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ASSISTANCE TO THE NATIONAL BUREAU OF STANDARDS
AND METROLOGY

DP/NEP/84/031

NEPAL

Technical report: certification and laboratory accreditation*

Prepared for the Government of the Kingdom of Nepal
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

Based on the work of P.J. Campion
Expert in Certification and Laboratory Accreditation

Backstopping Officer: V. Kozlov
Institutional Infrastructure Branch

United Nations Industrial Development Organization
Vienna

* This document has not been edited.

EXPLANATORY NOTES

The rate of exchange varied from 1 US\$= 30.4 NRs at the beginning of the mission to US\$=32.0 NRs at the end

Abbreviations

A.U.	Accreditation Unit
HMG	His Majesty's Government (of Nepal)
ISO	International Standards Organization
LAC	Laboratory Accreditation Committee
NBSM	Nepal Bureau of Standards and Metrology
NEA	Nepal Electricity Authority
RNAC	Royal Nepal Airlines Corporation

ABSTRACT

This 3 month mission is part of the 5 year UNDP/UNIDO Project (DP/NEP/84/031) entitled "Assistance to the Nepal Bureau of Standards and Metrology". It concerns the feasibility of establishing a laboratory accreditation scheme operated by the Bureau. While it is concluded that this is not possible at the present time, a strategy is proposed whereby this can be achieved in the future. Two major hindrances prevent the immediate implementation, first the lack of an adequate metrological infrastructure and second, the restrictions, financial and otherwise, imposed on the Bureau as a consequence of its being part of the Civil Service.

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INTRODUCTION

As part of the activities included in the project entitled 'Assistance to the Nepal Bureau of Standards and Metrology' consideration was given to the possibility of establishing a Laboratory Accreditation Scheme as part of the on-going work of the Bureau. In general the necessity for a fully developed laboratory accreditation scheme usually arises when a country's manufacturing base contributes significantly to its GNP; this need is further enhanced if there is a considerable export trade in manufactures. With an MVA of about 5% of GNP and exports approximately 3% of GNP (mainly food, textiles and non-metallic minerals), Nepal is clearly not yet in this category although manufacturing is said to be the most dynamic sector of the economy so that this situation may perhaps change. However, although the manufacturing sector has an overall growth rate of the order 10% per annum it is very variable between years; the index has actually declined over the last two years. A number of testing laboratories exist in Nepal; some are attached to Government ministries but some are part of public and private sector industries, while there are a few independent laboratories mainly in the microbiological field. Although the government testing laboratories do most of their work for their respective ministries some also undertake testing, usually on a repayment basis, for outside organisations and to this extent it would be desirable to have some assurance of a minimum quality of testing provided that the ministries could be persuaded to accept such a scheme.

In addition the Bureau of Standards and Metrology has a Certification Scheme under which manufacturers may use the Certification Mark provided their products comply with the relevant Nepal Standard. While it is true that only some 15 firms have been so licenced over a period of years, it is to be hoped that this number will increase significantly particularly if the recommendations of recent expert in Public Relations are implemented (DP/NEP/84/031/11-59). In order to confirm compliance within such a certification scheme the products must be tested and this testing is carried out at the most appropriate laboratory available including those of the Bureau itself. Thus in order to ensure a minimum quality of testing - and hence to maintain the credibility of the Bureau's certification programme, a modified accreditation scheme would seem to be desirable. This then is the background to the present mission carried out by Mr. P. J. Campion who arrived on station on 13 February 1991 and completed the programme on 7 May, 1991. The expert's job description is reproduced as Annex 1.

Office accommodation was provided by NBSM, the executing agency on behalf of His Majesty's Government. At the outset of the mission the counterpart arrangements for the expert were split between two NBSM staff members owing to the fact that the principal counterpart, Mr. Puspa Raj Shrestha, had been recently promoted and, as consequence, was likely to be transferred to another Government Department during the expert's stay. However, this rather unsatisfactory arrangement was partially resolved during the course of the mission by the Government allowing Mr. Shrestha to remain on the Bureau's staff at least for the

time being. Mr. Shrestha was available part time only in view of his other responsibility as head of the Bureau's Chemical and Food Testing laboratory.

ACTIVITIES AND OUTPUTS

The situation concerning standardization, testing and certification as presently carried out by the Bureau was examined. Over 240 standards have been published (as of April 1991) although only 15 certification marks have been awarded over a period of 5 years or more. Moreover there are no less than 57 applications for the mark awaiting processing. The reasons for the admitted delay in this processing procedure are listed in the following table.

TABLE I

Reasons for delay in processing applications for the Certification Mark.

	<u>percentage</u>
1. Standard not yet available	26%
2. Results of laboratory test not available	19%
3. Factory visit being arranged or postponed due to problems at factory	16%
4. No testing facilities available for product	10%
5. Factory has no test facilities	9%
6. Applicants have lost interest	7%
7. Product does not conform to the standard	5%
8. "Bureau's top management complication" (sic)	4%
9. Only initial contact made	4%

Clearly reasons 1,2 and 8 are within the control of the Bureau and therefore should be eliminated or at least the time associated with them significantly reduced. It is estimated that these three causes of delay account for nearly 50% of the backlog of the applications and represent an unsatisfactory situation. It is little wonder that reason 6 forms part of the breakdown.

In the context of laboratory accreditation it has to be said at the outset that it is not possible to introduce an internationally acceptable system until Nepal has access to a suitable metrological infrastructure. This need has been noted in previous experts reports and, indeed, a draft Pro Doc. (DP/NEP/34/031/11-52) has been prepared for a future project designed to fulfil this requirement. However, this apart, there are other factors which preclude the introduction of an accreditation system at the present time.

In order to test support for the concept of a laboratory accreditation system the Bureau wrote to some 17 organizations with a request for information regarding their testing facilities, as suggested by a previous expert. The result was very disappointing in that only one enterprise saw fit to reply and this one has now gone out of business.

As a further study to ascertain the needs of Nepal in respect of testing and laboratory accreditation more than 30 visits were made to factories, laboratories and other organizations whose personnel could reasonably be expected to contribute to the general dialogue on quality. In these visits a point was made to interview the chief executive (however named) of the enterprise in order not only to ascertain the future needs of their own particular concerns but also to seek their views on the industrial infrastructural requirements of Nepal. Nevertheless the opportunity was taken, where appropriate, to see the laboratory facilities and to talk with the technical staff. A list of the principal persons met during the mission is given in Annex 2.

It early became apparent in these studies that much of Nepali industry is composed of a large number of small enterprises most of which have no testing facilities. Further, in those which do, the facilities are very basic and virtually no testing is carried out for external customers. The larger scale industries, both government and private, do, of course, have testing facilities but again they are little used except for internal purposes. Government itself has some testing laboratories which serve the needs of the ministries to which they are attached; a few do tests for external customers, usually on a repayment basis, but this is not extensive. A breakdown of the distribution of testing laboratories is given in TABLE II.

TABLE II

Distribution of Testing Laboratories

Government Laboratories	12
Laboratories attached to government owned industries	7
Laboratories attached to private industries	N/A*
Independent laboratories (excluding path labs.)	5
Pathological laboratories	Very many, of variable quality

In general the reaction of the chief executives to the concept of accreditation was not encouraging; most saw it as another form of government control as well as a potential cause for reduced profits. It was clearly evident from these factory/laboratory visits that a very great deal will need to be accomplished in order to come anywhere near the quality level required by international recommendations such as ISO Guide 25. In particular the concept of a laboratory quality manual was not appreciated or even understood. As discussed below, this situation contributed to a decision to adopt a step-wise approach to the problem. This attitude of the chief executives is in contrast to the attitude apparently displayed at a talk programme

* This number depends on the definition of a laboratory. Many so called laboratories are staffed by one person very much on a part-time basis.

on accreditation held at the Bureau in 1988 to which some 17 technical people were invited although very few of these were at chief executive level. This probably accounts for the difference in attitude and, since it is the chief executives that control industry, this is the view that must be accepted, regrettable though that may be. Of course this general view may change in the future particularly if industry is persuaded to become more quality conscious but this will take some considerable time and much persuasion under present circumstances.

This lack of support from the captains of industry coupled with the negative response to the letter circulated by the Bureau and the very basic state of testing laboratories in most enterprises suggests that a more subtle approach is required so far as laboratory accreditation is concerned. As a consequence a two-pronged solution to this problem was proposed. In view of the fact that the quality manual concept was not well understood the first prong involved drafting and putting into practice a laboratory quality manual for one of NBSM's own laboratories. The only two laboratories operational at the time were the chemical plus food and the building materials laboratories; the chemical plus food testing laboratory was chosen since the expert's counterpart was also head of this laboratory and this constituted a useful training exercise. The manual was amended after joint discussions and the final version is given in Annex 4. Having established this manual in a real-life situation the intention is to approach other laboratories, both internal and external, to see if help could be offered, by NBSM, in drafting a similar quality manual tailored to the particular needs of the laboratory concerned. The first external laboratories for this approach should be those attached to enterprises which already have the certification mark for their products. At some stage in the future the existence of a manual should be made mandatory for all further certifications.

