INDIAN RUBBER MANUFACTURERS RESEARCH ASSOCIATION

Affiliated to Ministry of Commerce & Industry,
(Government of India)

QUALITY PROCEDURE MANUAL

[ISO-9001:2015 & ISO/IEC 17025:2017]

No: - IRMRA / QPM / 05

ISSUE No. 06 dated 24/12/2021 Rev. No. 00

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APPROVED BY:	ISSUED BY:
DATE: 24/12/2021 DIRECTOR	DATE: 24/12/2021 MR

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2.	HOD (Processing)
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I hereby acknowledge that I have received the electronic version of Quality Procedure Manual [Issue No. _____ Rev. _____ dtd _____ by e-mail. I confirm that I have read the mail and I can refer as and when required.

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Signature of
The copy holder

Signature of
Management Representative

QUALITY PROCEDURE MANUAL - ISSUE RECORDS			
Doc. No.	ISSUE NO.	DATE	REASON FOR CHANGE
IRMRA/QPM/04	04	07/05/2017	On Up-gradation to ISO 9001:2015
IRMRA/QPM/05	05	27/11/2017	Upon incorporation of findings at stage 1, up gradation audit as per ISO 9001:2015, conducted by TUV India Pvt. Ltd certification body on 07/11/2017
IRMRA/QPM /05	06	24/12/2021	Upon extension of scope to include the regional centers activities in the scope of certification.

AMENDMENT RECORD SHEET

Sr. No.	AMENDMENT PARTICULARS	Date	Sign of MR	Sign of Director

PREPARED BY	ISSUED BY
Management Representative	Management Representative

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Title of the procedure	CONTROL OF DOCUMENTS
Purpose	To establish a documented procedure for control of Documents.
Scope	This procedure is applicable to control all the documents related to ISO –9001-2015 Quality systems, and ISO / IEC 17025: 2017 of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO-9001-2015 - Cl. No. :- 4.2.3 ; ISO /IEC 17025: 2017; Cl. No. :- 8.3
Responsibility	1. Director for total control. 2. MR for control, issue, revision & amendments. 3. Section Heads for sectional records. 4. Assistants for maintaining observation records 5. Library I/C for upgradation & control of external documents. 6. System Administrator/EDP I/C for electronic data security.
Procedure NO.	IRMRA/QP/01

PROCEDURE:

01.1 Internal documentation: -

Quality system manual – QSM.

Quality procedure manual – QPM.

Quality Process manual – QPROCM

Sectional Operating Procedure – SOP

Work instruction – WI

Quality Annexure Manual – QAM

Forms, formats, records, register.

Quality plan

01.1.1 Preparation, Review, and Approval:-

A Documented Responsibility Matrix is displayed in a tabular form as under :

a)

Sl. No.	Type of Document	Prepared by	Approved by	Issued by
1.	QSM	MR	DIRECTOR	MR
2.	QPM	MR	DIRECTOR	MR
3.	QPROCM	MR	DIRECTOR	MR
4.	SOP/WI	SH	HOD	MR
5.	FM / FT	MR	Director	MR
6.	Quality Annexure Manual	MR	Director	MR

b) The system of QSM, QPM & QPROCM approval :

PREPARED BY	ISSUED BY
Management Representative	Management Representative

Declarations of approval of all pages of the QSM, QPM and QPROCM are given on the first page of the respective manuals, after the title page.

(i) Quality System Manual:
This is identified from the No: - IRMRA / QSM /05.

(ii) Quality Procedure Manual:
This is identified from the No: - IRMRA / QPM /05.

(iii) Individual Quality Procedure is identified as: for e.g.: IRMRA /QP/01

Where IRMRA – Name of the organization.
QP – Quality Procedure.
01 – Serial No. of procedure.

(iv) Quality Process Manual :
This is identified from the No.:- IRMRA/QPROCM/05

(v) Individual Process is identified as : for e.g.: IRMRA/QPROC/01
IRMRA/QPROC/02

Where IRMRA – Name of the organization.
QPROC – Quality Processes
01 – Serial No. of Process.

(vi) Formats :

These are identified as: - For e.g. IRMRA /FT/-----/01
IRMRA – Name of the organization.
----- about the format.
01 – Serial No. of procedure.

(vii) Registers :

These are identified as: - For e.g. IRMRA /REG/PHY/01
IRMRA – Name of the organization.
REG- Registers.
PHY- Section Code.
01 – Serial No. of procedure.

01.1.2 **Identification of system document.**

Any printed documented pages related to quality management systems are identified by the following minimum information's:

Document	Quality system manual	Quality procedure manual	Quality Process Manual	Sectional/ Operating procedure
Header	1.Name of organization 2.Type of manual 3. Document page number. 4. Chapter No. 5. Issue No. 6.Rev.No 7.Date 8.Approved by	1.Name of Organization 2.Type of manual 3.Document page number 4 .Issue No. 5. Rev.No. 6.Date 7.ISO-9001Cl.No. 8.Approved by	1.Name of Organization 2. Type of manual 3.Document page number 4. Issue No. 5. Rev.No. 6.Date 7.Approved by	1.Name of Organization 2. Type of manual. 3. Document page number 4. Issue No. 5.Rev.No . 6.Date 7. Name of section/dept.
Footer	1.Prepared by (MR) 2.Issued by (MR)	1.Prepared by (MR) 2.Issued by (MR)	1.Prepared by (MR) 2.Issued by (MR)	1.Prepared by (SH) 2. Approved by (HOD) 3. Issued by (MR)

01.1.3 **Control of documents:**

01.1.3.1 All Master documents related Quality systems including SOPs will be stamped as "MASTER COPY" on the backside of each document in green colour and retained in MR's office.

01.1.3.2 MR controls distribution of copies as per distribution list. The copies of all quality system related documents such as QSM, QPM, QPROCM, SOPs and WIs are controlled by stamping in red by a rubber stamp as "CONTROLLED COPY". A soft copy of a controlled version is made available on the network system, which are "READ ONLY DOCUMENTS", having "water mark in Red colour" and towards access of the control copy holders. In such case, hard copy need not be circulated.

01.1.3.3 One Control copy of SOPs/WIs are made available with the section head for reference purpose. Control copy of SOPs/WIs or operating manual are made available near the Instrument/equipment which is used by the operator for reference purpose.

01.1.3.4 MR maintains records of Issue Nos., and revision status indicated on every document. Original documents may be amended by hand if minor. But for major changes newly typed and approved pages shall replace. Amendment records shall be maintained for amendments in documentation. Issue no. is changed after every 5 revisions of documents and the issue is totally made new if International Standard is revised. If several revisions are affected more than 2 or 3 documents, then the entire manual has been changed with new issue number and with revision no. 00.

01.1.3.5 OBSOLETE copies shall be marked "OBSOLETE COPY" by violet ink and must be removed promptly from the working place and valid documents to be replaced with immediate effect.

The new amended version document is circulated to the controlled copy holders through electronic mail system. An acknowledgement of mail is also obtained.

The electronic copies of old versions are deleted when new documents are circulated and replaced by the new document. This is further confirmed by obtaining a signature of controlled copy holder on the amendment circular.

