works for qualified auditors and for the administrative works concerned with the Council, the Specialist Committee and Evaluation Committee. At least 3 officers will be necessary.

(b) Determination and publication of registration requirements (qualifications) for qualified auditors

The registration requirements (qualifications) to be met by auditors and lead auditors should be determined and made public. In this case, the provisions of ISO10011-2 (Qualification criteria for auditor) should be the basis and the qualification criteria should best be drawn up by taking the conditions of Chile into consideration.

The Registration criteria should cover the following aspects:

a) Level of education
b) Training
c) Experience
d) Personality
e) Management capability
f) Maintenance of competence
g) Language

Accreditation of the training organizations for qualified auditors should imply the acknowledgment of the capability of conducting the necessary training in accordance with the registration criteria laid down for qualified auditors. In addition, the training bodies' financial position must be assured and must be impartial and neutral. Annex 5-8 gives an example of "Guideline for the accreditation body in conducting accreditation of auditors"

3) Establishment and official announcement of the registration scheme for qualified auditors

The rules and procedures for carrying out of the registration duties for qualified auditors should be clearly established and officially announced in an effort to ensure that it is properly understood by all concerned, including training organizations, involved in the execution of training activities for qualified auditors and persons desiring to become qualified auditors. In concrete terms, it is desirable that the following items be defined:

(a) Purpose
(b) Scope
(c) Management of the scheme as a whole
(d) Registration conditions
(e) Registration procedures
(f) Registration
(g) Period of validity of registration
(h) Certificates
(i) Training courses
(j) Registration fees, etc.

5.1.5 Program for Establishing Training System for Qualified Auditors

Training organizations for qualified auditors will train and hold qualification examinations for persons capable of carrying out

assessment duties for the certification of products, and quality systems. Their organizations, training programs and qualification examinations, will be subject to the approval of INN as the Registration Body for qualified auditors. The most important factor for assessment for product and quality system certification is the quality and qualification of the auditors. Thus, in the certification system of Chile it will be vital above all that auditors of this system should gain international recognitions for their quality and qualifications as auditors. Only this international acceptance can and will earn the system an international reputation. It is, therefore, desirable to make efforts to reinforce the training organizations and upgrade the contents and execution of the training courses.

(1) Organizations in charge

Training organizations accredited by INN

As stated previously, training programs (including the curricula), the examination methods and their contents of training organizations have to be approved by INN.

(2) Contents of program

1) Strengthening of functions of training entities for qualified auditors

A Founding Committee should be established in line with 5.1.2-(2)-1). The appropriate programs should be provided in close consultation with this Committee concerning all important matters. The members of the Founding Committee should include representatives of educational facilities, in addition to some specialists on QC and certification. It is also desirable to have representative of INN participate.

2) Structure and functions of training entities for qualified auditors

(a) Establishment of the organization

It is desirable that training entities for qualified auditors should have an organizational structure of the nature described below.

a) Administrative structure

i. Establishment of a Council

. This Council will examine and adjudicate all important matters pertaining to the operation of the training entity for qualified auditors.

ii. Establishment of a Specialist Committee

. This Committee will attend to the examination of the training programs (including curricula)
. This Committee will attend to the scrutiny of the methods and contents of the qualification examinations.

b) Strengthening of an administration office

. Recruitment of training staff
. Practice of training
. Preparation of training facilities and textbooks/ training materials, and
. Publicity for training programs should be executed by strengthening an administration office.

c) Recruiting of training staff

Training staff will be required to have the same or equivalent knowledge and experience of a registered

auditors. Trainers must preferably have the qualifications of lead auditors. They should also have experience as consultants and have the expertise of a trainer to provide training. Trainers need not be full-time employees, but it is important that the organizations retain a sufficient number of trainers.