The second prong involved the instigation of inter-laboratory tests in order to gain some first hand information on the degree of conformity laboratories could achieve when asked to measure a given quantity. From informed sources it would seem that the many pathological laboratories in the Kathmandu Valley should be a prime target for such an exercise; however pathological quantities are outside the remit of NBSM. Instead, since there is considerable construction work undertaken in Nepal together with a certain amount of public concern over the material, cement was chosen. In this case, in the first instance at least and with the agreement of the head of the building materials laboratory, the exercise concentrated on the physical tests concerning cement. The expert, together with his counterpart visited a number of laboratories capable of making such measurements with a view to persuading them to take part and a very satisfactory response was achieved. The details of the comparison were

Nevertheless it is recommended that HMG should take steps, perhaps through its Central Pathological Laboratory, to examine the quality of these private pathological laboratories. If required, NBSM should provide advice on the conduct of an interlaboratory test.

discussed and agreed following which the necessary documentation was prepared. 120 kg of cement was purchased in the market together with some standard sand. At the time of writing the comparison is underway,—the first to be undertaken by NBSM,—but no results are yet available. Following an analysis of these results, laboratories with apparent discrepancies will be offered help in identifying the causes. It is hoped that this comparison will form a prototype to be followed by others on different products (reinforcing bars are suggested for the next product) and that in this way the industrial sector generally will come to see the usefulness of cooperation with NBSM. In order to assist in future inter laboratory comparisons it is recommended that the project purchase the text books and manuals listed in Annex 3.

The reader will observe that if this two pronged approach is successful considerable help will have been given to laboratories in one form or another to improve their overall quality and in so doing many of the requirements needed for a laboratory accreditation system will have been achieved. Yet,—and this is an important point,—at no stage will a laboratory accreditation system have been mentioned. At some point in the future, and it will be a matter for NBSM to judge this moment, a system can then be introduced with some degree of confidence that it will be accepted by industry and others. This then is the strategy proposed. Although in the expert's view this is the only practical solution to the situation it has to be said that it will involve a learning process that will extend over several, perhaps many, years. Nevertheless a constructive start has been made.

In order to provide guidelines for the eventual establishment of a laboratory accreditation system some of the essential documents needed for such a system were proposed and drafted by the expert. Of these perhaps the most important is the document entitled "NBSM Criteria of Competence to be met by Testing Laboratories" which is reproduced as Annex 5 to this Report. It is compatible with both ISO Guide 25 (1990 revision) and the European Standard EN 45,000. As mentioned above, it will be impossible to introduce such criteria for some time to come, not least because there is no adequate metrological infrastructure in Nepal at present, but also because industry would not participate in it, seeing it only as a bureaucratic interference rather than as a beneficial activity on the part of Government. Of course it is always possible to introduce a system based on such a document with some of the clauses held in abeyance, but under these circumstances it will not be possible to seek international recognition for the Nepali system. In this respect it is noted that India has very recently introduced an accreditation system,

So as to provide NBSM with the administrative procedures necessary for the operation of a laboratory accreditation system an "Accreditation Procedure Flow Chart" with explanatory notes has been drawn up and is given in Annex 6. Next, although perhaps a little premature but nevertheless providing a useful succinct general description of laboratory accreditation, Annex 7 contains a proposed text for a publicity leaflet. Finally in this context, a

set of documents published by the U.K.'s accreditation system, the National Measurement Accreditation Service (NAMAS), has been deposited in the Project Office.

The Standardization (Certification Mark) Act was analyzed. In due course, it is suggested that the Act should be strengthened by the introduction of a new clause to specifically empower the NBSM to operate a laboratory accreditation scheme and, as a preliminary to this, to require testing laboratories to take part in inter laboratory comparisons. The proposed amendments are given in Annex 8.

CONCLUSIONS

For the reasons given in the previous chapter it is not possible to introduce even a modified accreditation scheme at the present time. Nevertheless a strategy has been suggested that will enable such a scheme to be launched in some years time. To this end NBSM needs to significantly improve its standing in industrial circles and this can best be achieved by offering industry practical help in the drafting of laboratory Quality Manuals and in organizing inter-laboratory comparisons; prototype examples of both these forms of help have been demonstrated during this mission. As has been noted in other reports, help to industry should be offered in other areas notably quality control procedures. Some of the reasons why such help has not been apparent have also been noted, these being largely the result of the restrictions, financial and otherwise placed upon the Bureau and its staff as a result of the necessity to comply with the Civil Service Regulations. This expert confirms and reiterates these prior observations.

In view of the fact that the establishment of an accreditation scheme in Nepal is some years hence and also because a recent expert, Mr. Oke, had already held a seminar on the subject, it was agreed that any further lectures and seminars would not benefit the project or the Bureau at this time.

RECOMMENDATIONS

The first recommendation is by far the most important and is fundamental to the operation of the whole Bureau.

1. NBSM needs to seriously consider its standing with those whom it seeks to serve. By and large, industry has a poor impression of the Bureau and, whether this is justified or not, steps must be taken to correct this. To a large extent this poor image is a result of the restrictions, financial and otherwise, placed on NBSM as a result of it being part of the Civil Service. To a lesser extent it is also due to the fact that the Bureau has not advertised its services widely. *It is recommended* that it should be a matter for discussion within HMG as to whether NBSM could operate more effectively as a quasi-Government agency having more freedom to conduct its affairs than that allowed by the Civil Service Regulations. If it is decided that the status quo should remain, then alternative solutions must be found such as granting the Bureau dispensation from some of the Regulations. It is also suggested that the Bureau should enhance its public relations activities but it must be stressed that this is not an alternative to the above recommendation but is an adjunct to it.
2. Exports are vital to Nepal's economy and industry should be encouraged in this direction. But successful trading on world markets can only be achieved if the products are competitive in both price and quality. While the first is probably outside the scope of this report, the second needs serious attention by Government. *It is recommended* that His Majesty's Government considers mounting a Quality Awareness Campaign in order to convince chief executives (a) of the need for quality and (b) that quality pays, i.e. it does not detract from the bottom line. While it is not suggested that the U.K.'s efforts of a decade ago should be followed even in outline, the remarkable turnaround of the U.K. economy was certainly due in part to a nationwide Quality Awareness Campaign and useful pointers might be gleaned from a study of this.
3. In view of the strategy proposed to establish a future laboratory accreditation scheme *it is recommended* that UNDP/UNIDO purchase the books listed in Annex 3 as part of the project.
4. For the same reason as in 3 above *it is recommended* that fellowship training be arranged for one NBSM staff member to gain first hand experience of interlaboratory testing. An attachment to NAMAS or NATA for 2 months would be suitable.
5. In order to maintain the present momentum *it is recommended* that the CTA and NPD should agree a target for the number of interlaboratory comparisons to be carried out in each future Module. Likewise, a plan should be developed for the introduction of Quality Manuals within NBSM laboratories, together with offers of help for external laboratories.

UNITED NATIONS



UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

UNIDO

JOB DESCRIPTION

DP/NEP/84/031/11-62 /J12102

- Post Title : Expert in Certification and Laboratory Accreditation
- Duration : Three months
- Date Required : June, 1990
- Duty Station : Kathmandu, with travel within the country
- Purpose of Project : To improve the quality of industrial products through standardization, quality control and certification procedures in order to rationalize the expansion of industry sought by His Majesty's Government of Nepal and expressed in its document Industrial Policy (1984).
- Duties : Under the direction of the Chief Technical Adviser, the expert will be expected to:
1. Study and analyze the existing situation with regard to standardization, certification, testing and laboratory accreditation within the country and in the Nepal Bureau of Standards and Metrology (NBSM) in particular and determine the certification and laboratory accreditation needs of the country required for future development in the above fields.
 2. Initiate, and assist establishing contacts with industries, institutions, Government authorities, enterprises etc. concerned actually or potentially with, or interested in certification and laboratory accreditation in order to initiate/enhance implementation of these activities.

Organize/participate in lectures, courses and seminars as well as in elaborating corresponding information materials, manuals on the topics.
 3. Review organization and operation of NBSM's Certification and Research Division in view of the needs for operating certification and laboratory accreditation system in the country.
 4. Analyze Standardization and Certification Act 2037 and prepare proposals for amendment or reviewing if analysis proves necessary concerning legislative requirements for certification and laboratory accreditation.

Applications and communications regarding this Job Description should be sent to:

Project Personnel Recruitment Section, Industrial Operations Division
UNIDO, VIENNA INTERNATIONAL CENTRE, P.O. Box 300, Vienna, Austria

5. Draft a proposal for establishing and operation of an accreditation system.

6. Present a lecture and conduct a seminar for experts of the industries and representatives of the authorities concerned, on economic advantages, technical needs, organizational conditions of certification, laboratory accreditation. The lecture and the minutes of the seminar will be issued as a technical paper of the project and attached to the project outputs.

The expert will also be expected to prepare a final report setting out the findings of his mission and his recommendations to the Government on further action which might be taken.