01.1.3.6 Any documents, which are not traceable to the MR's office, shall not be considered as part of the system and hence no accountability claimed thereafter.

01.2 **External documentation**: -

01.2.1 Equipments / Instruments manual (operational & maintenance) maintained by Section Heads. A copy of the same for some critical equipment may be available with maintenance Head.

01.2.2 Various standards such as ASTM, IS, ISO, BS, DIN etc. are controlled by Library cum Information Officer. The master copies of all specifications are preserved in Library under lock and key. The controlled copies of necessary specification are issued to the Section Heads and Assistants. Library cum Information Officer maintains records of such issues. Library cum Information Officer updates the entire specification lists time-to-time basis as and when required but at least once in three months. The Library cum Information Officer updates all specification using software and copy of updated version i.e. the necessary amendments are issued to the SHs and the assistants, which are in use.

01.2.3 The obsolete copies of any outdated versions are taken out of use and they are stamped as "OBSOLETE" and records are kept by Library I/C / Asstt.

01.3 **Amendment request Note: -**

Document changes may be requested by any employee with justification by forwarding an inter office note to his superior. MR will discuss with Director for his approval and then the necessary amendments are made. Such amendments are then notified to all copy holders through internal mailing system and old documents are removed from use. Such amendments are done once in 6 months unless otherwise urgently notified by the Director. The need of revision or new issue shall be discussed in MRM in such case no formal amendment request note will be prepared. The documents shall be amended / revised / issued with reference to minutes of meeting.

01.4 **Documented data in electronic media:**

System Administrator / EDP In Charge will keep back up periodically for ensuring the security of electronic data in a hard disk. A periodic checks are done to ensure that the electronic data back up is done on regular basis.

01.5 **Records:**

01.5.1 Distribution list of controlled copies holders.

Title	CONTROL OF RECORDS
Purpose	To establish a documented procedure for control of Quality records.
Scope	This procedure is applicable to various sections of IRMRA at Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 - Cl. No. :- 7.5.1 ISO/IEC 17025:2017 Cl. No. :- 8.4
Responsibility	1. Director for total control. 2. HODs for guiding the Sectional Heads. 3. MR for prepare, Issue,control & amendments 4. Section Heads for sectional documents 5. Administration dept. for control of customer letters
Procedure Number	IRMRA/QP/02

PROCEDURE: -

02.1 Identification: - All the quality documents / records are given identification number according to the Procedure No.: IRMRA/QP/01 and is listed in the master of Records.

02.2 Storage and Preservation: - All the quality records are stored in the appropriate place where they are required for day to day activities. Care is taken to ensure that the records are stored in safe conditions so that they are not deteriorated over the period.

02.3 The person concerned fills up quality records legibly

02.4 The records after the retention periods are destroyed.

02.5 MR maintains statement showing the details of all the records in the following respect.

02.5.1 Title of records.

02.5.2 Identification No.

02.5.3 Maintenance responsibility for this record.

02.5.4 Location

02.5.5 Retention period

02.6 RECORD: IRMRA/SOPM/06, IRMRA/QA/05.

Title of the procedure	Internal Audit
Purpose	To establish a procedure for Internal Audit of Management System implemented at IRMRA.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City as applicable.
Reference	ISO 9001:2015 - Cl.No. 7.2, 9.2, 10.2.2 ISO/IEC 17025-2017 Cl. No. 8.8
Responsibility	1. Director for total control 2. MR/QM for prepare, Issue, control & amendments. 3. Qualified /trained Auditors for conducting audits.
Procedure Number	IRMRA/QP/03

PROCEDURE: -

03.1 Internal Audits shall be conducted once in a year. Annual audit plan is prepared to meet this requirement. If the need occurs the number of Audits will be increased. These additional Audits may be due to the following reasons.

03.1.1 Nature of NCs.
03.1.2 Number of NC, - more than normal.
03.1.3 Changes in Departmental / Sectional Organisation
03.1.4 Changes of procedures/Machinery/testing method etc.
03.1.5 Customer complaints.

03.2 List of qualified Internal Auditors for ISO 9001 QMS & ISO 17025 is maintained by the MR/QM.

03.3 The planning, scheduling of the IQA is done by MR/QM. Actual Auditing will be done by trained Auditors deputed for the purpose by MR/QM.

Auditor selection is done based on the criteria where objectivity of audit as well as the impartiality is ensured. No auditor will do audit of his own work or in his own section. Scope of audit also well defined.

03.4 <u>PLANNING OF IQA.</u> :-

03.4.1 QM/MR will prepare, plan to cover the entire elements of the standard.

03.4.2 QM/MR will make a pertinent audit Schedule-Cum itinerary on the basis of the following factors.

03.4.2.1 Annualized plan.
03.4.2.2 Status - Change of persons.
03.4.2.3 Importance of the sections in respect of their contribution to the quality in direct manner.

03.4.2.4 The quality records of the sections Vice-versa the number of NC's found in the previous Audits.

The basis of making schedule will be based on the availability of Auditor, Availability of Auditee, verbal approval from Director and other relevant factors etc.

03.5 Once the itenary is finalized, it will be circulated to the Auditors, Auditee by mail. The auditors will study the documents and prepare checklists for Audit purposes. Any ready checklists are available, they are used as guidance purpose.

03.6 Actual auditing;

03.6.1 The auditors will conduct the Audit in formal manner in a professional way. He will remain unbiased during Audits.

03.6.2 The Auditing will be based on the techniques of interviewing and scrutiny of documents in proof of objective evidence.

03.6.3 He will record his findings in the checklist and detect the non-compliances if any. The internal auditors will issue corrective action request forms to the auditees, whenever the NCs are detected. NC closure will be done within 30days from date of issue of NC. Those NCs which can not be completed within 30days, needs to have approval from Top Management for extension.

03.7 Auditees shall propose corrective action plan and accordingly initiates to take appropriate corrective action.

03.8 QM/MR will prepare audit summary report based on audit findings and present in MRM meetings to review. The audit findings including observations / scope for improvements are discussed and recorded with a time bound action plan.

03.9 Corrective action taken by Auditee are verified by audit team and then closed by QM/MR. A follow up audit is arranged by QM/MR depending on the convenience to close the CAR.

03.10 QM/MR calls for a MRM in consultation with Director to review the audit findings, as per Procedure No. IRMRA/QP/12.

03.11 Records :

03.11.1 Annual Audit plan

03.11.2 Audit schedule cum itenary

03.11.3 Checklist cum Audit report.

03.11.4 Audit summary report.

03.11.5 Corrective Action Requests.

Title of the procedure	Non-conforming product / test report / process
Purpose	To establish a procedure for control of Non-Conforming product / test report / process.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 - Cl. No. 8.7.1 ISO/IEC 17025: 2017 cl no. 7.10
Responsibility	1. Directors for total control. 2. HODs for guiding the Sectional Heads to implement. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/04

PROCEDURE:

04.1 **Identification of Non- Conforming activities :**

IRMRA identifies the non-conformity of the test reports/developed products/any service during stage of verification. The Non-conforming test reports/products if any observed and the same is recorded and the required corrective action is taken, before release/despatch to the customer.