(b) Preparation of training programs and curricula

The training programs should cover:

a) Knowledge in quality assurance, quality control, quality system, standards, etc.

b) Method for performing assessment for certification of products and quality systems

c) Assessment administration skills such as preparation of assessment plans, organization, communications and guidance

To ensure that registered auditors will maintain their capabilities, it will be important to provide training opportunities for:

a) Acquisition of new knowledge on quality system and conditions

b) Acquisition of new knowledge on procedures and methods of assessment

c) General refreshing

Annex 5-9 gives an example of "Auditors training program"

5.1.6 Program for the Diffusion of the Unified Certification System

The certification system cannot achieve its objective unless it is recognized and accepted by the general public and properly applied by the companies in the private sector. It is therefore essential to make efforts to propagate and disseminate the system. Yet, the certification system will not easily spread by virtue of the existence and operation of the system alone. Rather, to ensure the diffusion of the system to the private sector companies and the general consumer, it will be vital to devise effective measures for its diffusion. These measures must come in addition to the availability and fair, proper operation of the system.

(1) Organizations in charge

INN will be in charge. Success of the diffusion programs depends largely upon the cooperation of the government bodies in providing political privilege. In this sense, it will be of paramount importance to enlist the cooperation of the relevant government bodies and government authorities, notably MINECOM.

As the certification and training entities will have much influence, their cooperation will also be essential. INN as the core entity should draw up diffusion measures and be active as a promoter of the spread of the certification system by bring suitable pressure to bear on the relevant institutions and authorities in accordance with necessity so as to achieve system propagation. At least 2 officials will be necessary for carrying out INN's diffusion activities.

(2) Contents of program

1) Preferential procurement by the government and government bodies of products bearing the certification mark or products produced by the factories whose quality systems have been certified.

This system of giving preference to product bearing the certification mark or products from QS certified factories should be concentrate in particular on the products typical of small and medium companies. If these products present problems in terms of price and/or delivery date, it will be essential to provide appropriate guidance on this. The cooperation of government such as MINECOM, MINVU and MOP will be critical.

2) Grant of political privilege to companies aspiring to acquire certification permission

In most cases, it will be very, if not too, difficult for small and medium companies to provide the necessary facilities for testing and implementing quality systems through own resources. In these cases, it would be desirable for the government bodies to grant certain tax and funding benefits or privileges commensurate with the contribution such improvement in quality is likely to make to exports or the impact the provision of these facilities is likely to have on raising the quality standards of the products manufactured by a small or medium company. For very small companies, it may be important to provide such benefits to permit growing intensification and assimilation in order to improve quality. In this respect, the cooperation of SERCOTEC and CORFO will be vital.

3) Provision of technical guidance to companies

For small and medium companies, it is important to provide practical technical guidance in connection with the creation of a quality system, internal standardization, and quality control. For very small firms unable to enlist the support of a consultant, it is desirable to have special measures available in the form of a low-cost technical consultancy service to guide them. In this respect, the cooperation of CORFO, SERCOTEC, INTEC, ASCAL and other related organizations will be vital.

4) Supply of overseas information to all concerned with exports

In a particular effort to promote exports, it will be essential to collect, make available and provide to exporters micro-information on products (prices, quality, level of finishing/processing technology, and distribution channel) as well as macro-information on export trends, industrial structure, consumer preferences, etc. in importing countries. In this respect, the cooperation of PROCHILE will be vital.

5) Diffusion of the certification mark to the general consumer

Products distinguished by the certification mark must be acknowledged being of high quality and a suitable price, and this recognition must be made to penetrate, through various means, to the general consumer. To ensure that the ordinary consumer easily understands the meaning of the certification mark, it will be best to reduce the number of certification mark types to a minimum and to use a simple, easy-to-discern design. In this respect, the cooperation of SERNAC will be vital.

5.2 Quality Control/TQC Diffusion Program

5.2.1 Contents of Diffusion Program

The diffusion program consists of the following items.

(1) Setting up a technical committee (including a subcommittee) for innovation of education and diffusion organizations for Quality Control and TQC.

(2) Decision of a program for consolidation of education and diffusion organizations by the technical committee.