- Qualifications : University degree or equivalent in engineering or applied physical science with extensive experience in organization and operation of national system of certification and laboratory accreditation.
- Language : English
- Background Information : See attached

LIST OF PERSONS MET

Mr M. B. Pradhanang	Director, Central Road Research Laboratory
Dr R. K. Poudel	Chief, Central Material Testing Laboratory, Institute of Engineering, Tribhuvan University.
Dr T.B. Karki	Chief, Central Food Research Laboratory
Dr I. L. Shrestha	Chief, Analytical Laboratory, Department of Mines and Geology.
Dr B.N. Chalise	Joint Secretary, Ministry of Industry
Mr Mahes Abou El-Khair	Leather Industries Co-ordination Cell
Mr M. Satyapal	CTA, Industrial Planning Division, Ministry of Industry.
Mr W.S. Nanayakkara	CTA, Foreign Investment Promotion Project, Ministry of Industry
Mr Bindu D. Adhikary	General Manager, Trade Promotion Centre
Mr H.P. Sharma	Director, Export Services Centre
Mr Ray Brown	CTA, UNCTAD/GATT/ITC
Mr R. B. Shrestha	Manager, NEBICO(PVT) Ltd
Mr P.D. Rajbhandari	Deputy General Manager, Himal Cement Company Ltd
Mr S.B. Manadhar	Chief Customs Officer, Tribhuvan University
Professor P. Chettri	Department of Economics, Tribhuvan University
Mr B. Sigdyal	Director, Expothene (PVT) Ltd.
Mr K.G. Shrestha	Chairman, Prakash Cable Industries (PVT) Ltd.
Mr P.K. Shrestha	Managing Director, Pancha Kanya Iron Industries (P) Ltd
Dr V.P. Agrawal	Executive Director, Research Laboratory for Agriculture, Biotechnology and Biochemistry.
Dr M.P. Sharma	Executive Director, Research Centre for Applied Science and Technology, Tribhuvan University.
Mr K.S. Karki	General Manager, Karki Carpet Industry.
Dr L. Champness	Consultant, Patan Hospital
Mr P.M. Sakya	Chairman, United Carpet Manufacturers Incorporated.
Mr K.S. Kasaju	Manager, Everest Chemical Services Centre
Mr S. Giri	Director, Soil Test (P) Ltd.
Mr I.P. Shrestha	Chairman, Gandaki Industries Ltd.
Mr B. Pokhrel	Chief, Soil Rock and Concrete Laboratory, NEA.
Mr V.P. Sharma	Director Engineering, RNAC Tribhuvan Airport
Mr S. R. Pokharel	Chief, Workshop (Tests) Division RNAC, Tribhuvan Airport
Mr J. M. Pradhan	Chief, Meter Testing Laboratory, NEA.
Mr M.T.J. Shah	Managing Director Himalayan Distillery Ltd

Mr V.B.Barjracharya

Deputy General Manager, Nepal Telecommunication
Company

Mr P.K. Roychoudhury

Area Representative, International Telecommunications Union
CTA, UNDP/ITU

Mr U.R.G. Acharya

Mr. J.P. Agrawai

Secretary General, Federation of Nepal Chambers of
Commerce and Industry

BOOKS TO BE PURCHASED BY THE PROJECT

1. "ASTM Manual for Conducting an InterLaboratory Study of a Test Method"
STP 335, ASTM, Philadelphia PA, USA. (1963)

2. "Statistical Technigucs for Collaborative Tests" W.J. Youden.

Association of Official Analytical Chemists, Washington D.C. USA (1967)

3. "Laboratory Quality Assurance Manual" Department of Health, Welfare, Ottawa,
Ontario Canada.

4. "Testing Laboratory Performance, Evaluation and Accreditation" G.A Berman.
NBS Publication 591, U.S. National Institute of Science and
Technology, Gaithersburg M.d., USA.

**Quality Manual
for
Chemical and Food Testing Laboratory
Nepal Bureau of Standards & Metrology
Balaju, Kathmandu**

This Manual is issued under the authority of
Mr. Dinesh Raj Bhattarai, Director General
Nepal Bureau of Standards & Metrology

Issue Date _____

Issue No. _____

Copy No. _____

Holder _____

1. AIMS AND FORM OF QUALITY SYSTEM

All works that are carried out in the Chemical and Food Testing Laboratory should be in accordance with the policies and normal procedures of the Nepal Bureau of Standards and Metrology. Test procedures should be strictly followed in accordance with Nepal Standards. Where tests procedures are not covered by Nepal Standards the tests should be carried out according to other related standards or universally accepted procedures suitable to the laboratory conditions.

1.1 Quality Manual

This manual is the working document that identifies the organization, staff responsibilities, range of facilities and scope of operation. It also defines the procedures to ensure that the quality policy statement are met and is the basis of laboratory's quality system.

The distribution of the manual is controlled by the head of the Chemical and Food Testing Laboratory. Each section of the Laboratory Quality manual is authorized by the Director General of the NBSM.

1.2 Distribution List:

- Copy No.1) Master copy (Head of Laboratory)
- 2) Director General, NBSM
 - 3) Divisional Chemists
 - 4) Chemists
 - 5) Food Technologists
 - 6) Assistant Chemists
 - 7) Library
 - 8) Laboratory Desk

2. QUALITY MANAGEMENT

The Head of Chemical & Food Testing Laboratory is the person responsible for the compilation, distribution, amendment and maintenance of this manual. It is his responsibility to ensure the quality output of the laboratory (Appendix, Job description)

The Head of the laboratory will number each copy of the manual and issue as required with the approval of the Director General. The master copy will be kept safely by the head of the laboratory, who is responsible for all issues and withdrawals and maintenance of the master copy.

It is the duty of the head of the laboratory to review the manual annually.

Except in special circumstances, it is mandatory that all activities be carried out in accordance with the manual. Where circumstances do not permit to adhere to the manual the facts and details of the circumstances must be clearly stated on all worksheets (Analyst work sheet), and the communications relating to calibration tests clearly identified. The head of laboratory will take steps to ensure that the procedures and processes mentioned in the manual are strictly followed by all members of the laboratory. Such steps will include

- 1) All amendments or revisions to related Nepal Standards to be incorporated in the manual.
- 2) Modification of test procedures as necessary to incorporate new instruments and methods.
- 3) Formal laboratory quality audit

All amendments and changes will be incorporated on an Amendments Record Sheet (Appendix). Amendments will be made by the replacement of a complete page or pages.

Hand written or typed amendments to the existing pages without the signature of the head are not acceptable.

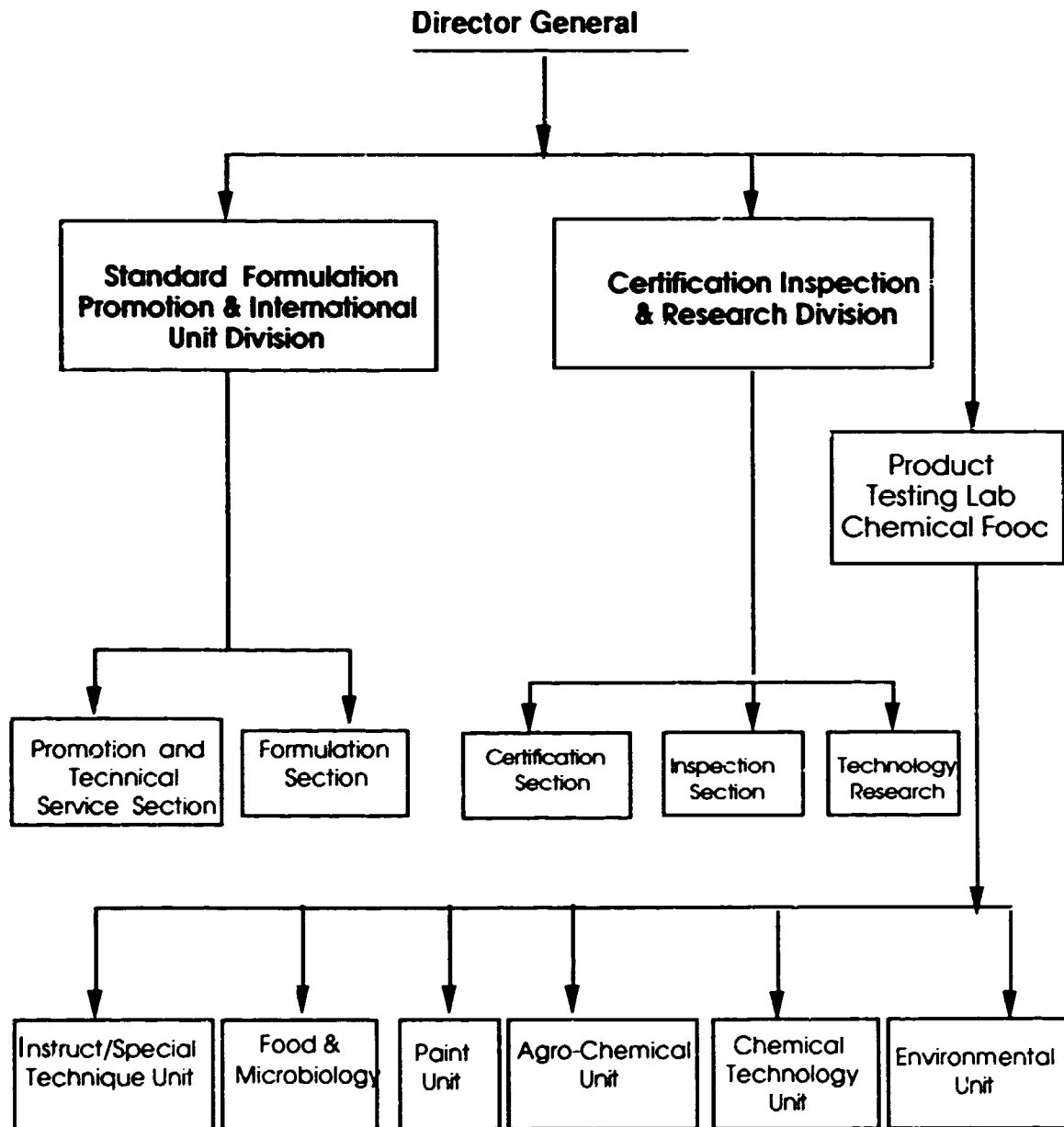
Each amendment sheet will be accompanied by a full amendment instruction bearing the signature of the laboratory head.