04.2 **For raw material received for IRMRA.**

The raw material such as raw rubbers, rubber chemicals are found not confirming to desired quality are identified as "non conforming incoming materials " and they are either returned to the supplier or possibility is worked out, in some alternate use.

04.3 **For non conformity of the product :-**

During development of a product or prototype supply, it is ensured that no non conforming products are delivered to customers. A thorough review is taken by section I/C and HOD to study the non-conformity. Corrective action is taken to rectify this non-conformity if any.

For non conforming of the Testing service:-

During testing, any reports are generated which are not as per the customer's specific requirements such as specification or method to be followed etc, then they are segregated, recorded and filed in NCP file. In case it is impossible to take a corrective action the matter is referred to HOD/ Director and the customer is informed about inability to take corrective action. However if the non-conformity can be rectified after specific period, the customer is informed accordingly and after the action is taken and test report is sent to the customer, after getting his prior consent. If customer requests any modification required in the test report and the same is done by canceling the original report and new reports are prepared as per cl. No. 5.10 of ISO 17025. Such types of activities are recorded.

For non-conforming Service: IRMRA takes most care to deliver the service like training, consultancy as per their need. In case of any non conforming service provided, then it is immediately corrected as deemed necessary and delivered to the customers. The records are kept in respective customer file as the case may be.

04.4 **RECORDS**: - Complaint file & NC- Test report; respective development file.

Title of the procedure	Corrective & Preventive action
Purpose	For implementing Corrective & Preventive Actions, to eliminate cases of actual or potential non-conformity in testing of customer supplied material.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001: 2015, Cl. No. 10.2 ISO/IEC 17025:2017, Cl. No. 8.7
Responsibility	1. Director for total control. 2. Dy. Director/HODs for guiding the Sectional Heads. 3. HODs / SHs / Supervisors to implement. 4. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/05

Procedure :-

05.1 **Identification of non conformity: -**

05.1.1 Non - conformity is detected from :-

05.1.1.1 Non accuracy of test results which may be identified by the variation of the results in the same sample analysis or duplicate run.

05.1.1.2 Non compliance of process activities during any internal review meeting/supervision.

05.1.1.3 External or Internal Audits which will identify the deviation from the documented systems and procedures.

05.1.1.4 Customer complaints.

05.2 **Corrective Action** :-

05.2.1 Corrective Action Requests are issued by the auditors if any NCs are detected to initiate the necessary corrective action.

Any product is identified to nonconforming to the specific requirements, then they are segregated and removed from the dispatch to customer.

05.2.2 Root cause analysis is carried out and Corrective action is taken to eliminate the causes of an existing non-conformity or defect or other undesirable situation.

05.2.3 The Preventive Action is taken to any potential nonconforming activities likely

to be identified.

05.2.4 Any critical C & P Actions are discussed with HOD & MR along with Director and the necessary actions are initiated by SHs.

05.2.5 Investigating causes and their effects.

05.2.6 Problems are defined and evaluated its significance in terms of potential impact on performance dependability, safety and customer satisfaction

05.2.7 Root causes are carefully analyzed, for any internal/external complaints.

05.2.8 Where root causes are not obvious, careful analysis of test specification and related process, operation, quality records and customers complaints are carried out. Statistical techniques are also used in problem analysis.

05.2.9 By this way, the Corrective and Preventive Action is determined and implemented through proper channel.

05.2.10 Relevant procedures, if needed are amended.

05.3 Preventive Action : -

Preventive action is taken to eliminate the causes of a potential non-conformity or other undesirable situation. The review of the major and frequent non-conformity may form the basis for taking preventive action.

05.4 RECORD :-

05.4.1 Customer Complaint file.

05.4.2 IRMRA/FT/AUDIT- CAR/01.

Title of the procedure	**Procedure for purchasing of Externally provided Products & Services**
Purpose	To establish a procedure for purchase activities of IRMRA.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001: 2015 Cl.no. 8.4.2 ISO/IEC 17025:2017– Cl.no. 4.6
Responsibility	1. Director for total control. 2. HODs/Functional Heads for guiding the Section Heads. 3. Purchase Co-ordinator / Project Leader to co-ordinate the purchase activities through Store Incharge. 4. Stores Incharge for control & maintaining records of receipt, issue stock & inventory. 5. SH/HOD of Accounts for release of payments. 6. MR/QM for prepare, Issue, control & amendments
Procedure Number	**IRMRA/QP/06**

Procedure: -

06.1.	**The following items/goods are involved in IRMRA's purchase activity: -**
06.1.1	**Capital goods/Machinery purchase.** The purchases of capital items such as machinery, equipments, civil work, building etc is based on a set pattern, as described below: The needs for capital items are identified and a Report or Note is prepared by user depthighlighting the need/justification for creating such a facility. This is presented to the Director and after due discussion, the same is incorporated in the budget under the project plan. After necessary approval and allocation of funds/sanction from sponsor, necessary quotations are invited from potential authorized supplier/ manufacturers either through tender, where necessary as per Govt. regulatory requirements and/or through letter/E-mail/website communication. Based on the above factors, authorized suppliers or manufacturer is selected for negotiation of price.
06.1.2	**Special purchase** (AMC/Calibration/spare parts/ project activities) When it is not possible to have more than one supplier, IRMRA exercises the special purchase process. Procurement or services such as AMCs or Spares for instruments / equipment are usually done from the OEM suppliers. Such suppliers are called unique suppliers. Order is placed on such unique supplier with due approval from Director.

06.1.3	**Consumable items such as Raw rubbers, rubber chemicals, and Laboratory reagents:** All consumable items such as raw rubbers, rubber chemicals and laboratory reagents and lab apparatus, are purchased within the scope of the purchasing authority on need base only. Annual rate contract can be made for the regular consumption of materials or services as and when required after following the process.
06.1.4	**Maintenance items: -**Purchase of the machinery spare parts and maintenance items are done on need base. The quality of the items and grades are identified by the actual user of the item and forwarded to the Director for his approval. After this approval, the order is placed by the purchasing Authority.
06.1.5	**Contract and purchase of services** External sub-contractors are sometimes contacted for the jobs, which cannot be carried out by IRMRA. Work contract is allotted only to sub- contractors who can give quality services. Subcontractors are contacted over phone or in writing for the required purpose. The bill is received after successful completion of the jobs. The bill is forwarded to the finance section through proper channel in the prescribed format. Advance payment is made as per needs of suppliers with the recommendations of Section Heads/ HODs/ Director...
06.1.6	**Stationary and printing items: -**The stationeries are purchased by purchase dept. on request of the section SHs and Departmental Heads/Functional Heads following due process. The SHs / HODs does emergency purchase and the bill is claimed later through proper channel if it is below Rs.5000.00
06.1.7	**Expert Services: -** Faculty/consultant/trainers/auditors IRMRA hires expert services from pool of competent experts. They are mainly hired as Faculty / consultant / trainers / auditors for appropriate jobs. They are only engaged on man day basis on the recommendation of HOD/SH and approval by Director. Resource of such expert services are carried out based on reference and/or through website advertisement followed by an interview.
Purchase process	
06.2	**"Call for Quotations, Publishing tenders& finalization of P.O. & Authorization of Purchase & P.O."**
6.2.1	**Regular Purchase Process**
6.2.1.1	After receipt of the purchase requirement from the End user department, Potential suppliers preferably from the approved supplier list are contacted to get the budgetary quote for the same.