(3) A program for consolidation of texts and curriculum for education and training

(4) A program for acquisition of competent lecturers and trainers

Staff of INN responsible for this project should be persons having a wide range of experience and knowledge who can carry out coordination between related departments. It is considered that 3 persons are required, and the staff should make coordination between a technological sector, an educational sector and an industrial sector for quality control.

5.2.2 Setting up Technical Committee for Innovation of Education and Diffusion Organizations for Quality Control and TQC

(1) The following items should be discussed in the technical committee

1) A program for education, diffusion and consolida-tion of quality control and TQC

2) A program for preparation of texts for education and training and arrangement of curriculum for quality control and TQC.

3) A program for enhancement of lecturers and trainers for quality control and TQC

Contents of each of these programs are described in (2), (3) and (4) below.

(2) Members of the technical committee for quality control and TQC

The main members of this technical committee should include representatives of INN, those of departments of industrial organizations responsible for quality control and TQC, those of educational and academic institutions, and other specialists of foreign countries, and carry out works described in (1).

(3) Period of action of the technical committee

The technological committee should be started in April, 1992 and programs stated in (1) above will be formulated until October, 1993. (The main activities of this committee will end when the above programs are decided.) Appropriate follow-up actions will be continued by the technical committee.

(4) Networks around the technical committee for quality control and TQC

The position of this technical committee is as shown in Fig. 5.2-1.