3. ORGANIZATION AND MANAGEMENT

3.1 Organization

The Nepal Bureau of Standards and Metrology is the National Standards body of His Majesty's Government of Nepal under the Ministry of Industry. The Chemical and Food Testing Laboratory offers a comprehensive range of services including tests of the N.S. certified products, and the assessment of their quality, together with the Provisions of test services to government, public and private organization industries and general consumers.

The Chemical and Food Testing Laboratory of the Bureau was established in 2041 B.S. and, since then it is steadily expanding the testing facilities and now enjoys an excellent reputation in the testing of chemicals and food products.



Staff directly involved in the operation of the Laboratory are

Sr. Divisional Chemist	-	Head of the Laboratory Gazetted II class (A)
Divisional Chemist	-	Deputy and Gazetted class 2 (B)
Chemists	-	Gazetted class 3
Food Technologists	-	Gazetted class 3
Technical assistants	-	Now Gazetted.

3.2 Inter relation with other Divisions or sections

The laboratory supports the inhouse activity in terms of quality control, technical service to the industries and other organizations.

The samples submitted to the laboratory from other section within the Bureau and from other agencies are dealt by qualified technical persons. Standard procedures and /or internal laboratory manual are to be followed strictly.

3.3 Management - Senior Staff

Head of the Laboratory -

Job Title — Senior Divisional Chemist

He is the person responsible for over all function of the laboratory, and promotion of its growth. The duties include :

- 1) In consultation with the Director General and other divisional chiefs, to prepare the long term as well as the annual plan and policy concerning work practices, quality, technical and overall development of the laboratory in the frame work of the Bureau's policy.
- 2) To take appropriate action to ensure that the laboratory operates in an efficient manner and produces high quality outputs.
- 3) To instruct the subordinates to ensure that the laboratory operates within the rules and complies with ISO guide 25.
- 4) To maintain liaison with other sections of NBSM.
- 5) Acting as safety officer and issuing the Bureau's safety policy
- 6) Control of overall operation of the units of the laboratory.
- 7) To ensure that the professional and technical staff are competent.
- 8) To check quality manual amendments and recommend to the Director General for approval.

3.4 Divisional Chemist

Reports directly to the Sr. Divisional Chemist head of the laboratory. He/she has the responsibility for the efficient running of the laboratory and the integrity and quality of the out put.

The duties are :

- 1) Over see the testing conducted in the laboratory
- 2) Checking and signing all test reports issued by the laboratory
- 3) Updating test methods and working instructions and submit same for approval by the head of the laboratory

- 4) Arranging and supervising on the job training for new staff
- 5) Responsibility for documentation and implementation of all quality control activities
- 6) To take proper action for the management of supplies and the maintenance of equipment
- 7) Maintenance of traceability records and associated certificates
- 8) Motivating staff to recognize the importance of the laboratory's quality policy and implementation of same.
- 9) To carry out research activities.

3.5 Chemist / Food Technologists

Report to the Divisional Chemist . He/She will assist the Divisional Chemist in overseeing the daily running of the laboratory and deputes for the Divisional chemist when the latter is absent.

The duties are :

- 1) Supervision of junior staff
- 2) Method development and the commissioning of new apparatus and the documentation of procedures
- 3) To up date the inventory of chemical glassware and apparatus
- 4) Responsible for the maintenance and the calibration of apparatus and the keeping of proper records
- 5) Verifying the validity of test apparatus on receipt
- 6) Conducting analysis
- 7) Other duties as may be designated by the superiors

3.6 Assistant Chemist /Lab Assistant

- 1) To receive, record and store the test samples in accordance with the procedures laid down.
- 2) To prepare reagents and tests in samples for analysis
- 3) To carry out some minor test accordance with the internal manuals and instructions of the chemist/food technologists
- 4) To assist in the calibration and preventative maintenance of the equipment
- 5) To file laboratory record sheets
- 6) Other duties may as be designated by the chemist/food technologists

3.7 Lab boys / Helpers

- 1) To clean the laboratory
- 2) To clean the glassware and working benches

3) To help the chemist / assistant chemist in any capacity

3.8 Staff qualifications and Training

It is the policy of the Bureau to employ qualified personnel to staff the laboratory in accordance with HMG public service commission's rules and procedures. The minimum qualification of the gazetted staff for chemist is a post graduate degree in chemistry and for food technologists is a bachelors degree in food technology. And for assistant chemist/ lab assistant the qualification is a Bachelors degree in chemistry or related field.

All new staff are placed on a minimum of two month probation during which he/she will be given on the job training by the Sr. Chemist on various tests performed routinely by the laboratory.

To keep abreast with the technology related to the field of testing, existing staff are also given the opportunity to update and refresh themselves through seminars, workshops, short courses and overseas training.

The head of the laboratory is responsible for the establishment and maintenance of a system of training feed back to the director on the identified need for training.

3.9 Confidentiality

To ensure absolute and complete confidentiality all employees are required to sign the secrecy undertaking which forbids the disclosure of any information concerning the dealings of the laboratory to any unauthorized person.

4. QUALITY AUDITS AND SYSTEM REVIEW

4.1 Purpose/Aim

The purpose of the periodic auditing is to check the effectiveness of the quality control procedures described in this manual.

4.2 Responsibility

It is the responsibility of the head of the laboratory to carry out periodic checks. He will carry out periodic audits at least once a year.

His responsibilities include :

- Planning of the quality audit
- Evaluation of the audit
- Ensuring that audit procedures are well documented. The results are formally recorded. Corrective actions are implemented in an effective manner.
- Audit procedures are to be amended, withdrawn or newly issued as and when necessary.

4.3 Implementation

The performance audit will be carried out by the head of the laboratory to evaluate the data produced by the laboratory's analytical system. It will include :

- Work sheet review
- Oral work sheet review
- On-site analyst work review
- Check sample inspection
- Intra laboratory check sample analysis

A system audit will be carried out for qualitative appraisal of the quality. It can cover any or all the operational programme elements, such as :

- Sample handling, sample analysis records and controls, preventive maintenance, proficiency testing etc.

It can also cover non-operational elements such as

- Personnel practices, training, work load, personnel needs.

5. FACILITIES AND EQUIPMENT

Chemical and Food testing laboratory of NBSM undertakes mainly analysis of food items, industrial chemicals, consumer items (chemical) petroleum, paints, environmental pollutant within the scope and capability of its facilities and equipment.

The methods used are generally nationally and international recognized standard procedures such as NS, IS, ISO, ASTM, BS, IP and some standard test methods. At times tests are carried out according to in house methods. Details of inhouse methods are to be kept in a file.

A range of test, measuring and inspection equipment are held inhouse. An inventory of this equipment is maintained by the chemist assigned.

5.1 Measuring and testing equipment

- 1) Atomic absorption spectrophotometer with accessory
- 2) UV visible spectrophotometer with accessory
- 3) Flame photometer with accessory
- 4)

5.2 Instruction for use

Operating Instruction manuals are available for all major equipments. These are kept in a separate file.

Copies are available in the drawers under the benches where the instruments are located.

5.3 Maintenance of equipment

The chemist/food technologist is to ensure that equipments are properly kept and covered by the maintenance programme of the manufacturer. The preventative maintenance is carried out as scheduled. The internal laboratory manual for inhouse preventative maintenance the instrument is prepared (Annex)

5.4 Monitoring

The divisional chemist is responsible to take immediate action for general arrangement in relation to equipment that requires checks calibration or that has suffered damage .

5.5 Authorization for use

A list of responsible persons is prepared for the authorization to handle the major sophisticated instruments.

6 CALIBRATION OF EQUIPMENT

6.1 Responsibilities

The divisional chemist is responsible for planning, co-ordinating and implementation of the over all calibration programme for the laboratory .

The master planner sheet is prepared and held by the divisional chemist showing calibration intervals of the equipment .

The programme of measurement and calibration is in accordance with BS 5781 for internal calibration. It includes the reference material used as a reference standard of measurement .

7. TEST METHODS AND PROCEDURES

7.1 General Procedures

All procedures used in the course of testing are documented. Two categories are used.

- a) Category 1- standard laboratory procedures .
example - calibration ,Maintenance house keeping ,safety e .t.c.
- b) Category 2 -Technical procedures
example - specialized test and measurement methods

The detailed information on test methods are listed in Technical Procedures. These technical procedures contain all the necessary information to ensure that the test can be well conducted using trained staff and adequate instruction manual or equipment

7.2 Control/availability

All technical procedures used in the work are required to be approved by the head of the laboratory.

All instructions , standards, manuals and reference data relevant to the work are maintained up to date and are available to staff .

Testing will be carried out to the latest issue of the relevant testing specification/standard. Where non - standard test methods and procedures are employed, these must be documented properly to provide traceability.

7.3 Responsibility

It is the responsibility of the divisional chemist to authorize the test methods and procedures for daily work to ensure the validity of the methods.

8. HANDLING OF TEST ITEMS

8.1 Routine handling

All samples submitted for test are registered, labelled and signed in accordance with the internal standard procedures(Annex.). Samples are removed from the laboratory at certain intervals under the supervision of a chemist and retained in the sample store for a period of three months .A standard request form is completed by staff who have requested for special retention. Samples taken by the client will also be recorded in a sample register.

8.2 Disposal

Sample are normally disposed after three months according to standard methods (Annex)

It is a strict rule of NBSM chemical laboratory that under no the circumstances the staff acquire specimens for personal use.