6.2.1.2	If the cost of any single item is less than Rs. 5000/-, then the items may be purchased with the Single quotation/direct purchase. In such case, the preference may be given to the vendor from the approved list. It can be authorised by Director/HOD without calling for quotations through standard vendors and the order placed by purchase officer.
6.2.1.3	If the cost of any single item is exceeding Rs.5000/- and less than Rs. 15000/-then quotations are called from at least three suppliers (preferable from approved list).In case of OEM item single quotation with justification is acceptable. The P.O is signed by concerned HOD/Director.
6.2.1.4	If the cost of any single item is exceeding Rs.15, 000/- and less than Rs. 100,000/- then only sealed quotations are received from at least three vendors are acceptable (preferable from approved list) and the technical and commercial bid evaluated and negotiated. Finally the PO is placed on the supplier who has offered the lowest quote with required specifications/quality. P.O is signed by concerned HOD/Director. In case of OEM item single quotation with justification is acceptable.
6.2.2	**Procurement through web advertisement:**
6.2.2.1	If the cost of any single item is exceeding Rs.1,00, 000 /- and less than Rs. 200,000/- then list of the items with specifications are uploaded in the IRMRA's web site (www.irmra.org) and registered potential suppliers are informed.
6.2.2.2	**Award of the Contract-** After receipt of the sealed quotation not less than 03 in Nos, the following processes are practiced for the award of the contract.
6.2.2.2.1	Quotations are opened in front of the Internal Purchase Committee (IPC) members of IMRRA and same is recorded.
6.2.2.2.2	Technical evaluations of the quotations are done by Technical Committee members.
6.2.2.2.3	Comparison Chart is prepared and put up before committee for review.
6.2.2.2.4	Price negotiation meeting is called with L1 supplier or telephonic price negotiation is done. After successful negotiation and discussion revised quote is taken in soft or hard copy, if required and then contract is awarded to L1 bidder
6.2.2.2.5	If it is observed in the comparison chart that the difference between L1 and L2 supplier is in the range of 10%, if require internal purchase committee may call L2 supplier for price negotiation meeting.
6.2.2.2.6	The report of this price negotiation meeting is produced before the Director for his approval. If the Director feels necessary, he may put up this report before the Chairman of the External Purchase Committee (EPC) of IRMRA for his review/recommendation.
6.2.2.2.7	On the basis of recommendation from Chairman, EPC, final decision for awarding the contract for the finalized supplier is recorded and processed further.

6.2.3	**E-Tendering (Two Bid System)**
6.2.3.1	This method may be adopted when estimated value of the goods/services to be procured is above rupees 2, 00,000.
6.2.3.2	The tender document format with necessary terms and condition/guidelines/specification are uploaded in the IRMRA's website (https://irmra.eproc.in). The potentials suppliers are invited to participate in to the bid within stipulated due date. If the no of bids are not received, then the due date is extended
6.2.3.3	After receipt of the tenders not less than 03 in Nos, the following processes are practiced for the award of the contract
6.2.3.4	Tenders are opened in the front of the Internal Purchase Committee (IPC) members of IMRRA and same is recorded.
6.2.3.5	Technical evaluations of the bids are done by Technical Committee members.
6.2.3.6	Commercial bids are opened in presence of IPC members.
6.2.3.7	Comparison Chart is prepared for the commercial bids of technically eligible suppliers. If single bid received against E-Tender then in that case negotiation will be done with that supplier only.
6.2.3.8	Price negotiation meeting is called with L1 supplier or telephonic price negotiation is done. After successful negotiation and discussion revised quote is taken and then contract is awarded to L1 bidder
6.2.3.9	If it is observed in the comparison chart that the difference between L1 and L2 supplier is in the range of 10%, if require internal purchase committee may call L2 supplier for price negotiation meeting and decide.
6.2.3.10	The report of this price negotiation meeting is produced before the Director of IRMRA for his approval. If the Director feels necessary, he may put up this report before the Chairman of the External Purchase Committee (EPC) of IRMRA.
6.2.3.11	On the basis of recommendation from Chairman-EPC, final decision for awarding the contract for the finalized supplier is recorded duly approved by Competent Authority and processed further.
6.2.4	**Limited Tender Process (Followed on National Security ground)**
6.2.4.1	This method may be adopted when estimated value of the goods to be procured is up above rupees 200,000 where, with recommendations of concerned HOD / PL. A) National security and Confidentiality of business related; B) Recommended by customers of IRMRA. Copies of the bidding document should be sent directly by speed post/registered post/courier/e-mail to firms which are borne on the list of registered suppliers for the goods. Efforts should be made to identify a higher number of approved suppliers to obtain more responsive bids on competitive basis.
2.5	**Single Tender Enquiry**
2.5.1	Procurement from a single source may be resorted to in the following circumstances: It is in the knowledge of the user department that only a particular firm is the

	manufacturer of the required stores / items/OEM and there are no other suppliers available.
2.5.2	In case of emergency, the required stores are necessarily to be purchased from a particular source and the sufficient reason for such decision is to be recorded and approval of competent authority obtained and then order is placed.
2.5.3	For standardization/calibration of machinery or spare parts to be suitable to the existing sets of equipment (on the advice of a competent technical expert and approved by the competent authority), the required item is to be purchased only from a selected firm / OEM / Authorized dealer, distributor or agent.
6.2.6	**Proprietary Article Certificate (PAC)**
	In procurement of goods / services, certain items/services are procured from Original Equipment Manufacturers (OEMs) or manufacturer's having proprietary rights or from their authorized dealers / stockists against a PAC certificate signed by the competent authority. User should enclose with their indent wherever applicable will give a PAC certificate indicating the justification for sourcing an item/service from OEM or PAC firms or their authorized agents/dealers/distributors. In certain unavoidable cases, the procuring authority may have no alternative but to waive payment of EMD/SD for procurement on a proprietary basis.
6.2.7	**Releasing Repeat Order**
	A repeat order may be released within 12 months in the following circumstances
	i) Need for additional quantity or supply is justified by the HOD/ User department and by the competent authority of IRMRA. ii) Market intelligent report should be prepared that there is no price advantage will be available if new tender is floated. The price benefit if any may also be recorded, in case of repeat order.
	Earlier supply should be delivered 100% and or successful installation and commissioning has been done by the vendor and recommendation from end user department after monitoring the performance of the machine or quality of the goods & service supplied by the vendor
6.2.8	**Make in India :**
	To encourage 'Make in India Policy' our endeavor will be to procure maximum material or services required from local suppliers and for indigenization of spares with the help of local suppliers without compromising the quality.
6.2.9	In case of any emergency due to any unforeseen reason, Director has the authority to procure direct materials / services based on recommendations by the internal purchase committee to avoid any major loss or any similar significant reason there of.
	Any critical requirement/tailor-made items or no competitive vendors available in the market for supplying any such items/services, then the same may be recorded

	and approved by the Purchase Committee Members & Director and such vendors must be listed in the trial based vendor/unique vendor and Management must upgrade the assessment every year by reviewing the availability of alternate vendor for such items.
06.2.8	Categorizing a vendor as Trial / Unique / Approved / Black-listed will be done through regular review by Purchase Committee. Normally, 2 or 3 successfully satisfactory transactions with a Trial Vendor may make him eligible to be put under Approved List.
06.2.9	All purchase activity is done through the approved vendors unless otherwise specified.
06.2.10	**Opening of quotation:** The received quotation will be opened in the presence of01 representative from each finance, purchase and user department.
6.3	**Purchase Authority Matrix**