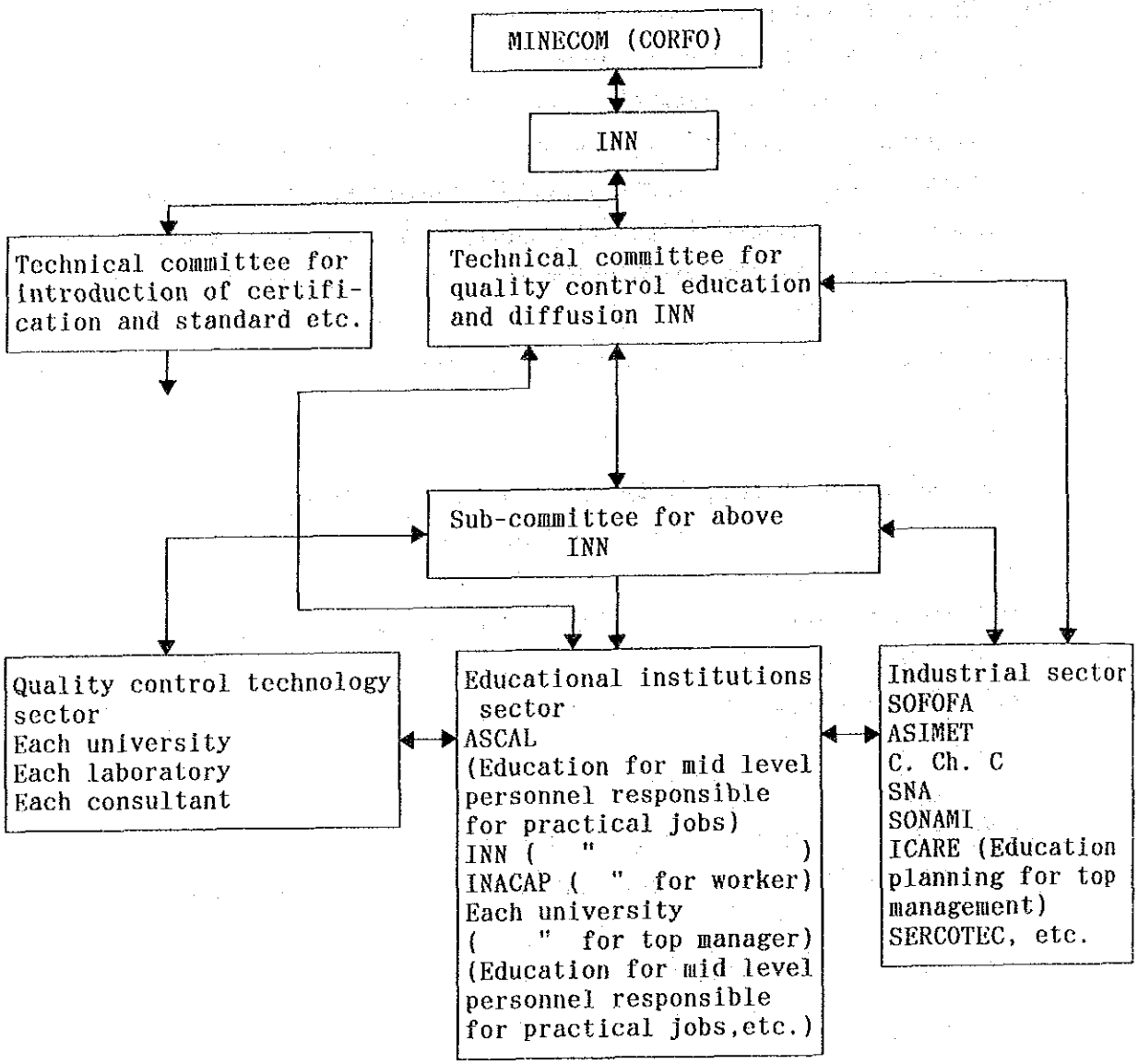