9. TEST RECORDS

9.1 System

Procedures for recording test results are contained in the relevant standard procedure. A brief description of the main features is as follows.

Observations made are to be recorded immediately in log books or formally referenced files. In addition to test results, the following data is to be recorded (internal standard annex analyst worksheet).

- a) Technician's name
- b) Date
- c) Job description
- d) Specification number
- e) Identification of measurement procedure
- f) Ambient conditions if required

When the test results are not available on "hard copy" e.g. .data store, then clear identifiable cross referencing between the stored data and the worksheet book is

mandatory. Where loose worksheets are present containing data, charts, recordings etc. then they are to be secured and retained in a formally referenced file.

9.2. Retention

The records retained by the laboratory are to contain enough information to allow the identification of sources of errors and to permit, where necessary the repetition of the test under similar conditions. All records are to be held secure and in confidence and are to be released only to a client. All records are to be retained for a minimum period of three years.

10. TEST REPORTS

10.1 Issuing of Test Reports

The end product of any testing is the production of a test reports. Such reports must be written in accordance with the following features.

The test report shall be prepared and signed by the divisional chemist /chemist /food technologist during the preparation he/she must take final check of the work ensuring

- test conditions laid down in the specification have been met
- the choice of measuring equipment and measurement procedures was appropriate to the specification and consistent with the accuracy required
- Transcription errors have not been made in the transfer of results from work sheet /book to the test report
- The status of the test specimen is fully recorded
- The specification as to which tests are carried out is precisely defined

Corrections or additions to a test report after use can be made only by a further document marked "Supplement to Test Report, Serial Number ..." and must meet the relevant requirements of the preceding paragraph.

Where evidence of possible malfunction of equipment comes to notice retrospectively (after issue of test report) the head of the laboratory has the responsibility of notifying the client immediately in writing, providing the client with the details of the circumstances.

10.2 Designated Signatories

Designated signatories are limited to the head of the laboratory, divisional chemist and chemist /ford technologist .Under special circumstances other staff may also be authorised to sign a test report by the head of the laboratory.

10.3 Format of Test Reports

The contents of the test report include the following :

- a) Name and address of testing laboratory
- b) Serial no of test report
- c) On each page, a page no, the total no. of pages and the test report serial no.
- d) Name and address of the client
- e) Description and identification of sample
- f) Dates of receipt of the sample and test conducted
- g) Identification of the test specification method
- h) Any deviations additions or exclusions from the test specification.
- i) Measurement, examination's and derived results
- j) Statement of uncertainties where appropriate
- k) Description of the sampling procedure where possible
- l) Signature and title of the staff accepting technical responsibility for the test report and date of issue

The laboratory has prepared two types of formats of test reports containing all above features.

Type 1- For NS certified products only (Annex)

Type 2 - For general measurements which are issued for any type of test /sample (Annex)

10.4 Retention of test reports

All test reports are to be retained for a period of three years.

10.5 Use of NBSM logo

Reports issued for tests must carry the NBSM stamp / logo

11. SUB CONTRACTING OF TESTS

11.1 Procedure

It is the policy of NBSM to sub contract tests only to the HMG laboratories and certified industrial laboratories.

11.2 List of Approved Sub contractors

The head of the laboratory will maintain a list of laboratories and the tests for which they are capable.

11.3 Acting as Arbitration laboratory

Since NBSM is an authorised government department its laboratory will act as an arbitration laboratory on disputes.

12. FAILURE PROCEDURE

Where ever evidence of possible malfunction of equipment during testing becomes apparent retrospectively (after issue of test report) the head of the laboratory has the responsibility of notifying the concerned client immediately in writing providing details of the circumstances and environment.

13. LABORATORY ACCOMMODATION/ENVIRONMENT

13.1 General laboratory conditions/Accommodation

The accommodation and environment is required to meet the following conditions :

- 1) The testing area is clean and well lit
- 2) Disturbances are very low
- 3) Temperature and humidity control and other conditions for testing are provided where samples under test are sensitive to these factors. Controlled areas are provided for use where precise measurements are to be made. Adequate bench and storage space is to be furnished consistent with the type or volume of work.

Where special safety precautions are needed for testing certain samples, such arrangements are made.

13.2 Access

Access to testing areas is restricted to authorized staff. There is no open access . Access to special testing areas where strict safety measures have to be taken is restricted to technical staff only. Permission is to be taken from the divisional chemist /working chemist in that area.

13.3 House Keeping

All staff must follow and maintain good house keeping throughout the laboratory. A special procedure will be adopted where appropriate .

13.4 Control of calibration

All inspection, measuring and test equipment used are strictly controlled and in a known state of calibration . Records of calibration are kept by the chemist .

Calibration Records are maintained and available for all equipment. Records include :

- a) Description of equipment
- b) Serial number/identification number
- c) Frequency of calibration
- d) Dates of last and next calibration
- e) Results of calibration (Reference to calibration certificate)
- f) Remedial action if any
- g) Limitations in use, if any

A tag or sticker is attached to the calibrated equipment showing the date of calibrations. Measurement audits and interlaboratory comparison.

If necessary, interlaboratory comparison for measurement and calibration will be carried out.

14. HANDLING OF COMPLAINTS AND ANOMALIES

The head of the laboratory shall be responsible for looking after complaints about the adequacy of testing and for implementing appropriate investigative /corrective actions.

The laboratory shall keep comprehensive records of complaints and anomalies and their handling.

15. SECURITY OF THE LABORATORY PREMISES

It is the policy of the NBSM laboratories to provide security and safety measures to the laboratory premises and staff. The head of the laboratory or designated person will be responsible for the safety measures to be taken in the laboratory.

All laboratory staff shall strictly follow the safety manual prepared and distributed to the staff (Annex.....).

16. REFERENCE MATERIALS

16.1 Records of Reference Materials

All reference materials are properly recorded by a designated chemist. There are two types of reference materials, viz those of international reference materials and internal reference materials.

The records shall indicate the type of reference material, its usages, sources, date received, and date certified.

17. OUTSIDE SUPPORT SERVICE AND SUPPLIES

When NBSM takes outside services in support of the food and chemical testing the head of the laboratory shall ensure that the services are of adequate quality.

The laboratory head shall keep a list of those suppliers who are reliable and provide adequate services and supplies.

NBSM CRITERIA OF COMPETENCE TO BE MET BY TESTING LABORATORIES

1. Scope

This document describes the requirements for testing laboratories irrespective of the different technologies involved; it covers their organization, staff qualifications, accommodation, test equipment, calibration, record keeping and issuing of reports. Additional requirements may be specified by the NBSM depending upon the specific character of the test of the testing laboratory.

2. Legally Identifiable and Financial Viability

The laboratory must be legally identified and financially viable.

3. Impartiality, Independence and Integrity +

The testing laboratory and its staff shall be free from all commercial, financial and other pressures which might influence their technical judgement. The following conditions must be respected :

- All influence on the results of examinations and tests exercised by persons or organisations external to the testing laboratory must be excluded.
- The testing laboratory shall be not engaged in any activities that may endanger the confidence in its independence and integrity in relation to its testing activities.
- The remuneration of the personal engaged in testing activities must not depend on the number of tests carried out nor on the results of such tests.

4. Technical Competence

The testing laboratory must be competent to perform the tests concerned and in the absence of a recognized test procedure must establish that the tests are suitable for the purposed concerned.

5. Organisation and Management

The testing laboratory should be organised in such a way that each staff member is aware of both the extent and the limitation of his area of responsibility. The organization should provide supervision by persons familiar with the test procedures, the objective of the test and the assessment of the test results.

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- + Note: In may cases products are tested by organisations (eg manufacturers) who have been concerned with their design, manufacture or sale. This may create particular problems with regard to establishing impartiality etc. and therefore additional provisions may be needed on a case by case basis.

The proportion of supervising to non-supervising staff should be such as to ensure adequate supervision.

The testing laboratory shall have a technical manager who has overall responsibility for the technical operations of the laboratory.

A document showing the organisation and distribution of responsibilities etc. shall be available and kept up to date.

6. Quality System, Audit and Review

The laboratory shall operate an internal quality assurance system appropriate to the type range and volume of testing undertaken. The quality assurance system shall be documented in a Quality Manual which is available for use by the laboratory staff. The Quality Manual shall be maintained up-to-date by a responsible member of the laboratory staff, who shall be so designated by the management.

The Quality Manual shall contain :-

- (a) A quality policy statement, by top management including the range of tests undertaken by the laboratory:
- (b) The organization and management structure of the laboratory:
- (c) The operational and functional duties and services pertaining to quality so that each person concerned will know the extent and the limits of his responsibility. This includes job descriptions for key staff.
- (d) Procedures for the control and maintenance of documentation
- (e) Identification of the laboratory's approved signatories.
- (f) Procedures for handling test items and their testing
- (g) A list of the major items of equipment
- (h) Procedures for the calibration, verification and maintenance of equipment
- (i) Procedures for the review of all new work to ensure that the laboratory has the necessary facilities and resources to carry out such work.
- (j) Procedures to be followed for feedback and corrective action whenever discrepancies are detected or departures from documented policies and procedures occur.
- (k) Procedures for dealing with complaints
- (l) Procedures for audit and review.

7. Audit and Review

The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system.