Sr. No.	**Cost of the items to be purchased**	**Authority for placing requisition**	**Authority of Review / Verification of technical specification / Commercial Terms.**	**Quotation**	**Authority for placing order**
1.	Below 5000/-	SH/HOD	Purchase officer/Use dept	Single/Cash	Director
2.	5000 to 15,000/-	SH/HOD	Purchase Committee	3 sealed / Email	Director
3.	15,001 to 100,000	SH/HOD	Purchase Committee	Atleast 3 sealed	Director
4	100,000 and above	SH/HOD	Purchase Committee	E-tender	Director
5	Special category (AMC, calibration & spare parts)	SH/HOD	Purchase Committee	Justification Note-> Negotiation	Director
6	< 25 lakhs	HOD	External Purchase Committee	E-tender	Director

6.4	**<u>"Role of Purchase Committee (PC)"</u>**
6.4.1	Purchase Committee consisting Chairman, Senior Scientists / representative from user departments, AD (Admin) and F.O as members.
6.4.2	Purchase of Capital goods costing more than Rs. 5,000/- shall be reviewed by PC and for all other purchases as decided by the Director through Purchase Co-

	ordinators.
6.4.3	The committee will decide the need of the machineries/instruments required as listed and put them on priority list for the financial year in the month of April/May and make decision for advertisement in leading Newspaper as well as website to call for technical and commercial bids in a sealed cover. The advertisement will clearly indicate the last date for tender receipt date.
6.4.4	A tender box is kept in the reception to receive such tenders/quotations.
6.4.5	The tender box shall be opened and tenders/quotations are collected by Secretary in presence of atleast any one of the other Purchase Committee members under instruction of Chairman.
6.4.6	These quotations/tenders shall be reviewed by Purchase Committee and decision is taken. The order shall be placed within **1 week** of opening of tender unless otherwise there is a proper/valid reason.
6.4.7	Purchase Committee will meet atleast once in three months or as needed by business exigency in a planned manner and agenda shall be prepared by Secretary and approved by Chairman may be circulated prior to the meeting.
6.4.8	The agenda shall include the progress on received tender, progress on receipt of the item against released purchase order and the progress on PO against opened tender, new items to be purchased for projects/planning for the next financial year & review of delivery of machineries etc.
6.4.9	Attendance of PC meeting is recorded and maintained by Secretary.
6.4.10	Purchase Committee members will recommend the matter to the Chairman of PC and Chairman's decision will be the final with respect to any matter.
6.4.11	Stores Incharge through AD (Admin) shall follow up with the vendors with regard to delivery schedule and then the same is put up in the meeting for any dispute regarding delay in delivery time etc.
6.4.12	Decision on the review of the technical and commercial aspects of purchasing of instruments/items shall be approved and circulated among the purchase committee by the secretary
6.4.13	Stores Incharge through AD (Admin) shall ensure that the order is placed only with the approved vendor. If the vendor is not registered, then the vendor may be asked to register himself prior to the release of Purchase Order.
6.5	**Role of external Purchase committee**
6.5.1	External PC consists of members constituted by governing council, purchase officer/in-charge & Director, IRMRA.
6.5.2	Purchase of capital goods costing more than Rs. 25/- lakhs shall be brought in the review of EPC through Director IRMRA. The committee will review the proposed need for the procurement of capital goods

6.6	**Role of Research Advisory Committee (RAC)**
6.6.1	The key members of RAC will meet once in a year to discuss the ongoing R&D activities and will also review the existing testing facilities. The recommendation made by the RAC on upgradation of existing test facility or procurement of new test equipments will be reviewed by PC/Director and accordingly procurement will be done by the purchase procedure.
6.7	**Customer's verification at sub-contracted products**
6.7.1	IRMRA do encourage the customer verification of our products in process at our sub contractor premises and the records are established for such activities.
6.7.2	**Amendments to Purchase memos:-** Amendments are made in P.O if required within the scope of govt. regulatory requirements.
6.8	**Role of Store I/c** (Receipt, Issue, Stock, Maintenance & Inventory)
6.8.1	He / She receive the materials from vendor and do the inventory.
6.8.2	He / She issues the material to user dept as per the specification approved on the purchase requisition slip.
6.8.3	He / She maintain minimum stock (chemicals/consumables) in co-ordination with user dept.
6.8.4	He / She prepare and submit a monthly report on the stock statement as discussed with Director and in co-ordination with purchase dept.
6.9	**Role of Supplier**
6.9.1	Registration
6.9.2	Approval
6.9.3	Performance Appraisal
6.10	**Release of Payment**

6.10.1	The supplier/vendor will submit a bill against supplied items, copy of delivery challan, purchase order, inspection report to account dept of IRMRA.
6.10.2	If the submitted documents by the supplier/vendor are found okay then account dept will release the payment as per the payment terms is stipulated in the P.O.
6.10.3	Any delay in payment to supplier beyond the stipulated period or release of payment before the due date will be viewed seriously. Such matter should be brought before the Director for necessary approval and advice.
6.11	**Records**
6.11.1	P.O file
6.11.2	Format for release of payment
6.11.3	List of approved vendors
6.11.4	Details of assets / records in soft copy
6.11.5	Stock register is maintained in soft copy.

Title of the procedure	Procedure for process control of testing activities.
Purpose	To justify the technical capability of IRMRA & to satisfy the customer needs.
Scope	This procedure is applicable to Testing Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 & NABL-212
Responsibility	1. Director for total control. 2. CSC Head for customer handling. 3. HOD (Testing) for testing of samples and report generation. 4. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/07

PROCEDURE:

07.1 **IRMRA** follows a systematic process for generating the test report from test materials / samples supplied by customer.

07.2 Customer supplied samples are entered in the office and sent to Customer service cell (CSC). CSC issues quotation / CR/ Pro-forma invoices and advises the client for making payment, at account section.

07.3 After receipt of payment, CSC divides the samples with the help of helpers and arranges to prepare the specimens. In case of mixing assignments / evaluation of chemicals / compound samples then physical section is involved for the mixing / moulding activities. The supervisor of physical section supervises the mixing / moulding activities under the guidance of the section head.