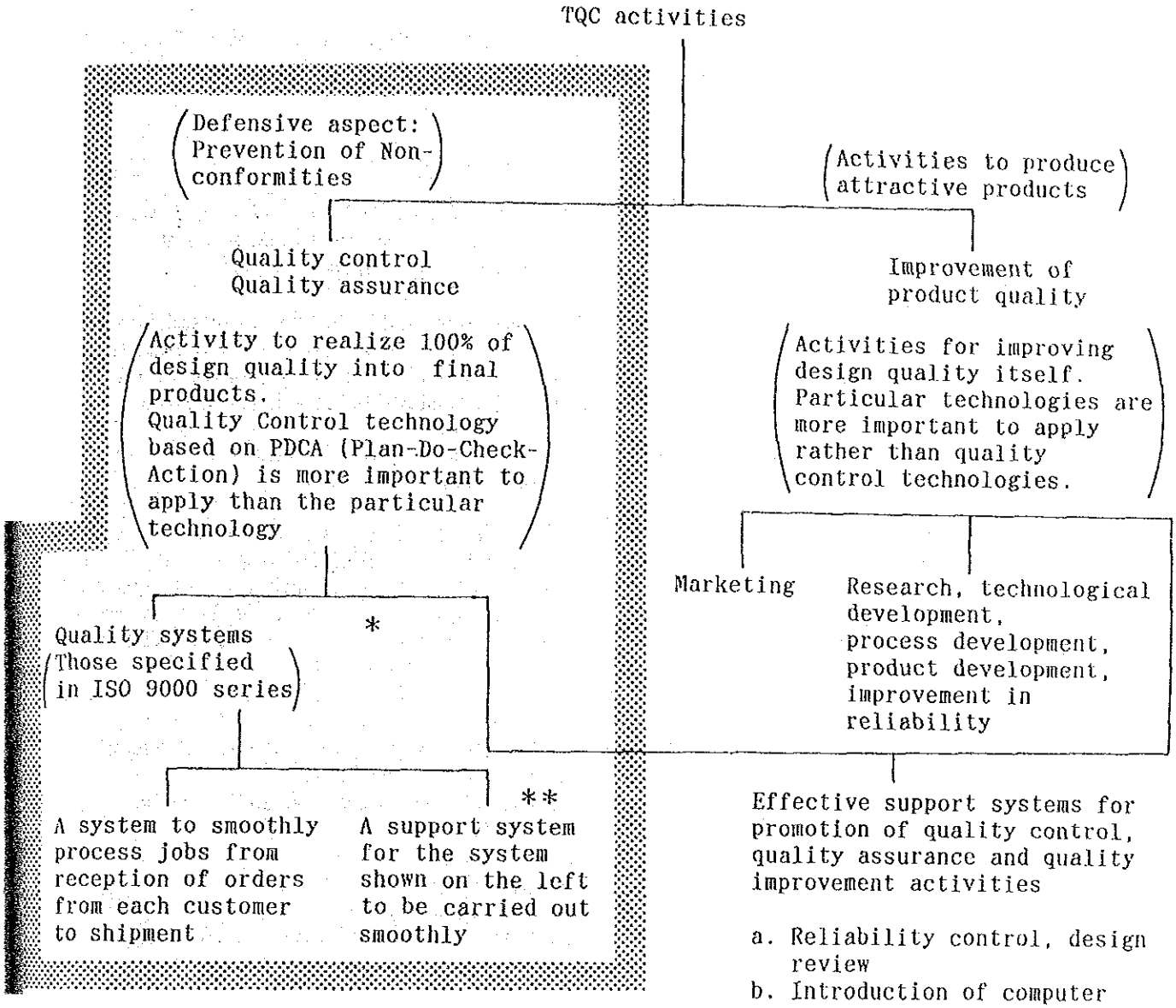