In addition to periodic audits the laboratory shall ensure the quality of the results provided to clients by implementing checks which shall include, as appropriate,

- (a) Internal quality control schemes using, whenever possible, statistical techniques.
- (b) Participation in proficiency testing or other inter laboratory comparisons.
- (c) Regular use of certified reference materials and in-house reference items.
- (d) Replicate testings using the same or different methods.

All audit findings and any corrective action that arise from them shall be documented.

8. Personnel

The testing laboratory must have sufficient personnel.

Staff shall have the necessary education, training, technical knowledge and experience for their assigned functions.

The testing laboratory shall ensure that the training of its personnel is adequate for the required tests.

Information on the qualifications, testing and experience of the technical staff shall be maintained by the laboratory.

9. Premises and Equipment

9.1 Availability

The testing laboratory shall be furnished with or, exceptionally, have access to all items of equipment required for the correct performance of the tests and measurements for which it claims to be competent to carry out

9.2 Accommodation and environment

The environment in which the tests are undertaken shall not invalidate the test results or adversely affect the required accuracy of measurement. The testing premises shall be protected as required from extreme conditions such as excessive temperature, dust, moisture, steam, vibration, electromagnetic disturbance and biological sterility. When the testing so requires the laboratory shall be equipped with devices to monitor the environmental conditions.

The premises shall be sufficiently spacious to limit the risk of damage or danger and to allow operators to make practical and precise movements. Access to and use of all test areas shall be controlled in a manner appropriate to their designated purpose and entry by persons external to the laboratory shall be defined.

Adequate measures shall be taken to ensure good housekeeping in the laboratory.

9.3 Equipment Calibration and Reference Materials

The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant criteria of this document are met.

All equipment shall be properly maintained to ensure protection from corrosion and other causes of deterioration and maintenance procedures shall be documented.

Any instrument which has been subject to overloading or mishandling or which gives suspect results or has been shown to be defective, shall be taken out of service, clearly identified until it has been repaired and then shown by calibration or test to perform satisfactorily.

Records shall be maintained of each major item of equipment including reference materials. The records shall include:

- The name of the item of equipment
- The manufacturer's name, type identification and serial number
- The date received and the date placed in service.
- Copy of the manufacturer's instructions
- Maintenance providers and maintenance records including history of malfunctioning or damage.

Testing Equipment shall be calibrated and/or verified before being put into service and thereafter according to an established programme and records kept. The overall programme of calibration shall be designed and operated so as to ensure that measurements made in the testing laboratory are traceable (where the concept is applicable) to national or international standards of measurement. When the concept of traceability to such standards is not applicable the testing laboratory shall provide satisfactory evidence of correlation or accuracy of test results (for example by participation in a suitable programme of inter laboratory comparisons)

Reference standards of measurement shall be authenticated by a body that can provide traceability to national standards of measurement. They shall be used for calibration only and for no other purpose.

10. Working Procedures

10.1 Test Methods

The laboratory shall have adequate documented instructions on the use and operation of all relevant equipment, on the handling and preparation of test items (where applicable), and on standard testing techniques. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

The laboratory shall use methods and procedures for all tests and related activities within its responsibility. They shall be consistent with the accuracy required and with any standard relevant to the test concerned.

Where it is necessary to employ methods that have not been established as standard these shall be subject to agreement with the client. The laboratory shall reject requests to perform tests according to methods that may compromise an objective result.

Where sampling is carried out as part of the test method the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

All calculation and data transfers shall be subject to appropriate checks. Where the results are derived by electronic data processing techniques, the stability of the system shall be such that the accuracy of the results is not affected. This generally implies an ability to detect malfunctions during programme execution and to take appropriate action.

Where data is stored in an electronic or magnetic memory duplicate storage shall be arranged so that the data can be retrieved if the memory is accidentally erased.

10.2 Handling of Test Items.

A system for identifying the samples and items to be tested shall be applied, either through documents or through marking, to ensure that there can be no confusion regarding the identity of the samples or test items and the results of the measurements made.

A procedure shall exist for the bonded storage of items where necessary. At all stages of storing, handling and preparation for these, precautions shall be taken to prevent damage to the items, for example, by contamination, corrosion or the application of stresses, which would invalidate the results. Any relevant instructions provided with the item shall be observed. There shall be clear rules for the receipt, retention and disposal of samples.

10.3 Records

The laboratory shall maintain a record system to suit its particular circumstances. It shall retain on record all original observations, calculations, and derived data, and a copy of the test certificate of report for an appropriate period. The records for each test shall contain sufficient information to permit their repetition and will include the identity of personnel involved in sampling, preparation and testing.

All records, certificates and reports shall be held secure and in confidence to the client.

10.4 Test reports/certificates

The results of tests carried out by the laboratory shall be covered by a report or certificate which accurately, clearly and unambiguously presents the data and other relevant information. Each test report shall include at least the following information.

- (a) A title, eg Test Report or Test Certificate
- (b) Name and address of the laboratory
- (c) On each page, a page number, the total number of pages in the test report/certificate and unique serial number of the report/certificate.
- (d) Name and address of client
- (e) Description and identification of the test item(s)
- (f) Date of receipt of test item and date(s) of test, as appropriate.
- (g) Identification of the test method used
- (h) Description of the sampling procedure, if appropriate.
- (i) Any deviations, additions to or exclusions from the test specification and any other information.
- (j) Measurements examinations and derived results, supported by tables graphs sketches and photographs as appropriate, and any failures identified.
- (k) a statement on the measurement uncertainty, where relevant

- (l) A signature and title or an equivalent identification of person(s) accepting responsibility for the content of the report/certificate and date of issue.
- (m) A statement that the report shall not be reproduced except in full without the approval of the testing laboratory.

Particular care and attention shall be paid to the arrangement of the test report especially with regard to presentation of the test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of test but the headings shall be standardized as far as possible.

Material amendments to a test report/certificate after issue shall be made only in the form of a further document suitably marked, e.g. "supplement to test report serial number....." or equivalent form of wording. Such amendments shall meet all the relevant requirements of the preceding paragraphs.

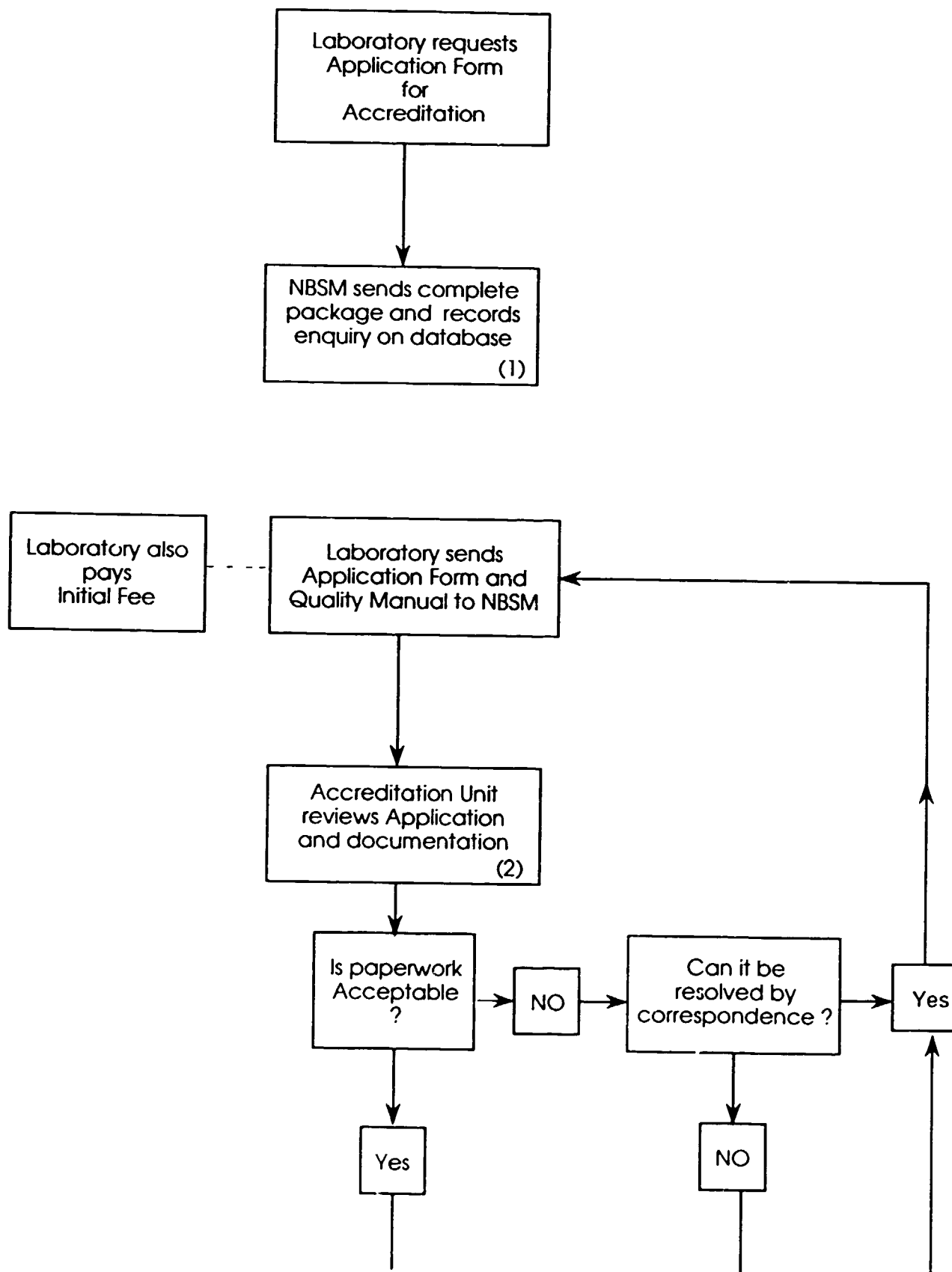
The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective equipment that casts doubt on the validity of results given in a test report report/certificate