CSC distributes the assignments to various sections through software. The samples / specimens are sent physically through helpers of Sections / or CSC. The test assignments are distributed by section supervisors to various assistants.

He also supervises the test activities under guidance of Section heads/Dy. Heads and compiles the results. Assistants do the testing of samples as per the SOPs/Test standards under the guidance of SH/Supervisors. The SH authorizes the test results and forwards for printing purposes. Then CSC supervisors estimate the actual cost and forward the report to the printing assistants.

07.4 The completion of the assignment is intimated to the Section Head through software and the enclosure (if any) personally / through helpers.

07.5 The letter is maintained in the CSC. The reports are printed with unique report number. Billing is also done as per the actual cost report available on the network or as per CSC's advice. Deviation if any from online information is recorded for future references.

07.6 The printed report is checked for its correctness by comparing with the observation records/online view status information by The Head or Dy. Head, CSC and authorized by HOD (Testing or CSC Head) and the technical reports checked for its correctness by SHs and authorized by HOD (Testing). Signed reports are verified at the CSC before despatch. The variation in testing charges if any also verified CSC and corrected and intimated to the party for the changes if any.

07.7 The signed & verified reports are sent to office for despatch. Despatch note is maintained at the CSC office.

07.8 Procedure for validation of process: -

07.9 The modified test methods or in house developed test methods, IRMRA shall determine the level of repeatability and reproducibility, keeping in view, the following factors which affect the results: -

07.9.1 Sampling

07.9.1.1 In case of sample preparation, it is ensured that Homogeneity is obtained and proper test method is selected, with right equipment with desired accuracy. Trained persons are used for such testing.

07.9.1.2 Effect of equipments & instrumental / technical factors are minimized and controlled by defining the capability (accuracy & range), establishing clear descriptive procedure for operation, calibration etc.

07.9.2 Human factors are controlled through basic education / knowledge, practical experience and on job training.

07.9.3 Environmental factors like temperature, pressure, humidity, contamination / mix up of samples etc are properly controlled in case such factors affect the quality of results.

07.9.4 IRMRA participates Inter laboratory testing to validate its process of testing time to time in order to show its technical competence / capability.

07.9.5 Any process found to be not meeting the requirement of the actual process is immediately notified to the reporting authority for making necessary arrangement of validation process through maintenance/training/or as applicable in the process.

07.9.6 **Records:**

07.10 All forms, Registers, slips, are completed and signed all quality records.

07.10.1 Back up records.

07.10.2 MIS reports.

07.10.3 Correspondence with customer / software testing module.

Title of the procedure	Quality Plan for verification of product's quality.
Purpose	To establish a procedure for verification of the product / test report.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers
Reference	ISO 9001: 2015
Responsibility	1. Director for total control. 2. HODs for guiding the Sectional Heads. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/08

08.1 **Procedure for verification of developed product's quality :-**

08.1.1 Project Leader verify all the process related to product development activity, including process control activities like Raw material testing, in-process testing, finished product testing activities with the specified accepted limits.

08.1.2 Project Leader establishes individual Quality Plan for development of products to ensure the quality of products requirement.

08.1.2.1 Project Leader certifies that product developed at IRMRA is complies the specified requirements. The samples are sent to the testing lab and receive the results based on which the product is certified.

08.1.2.2 PL verifies the compliance of product conformity before dispatch.

08.1.2.3 Despatch note with regard to the developed items along with the test report is made available with the administration for the record purpose.

08.2 Procedure for verification of test report :-

08.2.1 IRMRA established the procedure for verification of test report before despatch.

08.2.2 There are five stages of verification of report and signed :-

08.2.3 by the supervisor of section

08.2.4 by the SH & HOD

08.2.5 by the CSC Head & Dy Head

082.6 by A/C / billing section

08.2.7 by dispatch person.

08.2.8 If any stage is found to be faulty / not as per the requirement, then the test report is rectified as per the requirement and then only it is dispatched.

08.3 Records: - Dispatch note.

Title of the procedure	Procedure for plan / process modification & Authorization
Purpose	To establish a procedure for authorization of new process / modification of testing methods.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City as applicable
Reference	ISO 9001: 2015 Cl. No. 8.5.4 ISO 17025 : 2017 Cl. No. 7.2
Responsibility	1. Director for total control. 2 HODs for guiding the Sectional Heads. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/09

Procedure:

09.1 HOD/Section head identifies the new process / process modification requirements as per the need or customers request.

09.2 HOD/Section head prepare quality plan / procedure for testing, including all system requirements as per ISO-17025:2017.

09.3 Head of department approves the test procedure before implementation.

09.4 Operators are trained appropriately for executing the testing as per the approved plan / procedure.

09.5 Records: - Test plan / procedure – SOP.

Title of the procedure	**ASSURING THE QUALITY OF TEST RESULT**
Purpose	To establish a procedure for assuring the quality of test result
Scope	This procedure is applicable to all sections of testing Department of IRMRA, Thane and regional centres at Kolkata and Sri city
Reference	ISO/IEC 17025: 2017, Cl. No. : 7.7 ISO 9001: 2015
Responsibility	1. Director for total control. 2. HODs for guiding the Sectional Heads. 3. Lab Supervisors/SHs/TM for executing QA activities at different levels. 4. QM/MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/10

Procedure :-

10.1 In order to ensure the accuracy, precision, repeatability and reproducibility of the test results reported by the laboratory. IRMRA adopts the following quality control measures :-

10.1.1 **"Use of Standard/Certified reference materials/Reference Materials"**

IRMRA periodically uses Standard or Certified reference materials / ultra pure reference materials / in-house reference material to check the continuous suitability of equipment status / test method.

10.1.2 **"Inter-laboratory comparisons (ILC) / proficiency testing"**

IRMRA participates in proficiency testing (IL/PT) program conducted by NABL and any Inter-laboratory comparisons (ILC) conducted by any other national or international organizations. If required IRMRA also conducts inter laboratory testing programs involving other accredited labs along with its own lab.

10.1.3 **"Replicate tests"**

IRMRA conducts regularly replicate tests using the same or different methods. This replicate tests are done at lab level and coordinated by lab supervisor/SH, to verify the competency of person/methods, by using same or different persons/methods.

10.1.4 **"Retesting of Retained Samples"**

IRMRA conducts retesting of retained sample. This is done at Technical Manager level by coding the sample differently. The remaining samples after testing are retained for a period of three months. TM selects randomly any sample and sends to lab with different code for testing.

Then, TM compares the results of retesting with previous results and takes appropriate corrective action (if any).

10.1.1.5 **"Correlation of test results"**

Correlation of test results with other test results of same item/sample is done as per the requirement. This is done by experienced persons using their technology expertise knowledge on specification etc.

10.2 **Analysis of data**

Whenever IRMRA organises Inter Laboratory Comparisons, either Z-score (Robust / Classical) is calculated to evaluate the performance of each of the participants or other statistical techniques are adopted. Further, whenever the laboratory participates in more than one ILPT/ILC for a particular test parameter, trend analysis of the performance of the laboratory is done for the concerned parameter. The performance of the laboratory in various programmes of ILPT/ILC, trend analysis, retesting of retained samples etc., are reviewed by the management during MRM at least once a year.