Fig. 5.2-1 Technical committee for innovation of organizations for education and diffusion of quality control and TQC



*: Sometimes a quality system must be publicly certified by a certification system according to the necessity.

**: Calibration of measuring systems are included in this as a sub-system.

Fig. 5.2-2 TQC Activities

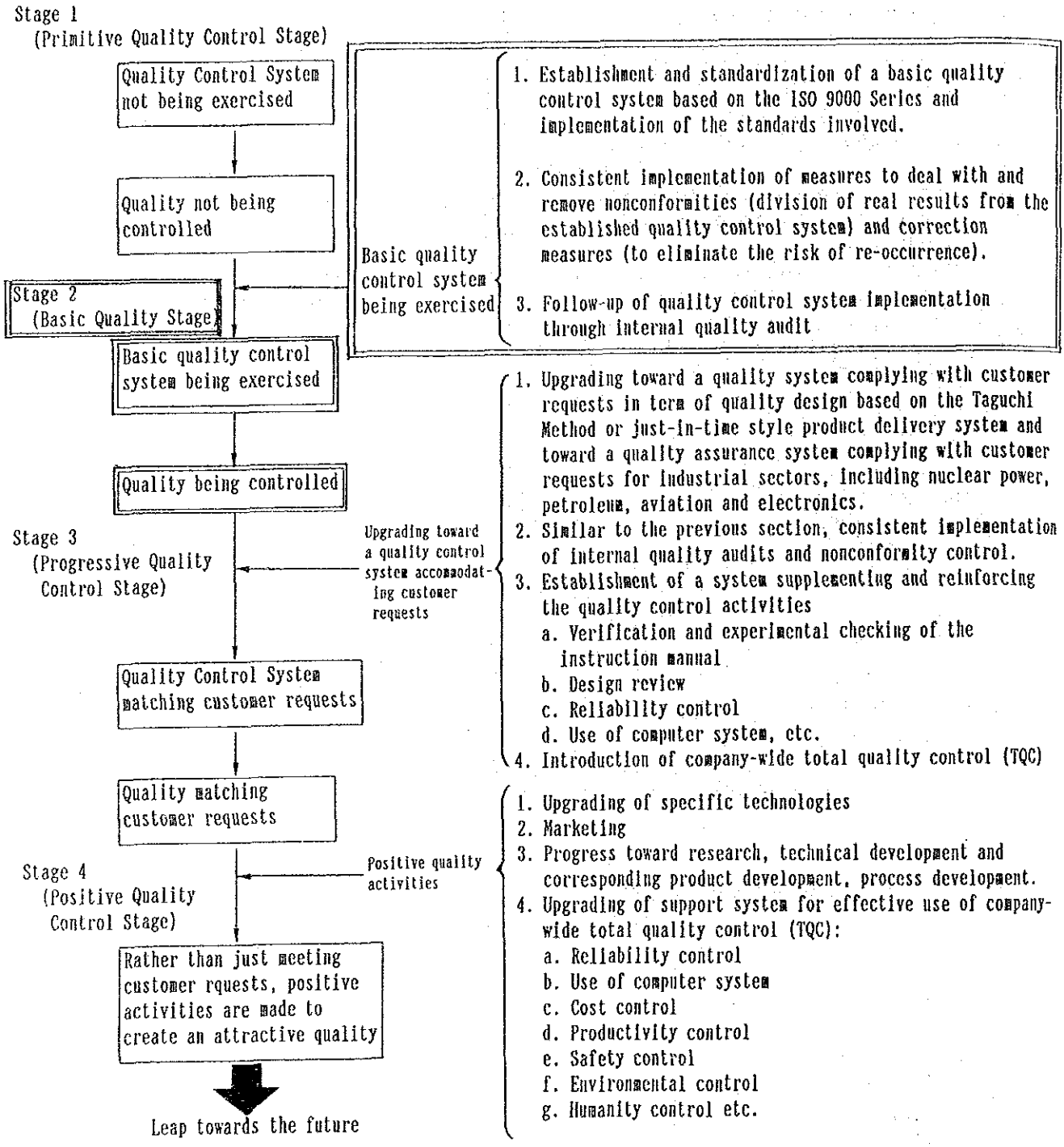


Fig. 5.2-3 Stages in the Upgrading of Quality Control/TQC Actitivies

5.2.3 Decision of a Program for Consolidation of Education and Diffusion Organizations by the Technical Committee

(1) Outline of the program for consolidation of organizations for education on and diffusion of quality control and TQC

Education on and diffusion of quality control should be carried out in both the defensive aspect and positive aspect of Quality Control/TQC activities because of its nature, as shown in Section 3.4.1, but the recommendations described here relate to education on and diffusion of only defensive aspect of TQC activities.

The recommendation described below aim at establishing the basic quality stage in the process of quality control/TQC activities as shown in Fig. 5.2-2, in other words at establishing quality systems based on the ISO 9000 series and sincere implementation of it.

This also matches the worldwide trend concerning Quality Control/ TQC activity described in 3.4.1.

It is needless to say that the positive aspect of quality control activities is important, but an organization for prevention of nonconforming product as the base for it is indispensable.

(2) Configuration of program

The program for education on and diffusion of quality control and TQC to achieve the objectives described above consists of the following 2 items.

1) Education on and diffusion of quality systems to make people understand quality control and TQC based on quality systems more deeply.

2) Education on and diffusion of practical technology for establishment and implementation of quality systems.

(3) Objects and purpose of the education

Purposes of the education are the following 2 points.

1) Bringing up management, including top management, who can control and manage organizations for quality control and TQC based on quality systems.

2) Bringing up promoters of quality control and TQC who have knowledge for establishment and administration of quality systems (Equivalent to responsible person for promotion of industrial standardization and quality control in JIS Marking System.) As a quantity of labor and time is required for establishment, maintenance and control of quality systems, it is necessary to make top management of industries fully understand the significance.

(4) Texts for education

1) The texts used for education to make people understand well quality control and TQC activities based on quality systems as shown in (2)-1) are based on those described in 3.4.1.

Using this text will be a good support to understand that in Quality Control/TQC activities, the positive aspect of creating attractive products for customers is important, but it is also important to make people understand that, as our society becomes more and more complicated, the defensive aspect of the Quality Control/TQC activities of preventing noncomformities is also significant, that establishment of quality systems is indispensable for achieving the latter objective, and that establishing the systems depending on the ISO 9000 series is one of the international trends in the field of quality control and TQC.

Also it is important to make people understand through using the text that establishment of quality systems in a company results in maintenance of a sound state of the company when