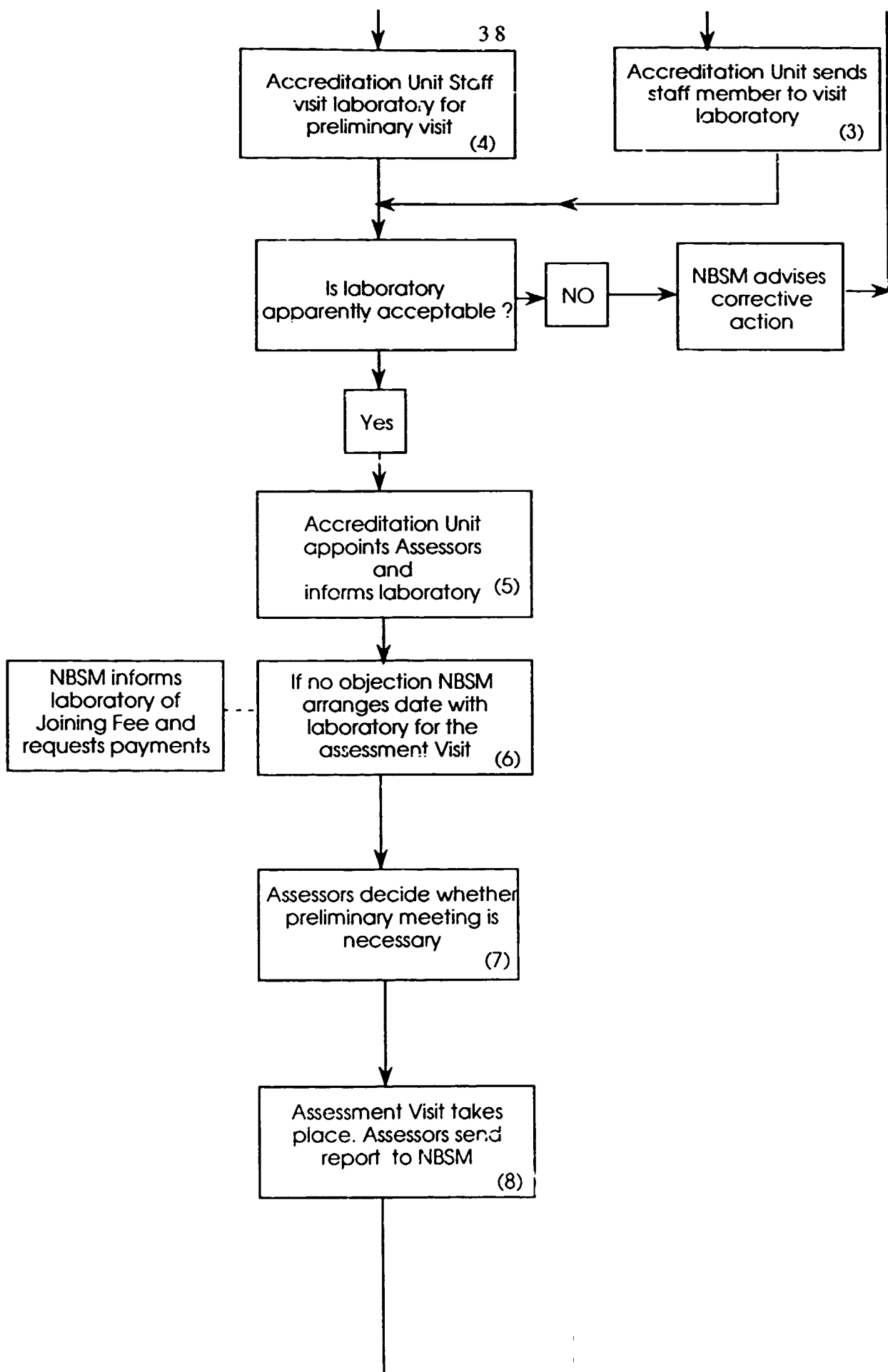
11 Complaints

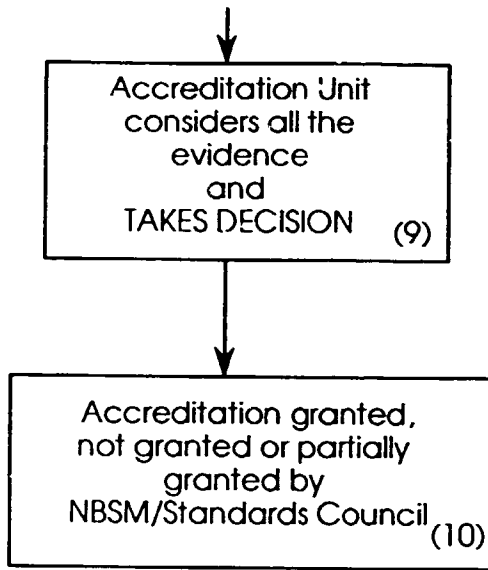
The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

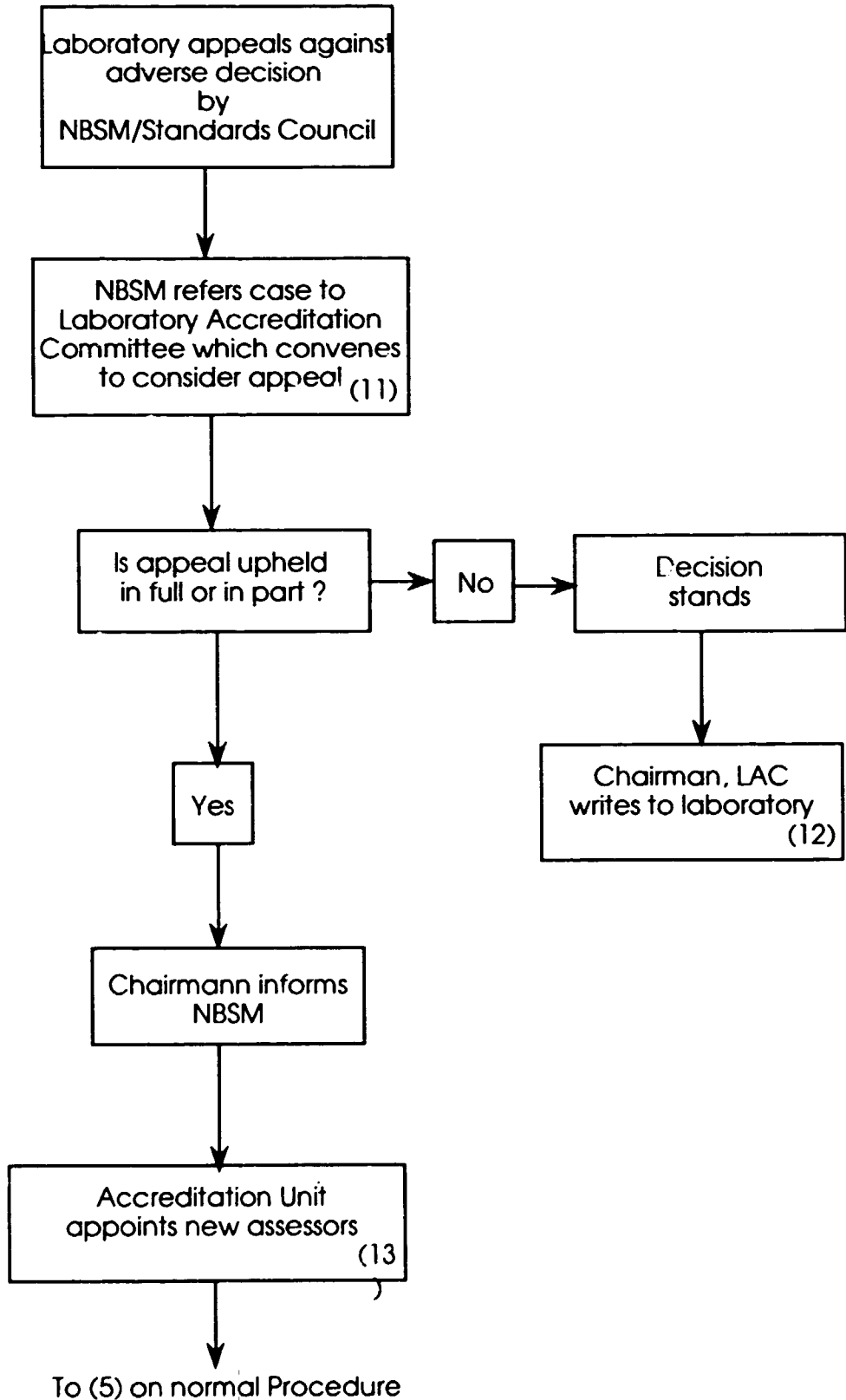
Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the stated policies or procedures the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited.

ACCREDITATION PROCEDURE FLOW CHART







APPEALS PROCEDURE

AUDIT PROCEDURE

Laboratory Accreditation Committee
meets once every
six months (14)

Explanatory Notes for the Procedural Flow Chart

The numbering corresponds to that on the Chart.