10.3 **Corrective and Preventive Action**

If the performance of the laboratory is not satisfactory in any of the above quality assurance test activities, then necessary corrective action and preventive action is taken as per the procedures for Non conforming activities (Proc no, IRMRA/QP/04) and CA& PA (Proc no. IRMRA/QP/05). The results of the above activities are recorded and reviewed in MRM as per the procedure No. IRMRA/QP/12.

10.4 **RECORDS: -**

a) Reference Checks/Replicate test results with Lab supervisors/SHs.
b) IL/PT test results, Retesting results with TM.
c) CA & PA Records.
d) MRM Records, with QM.

Title	CALIBRATION OF EQUIPMENT
Purpose	To establish a procedure to control, calibrate and maintain the Inspection, Measuring, and Test equipment.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001: 2015, Cl. No. 7.5.2, 8.5.4 ISO/IEC 17025 : 2017 : Cl. 6.4
Responsibility	1. Director for total control. 2. HODs for guiding the Sectional Heads. 3. MR for prepare, Issue, control & amendments 4. Section Head of individual section
Procedure Number	IRMRA/QP/11

PROCEDURE: -

11.1 The necessity and importance of the calibration of the IMT equipments are understood.

11.2 Records of Calibration certificates of IMT equipment are maintained by Section Heads with details.

11.3 Calibration of IMT equipment is done by the following agencies :

11.3.1 External Agency :-

This calibration is done by external agency whose name appears in approved vendor's list of IRMRA. Care is taken to see that these calibrations are made with Reference to National / International Standards and traceability of which is duly established and documented.

11.3.2 Internal Agency: -

11.3.2.1 Auto calibration:

This is done as per instrument manual by assistants / SHs or sometimes the sophisticated instruments itself does its own calibration whenever we give comment for base line correction, Tuning etc.

11.3.2.2 By other methods:-

This is carried out for the equipment, which could be calibrated internally by IRMRA using the standard method of calibration procedure given in literature or using Standard calibrated equipment having traceability certificate to either National or international standards. Work instruction for this type of calibration is prepared and implemented.

11.4 **Identification of instrument / equipment is done section wise.**

11.4.1 IMT equipment is identified by the number given by Manufacturer of the equipment/ Instrument or code number of individual instrument with the specific code by which they are traceable in master list.

11.4.2 The status of calibration of an instrument is labeled with the following particulars.

11.4.2.1 Date of calibration:

11.4.2.2 Calibration status

11.4.2.3 Next Calibration due on.

11.5 If any IMT equipment is found to be out of calibration, it is taken out from use and labeled as "OUT OF CALIBRATION".

11.6 The status of Calibration due date can be prepared monthly basis using the software operation and is circulated to section Head through HOD for further follow-up action.

11.7 RECORDS: -

11.7.1 Master list of calibration records.

11.7.2 Status of the calibration

11.7.3 Calibration certificates files

Title of the procedure	Management Review
Purpose	To establish a procedure to review the effectiveness of quality management system of IRMRA.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001: 2015 ISO 17025:2017 Cl. No. 8.9
Responsibility	1. Director for total control. 1. HODs for guiding the Sectional Heads. 3. QM / MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/12

Procedure:

12.1	IRMRA formed a committee to review the adequacy of Quality Management System and its effectiveness towards achieving the quality objectives.
12.2	**Structure of the Committee is as follows :-** Structure of Committee comprise of Director as Chairman, QM / MR as Member Secretary and all Officers/HODs/SHS/ as members of Committee.
12.3	**Frequency of meeting**: MRM will be held at least once in 6 months.
12.4	**Agenda :-** The following agenda will be discussed during MRM.
12.4.1	changes in internal and external issues that are relevant to the laboratory
12.4.2	Fulfilment of objectives
12.4.3	suitability of policies and procedures;
12.4.4	status of actions from previous management reviews;
12.4.5	outcome of recent internal audits;.
12.4.6	corrective actions;
12.4.7	assessments by external bodies;
12.4.8	changes in the volume and type of the work or in the range of laboratory activities;
12.4.9	customer and personnel feedback;

PREPARED BY	ISSUED BY
Management Representative	Management Representative

12.4.10	complaints;
12.4.11	effectiveness of any implemented improvements;
12.4.12	adequacy of resources;
12.4.13	results of risk identification;
12.4.14	outcomes of the assurance of the validity of results; and
12.4.15	other relevant factors, such as monitoring activities and training.
12.5	**Pre-meeting arrangements.**
12.5.1	Member Secretary after consultation with the Director, will fix up the date, place and time of MRM and notify all members of the MRC by a circular at least 2 days in advance unless it is very urgent.
12.5.2	This circular will consist of date, time, venue, and agenda of the meeting.
12.5.3	Member Secretary will request members to prepare back - up papers / presentation for discussion with reference to agenda.
12.6	**Conducting the meeting.**
12.6.1	The attendance of members for the meeting will be recorded in the register.
12.6.2	The proceedings of meeting will take place in a cordial manner and controlled by the Chairman.
12.6.3	Member Secretary will arrange to take notes for the meeting to enable him to make the final minutes.
12.7	**Post meeting activities.**
12.7.1	Member Secretary will prepare the minutes of the meeting and the same will be circulated to the members within two weeks time after obtaining approval from Chairman.
12.8	**Follow up activities.** All members are constantly to send a action status report to the Chairman (MRC) with an intimation to Member sec.

12.9	**RECORDS** :
12.9.1	Notice & Agenda of the meeting
12.9.2	The minutes and attendance of the meetings

Title of the procedure	Procedure for Competence, awareness and training.
Purpose	To establish a documented procedure for identifying Training needs & imparting Training for Employees.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 ISO /IEC 17025:2005, Cl. No. 6.2
Responsibility	1 Director for total control 2 HODs for guiding the Sectional Heads. 3 HR officer for coordinating Training activities & updating training records. 4 HODs / SHs for identifying training needs of their subordinates. 5 QM / MR for prepare, Issue, control & amendments of procedures.
Procedure Number	IRMRA/QP/13

PROCEDURE: -

13.1 HOD / SH [HR] co-ordinates the training activities of the employees who are responsible for quality activities.

13.2 HOD / SH [HR] will maintain a the employees file, which will give the following information about employees but not limited to .

13.2.1 Name of the employee.

13.2.2 Date of birth

13.2.3 Education.

13.2.4 Experience.

13.2.5 Date of joining IRMRA.

13.2.6 List of training received. This list is updated every year or when a new employer joins the organization.

13.3 **Identification: of Training Needs :-**

13.3.1 HOD / SH [HR] gets the training needs from the respective HODs / SHs either through mail or through APAR forms. APAR forms duly filled annually as per the HR Manual which also includes the training needs for the concern employee.

13.3.2 Director will identify the training needs of the HODs and also for himself as deemed necessary. HODs identifies training needs of SHs and Supervisors and assistants.

13.3.3 HOD / SH [HR] will prepare a training calendar, based on training needs identified and get the approval of Director.