1. On receiving an enquiry NBSM will send not only an application form but also a leaflet explaining the procedures, fees, etc. and other documentation such as an example of a quality manual. NBSM should record the enquiry on its database.
2. The Accreditation Unit must check every item in the application i.e form and associated documents. For example, is the scope of Accreditation completed satisfactorily? Has the laboratory included an example of its Test Reports and is it satisfactory? Much expensive assessor time can be saved by correspondence at this stage.
3. If the paperwork is so out of line that it cannot be resolved by correspondence a senior A.U. staff member will have to visit the laboratory to sort it out. A one day visit should be free. A record of the visit and the recommendations made by the staff member should be put on file. The recommendations should be confirmed in a letter from the A.U. manager to the laboratory.

N.B. As Nepal develops any consultancy (apart from the one day free visit) that the laboratory requires should be carried out by non NBSM staff in order to avoid any conflict of interest. Other sources of competent consultants will need to be identified.

4. Even if the paperwork is acceptable this visit is usually worth making. Staff should stress that it is not an assessment visit but simply to help the laboratory understand the process. Very often laboratories do not appreciate the procedures (despite the leaflet in 1) and this visit smooths the way. The cost of this visit should be included in the initial fee. A brief record for the visit and of the staff members observations should be put on file.
5. The technical background required of the assessors will be apparent from the application form and from the visits made at 2 or 4. An experienced A.U. staff member should be part of the team, at least in the first few years of operation. NBSM should inform the laboratory of the names of the assessors and give time for any objections.
6. A laboratory may object to a particular assessor on the grounds of possible disclosure of confidential information to a competitor. If so NBSM should choose a replacement. NBSM calculates the joining fee (based on assessors time etc) and request payment. The assessment visit cannot take place until this payment is made.
7. Assessors may feel it helpful to have a preliminary meeting to decide who covers what aspect of the accreditation. It also ensures that the assessors have seen all the standards and understand them. However this meeting is not mandatory but should be held if necessary.
8. The team of assessors should prepare only one report but all should contribute to it. If any non-compliance is observed during the assessment visit the assessor should record the factual evidence on a "Discrepancy Report Form" which should be signed by the assessor and the laboratory representative at the time the observation is made.
9. The evidence includes the application form and associated documents, the assessors report any other evidence. If there is any doubt the Accreditation Unit Manager should not hesitate to discuss the situation with the assessor(s). The options available include partial accreditation, i.e. accreditation for those tests for which the

- laboratory is considered satisfactory. The remainder of the scope can be accredited when corrections have been completed.
10. The Accreditation Certificate should be initialed by the Accreditation Unit Manager and signed by the Director General, NBSM, and the chairman of the Standards Council. The data base should be completed. If partial accreditation has been granted the database should be annotated to review the situation after i.e. an appropriate period.
 11. Appeals may be against adverse decisions or against favorable decision by a third party.
 12. The Laboratory Accreditation Committee should be a completely independent body, except that NBSM provides the secretariat. Members should be respected technologists who are able to take a broad view. NBSM must provide the LAC with all the evidence. The chairman of the LAC has the right to call for assessors or any other expert he considers necessary.
 13. The chairman for LAC should not use NBSM notepaper in LAC correspondence.
 14. If an appeal is updated only in part assessors need only be appointed for the upheld part. A further charge should be made.
 15. The LAC should meet once every six months to receive a report from the Accreditation Unit manager on progress in accreditation. The manager contends for this item. The report should list those laboratories accredited in the preceding six months and should also highlight any difficulties encountered in operating the system. The committee may, if it so wishes, select some of the accreditations for further investigation at a later meeting. NBSM must provide all the paperwork for these cases, the names of the assessors and any other details the Committee wishes. The objective is to provide an independent audit of NBSM procedures, i.e., to show that they are being carried out correctly. After completing each six-monthly audit the chairman writes formally to the Director General NBSM informing him of the Committee's findings.
 16. There are two schools of thought as to whether to use the same assessors as for the original assessment or different ones. One ever present danger in any accreditation system is that of corruption. Using different assessors each time reduces this possibility. On the other hand the use of the same assessors reduces the amount of preparation required since the assessors are already familiar with the firm. On balance the use of different assessors is preferred not only for the above reason but because it gives assessors wider experience.
 17. The procedure for a surveillance visit is the same as for an accreditation visit except that any general explanation of the accreditation system can be omitted in the initial meeting with management. Discrepancy Report Forms and a Summary Report Form should be completed as before.
 18. See comment 9.

PROPOSED TEXT FOR A PUBLICITY LEAFLET DESCRIBING THE NBSM ACCREDITATION SYSTEM

ACCREDITATION - WHAT IS IT AND WHAT CAN IT DO FOR ME ?

What Is Accreditation ?

Accreditation is the formal recognition that a laboratory is technically competent to carry out specific tests and to do so impartially. Such recognition is granted only after a laboratory had demonstrated, through formal assessment procedures, that it satisfies the "NBSM Criteria of Competence to be met by Testing Laboratories". Although it is not the purpose of this leaflet to repeat these criteria in detail, in brief they require a laboratory to demonstrate the following in respect of each of the tests covered by the accreditation:-

1. Staff competence
2. Suitability of the test equipment and environment
3. A quality manual which describes
 - The laboratory organization and, if not independent, its position within the parent organization.
 - The terms of reference of the key staff
 - Procedures for the conduct of each test
 - The facilities available for testing together with their maintenance and calibration history.
 - The internal quality assurance arrangements that enable the laboratory to have confidence in its testing services.

For What Tests Can a Laboratory be accredited ?

In principle a laboratory can be accredited for any objective test for which there is a well documented procedure. This includes tests associated with national and international standards, as well as tests which are described in textbooks and elsewhere. In-house test methods may be acceptable so long as they have been independently verified and are clearly documented. However it should be noted that the NBSM Accreditation System will be introduced on a field by field basis and hence accreditation for some fields of testing may not be available initially.

Why Should Your Laboratory Be Accredited ?

Clearly the "quality" of a firm's products depends in large part on the standard of testing by the laboratory it uses for this purpose. In this some laboratories are very good, others less so. It is the aim of His Majesty's Government to improve the overall quality of Nepalese products in order that they may compete more effectively in world markets and raise the standard of living in Nepal. Since testing is an essential part of the quality assurance process His Majesty's Government wishes to see the standard of testing raised and has authorized NBSM to implement an accreditation system to achieve this.

NBSM will promote the system by publishing a directory of laboratories and the tests for which they are accredited.

How Is Accreditation Achieved ?

An assessment of a laboratory against published criteria cannot be performed solely by examining written statements by the laboratory management, important as these are. NBSM will first examine the application and associated documents including the laboratory's Quality Manual, and, if these are in apparent conformity with the criteria, will then appoint a team of assessors to visit the laboratory to examine the reality of the written statements. The composition of the team will depend on the number of tests for which accreditation is sought and the size of the laboratory. The assessors will be chosen by NBSM for their technical competence in the relevant field and will be drawn from NBSM and other organizations.

The names of the proposed assessors will be made known to the laboratory before the assessment visit takes place and the laboratory will have the right to object to any of the proposed assessors who might prejudice their interests in any way. All information concerning the assessment including the fact that a given laboratory has applied or that an application has been deferred or rejected will be treated as strictly confidential.

An appeals system exists whereby any dispute over accreditation or non-accreditation can be considered by an independent committee.

How Are Assessment Visits Conducted ?

The assessment visit will normally consist of an opening meeting between the assessor(s) and the senior management of the laboratory, an assessment of the laboratory's testing arrangements and its facilities together with a final meeting. Assessments may take half a day or several days depending on the size of the laboratory and the range of tests involved.

At the opening meeting the assessors will explain the purpose of the assessment and how it will be conducted. The assessors will tour the laboratory and each assessor will be accompanied by a member of the laboratory staff with knowledge of and responsibility for the area of work concerned. The assessors may ask to witness tests or to see calibration certificates for items of test equipment or to compare test reports with work sheets. Where a possible failure to comply with the NBSM requirements is observed, an agreed signed record of the observation will be made by the assessor and the laboratory representative. These factual records will constitute the basis for the assessors recommendation on accreditation to NBSM.

What Will It Cost ?

(To be decided)

What Are The Benefits Of Accreditation ?

An accredited laboratory is allowed to use the NBSM Accrediation Logo on test reports and other literature and clearly has a commercial advantage over others in soliciting custom for its testing services. Moreover as the accreditation system becomes more widely known, purchasers of products will demand test reports from an accredited laboratory. His Majesty's Government is likely to demonstrate a lead in this respect.

How Do I Apply ?

An application form and further details can be requested from:

The Accreditation Unit
Nepal Bureau of Standards and Metrology
Balaju, Kathmandu Tel: 272447, 272818,

Amendments to Act No. 10 of 2037 "Standardization (Certification Mark) Act"

Para 4 (c) should be amended to read as follows :-

" To accredit, suspend or deaccredit government or non-government laboratories to carry out specific tests."

A new para to be inserted as para 13, as follows .-

"Establishment of a Laboratory Accreditation Scheme : His Majesty's Government may, if it deems it to be necessary, establish a Laboratory Accreditation Scheme whereby testing laboratories, in both the public and private sectors, may be formally accredited to carry out specific tests. Such accreditation will be granted by the Standards Council. The scheme will administrated by the Bureau of Standards and Metrology and technically audited by an independent Laboratory Accreditation Committee which will also consider complaints.

The Bureau shall have powers to insist on testing laboratories participating in inter-laboratory comparisons.

The existing para 13 and following paras to be renumbered.