13.3.4 Once the training need is approved either for the individual employee or for the group of employees, the HOD / SH [HR] will make arrangement for imparting training.

13.3.5 The training need is identified for ensuring the proper substitute for handling all

equipments / instruments at all the levels.

13.4 **IMPARTING TRAINING:**

13.4.1 Training is given to the employees in any of the following ways;

13.4.1.1 In house by company's senior employee.

13.4.1.2 By inviting outside experts.

13.4.1.3 Deputing a selected person for external training.

13.4.2 The employees are asked to give a full detailed report about training received by the person after the completion of training to HOD / SH [HR].

13.4.3 Sometimes the trained employees are asked to hold a group / lecture about their training to the group of selected employees.

13.4.4 Director/HOD/Section Head evaluates usefulness of the training received by the employees during their day to day performance in the work, which will form the basis for annual assessment of an individual.

13.4.5 Apart from this, whenever a new employee joins duty / old employee is transferred to a new assignment, when a new equipment is placed, when a persons performance is poor, when technology changes he is given an induction (on the job training) by an experienced co-worker / supervisor until he is familiar with the job.

13.4.6 The scope of training for employees will be for the purpose of,

13.4.6.1 Up gradation of working skills.

13.4.6.2 Familiarity with new machines for efficient operation and maintenance.

13.4.6.3 Improving organizational behavior.

13.4.6.4 Job motivation.

13.4.6.5 Leadership.

13.4.6.6 Safety and environmental control.

13.4.6.7 Discipline.

13.4.6.8 Special training such as ISO awareness / quality system etc.

13.4.7 Internal training programmes for employers of IRMRA.

1) The internal training program is arranged for enhancing the knowledge and skill of the persons.

13.4.8 Training records will be kept by HOD / SH [HR]

Title of the procedure	Procedure for Design and development, Planning and its Control for Training Services
Purpose	To establish a documented procedure for Training plan and its control.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001: 2015 Cl. No. 8.3.2, 8.3.4
Responsibility	1. Director for total control. 2. Training Head for plan and control of design and development of plan 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/14 (a)

Procedure:

14.1	IRMRA prepares design / developmental plan as under, before undertaking any training program for training services.
14.2	The whole design and development activity is subdivided into small manageable tasks and responsibilities is clearly defined and documented for each task. Assignments sheets are reviewed in the regular design reviews and records are kept.
14.3	The Training head in consultation with the Director shall prepare the training calendar for the year as per current requirement and needs of rubber and allied industry. The prepared training calendar is divided on 1) short term technical training courses on Rubber Technology, 2) training courses on Lab Management system. The training calendar comprises of title of the course, duration, course fees and the registration details
14.4	The prepared and finalized training calendar for year is uploaded in IRMRA's website and is circulated to all the existing customers by CSC& Marketing Department.
14.5	The course content along with other necessary details against each scheduled training course is circulated through email to all the target & concerned customers by CSC and marketing department well before the commencement of the training course
14.6	Design and verification activities are planned and assigned to qualified staff equipped with adequate resources.
14.7	The documents are tabulated and amended from time to time, as the design is getting evolved and will then decide upon a direction to start the work.

PREPARED BY	ISSUED BY
Management Representative	Management Representative

14.8	Training Head will collect all the information from the customer / Director to the maximum extent possible to decide the design input parameters.
14.9	The Training head will study all this available information and review the adequacy, locate all the gaps, where efforts are required to obtain the additional information.
14.10	**Organizational and Technical interfacing:**
14.10.1	Organizational and technical interfaces between different groups are identified and necessary information are documented, transmitted and regularly reviewed.
14.10.2	These are conducted by the training head and if required with the concerned section Head of various sections of IRMRA to obtain the input for development of work.
14.10.3	These inputs from the concerned section are noted down / recorded in the project file.
14.11	**Design changes :**
14.11.1	Design change may be required in any of the following reasons
14.11.2	Finding difficulty in executing the training services as per customer requirement,
14.11.3	Errors in design.
14.11.4	To achieve improvement in design
14.11.5	To meet additional demand of the customers
14.11.6	To incorporate advanced topics / new technologies.
14.11.7	The need for continuous improvement.
14.11.8	All the above factors are reviewed by the training head in a meeting with Director. The training head implements the design changes under due approval of the Director. The changes of the design are recorded and changes are intimated to the persons concerned and the training head will ensure that design change is reflected in all pertinent documents.
14.12	**RECORDS**: - Design Plan Record.

Title of the procedure	Procedure for design & development planning and its control.
Purpose	To establish a documented procedure for design & development plan and its control.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City as applicable
Reference	ISO 9001: 2015 Cl. No. 8.3.2, 8.3.4
Responsibility	1. Director for total control. 2. Project Leader for plan and control of design and development of plan. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/14

Procedure :

14.1 IRMRA prepares design / developmental plan as under, before undertaking any design / developmental activity.

14.2 The Project leader shall draw up plans that identify responsibility for each design and developmental activity.

14.3 The whole design and development activity is subdivided into small manageable tasks and responsibilities is clearly defined and documented for each task. Assignments sheets are reviewed in the regular design reviews and records are kept.

14.4 Design and verification activities are planned and assigned to qualified staff equipped with adequate resources.

14.5 The documents are tabulated and amended from time to time, as the design is getting evolved and will then decide upon a direction to start the work.

14.6 Project leader will collect all the information from the customer / Director to the maximum extent possible to decide the design input parameters.

14.7 Project leader will study all this available information and review the adequacy, locate all the gaps, where efforts are required to obtain the additional information.

14.8 **Organizational and Technical interfacing:**

14.8.1 Organizational and technical interfaces between different groups are identified and necessary information are documented, transmitted and regularly reviewed.

14.8.2 These are conducted by the project leader and if required with the concerned section Head of various sections of IRMRA to obtain the input for development of work.

14.8.3 These input from the concerned section are noted down / recorded in the project file.

14.9 **Design changes :**

14.9.1 Design change may be required in any of the following reasons

14.9.1.1 Finding difficulty in manufacturing the product as per specification,

14.9.1.2 Errors in design.

14.9.1.3 To achieve improvement in design

14.9.1.4 To meet safety requirements

14.9.1.5 To meet additional demand of the customers

14.9.2 All the above factors are reviewed by Project leader in a meeting with Director. The project leader approves the design changes and then it is implemented. The changes of the design are recorded and changes are intimated to the persons concerned and Project leader will ensure that design change is reflected in all pertinent documents.

14.10 **RECORDS**: - Design Plan Record.

Title of the procedure	Procedure for design & development input & outputs for training services
Purpose	To establish a documented procedure for design inputs & outputs
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 - Cl. No. 8.3.3 & 8.3.5
Responsibility	1. Director for total control. 2. Project Leader for collection of design inputs and output requirements 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/15(a)

Procedure:

15.1	**The design input for the development work is obtained from: -**
15.1.1	***In case of the customer proposed training requirement : -***
15.1.1.1	Scrutinizing the customer requirements thoroughly.
15.1.1.2	Referring customer requirement.
15.1.1.3	Related literature survey if required.
15.1.1.4	Customer specified technical requirements.
15.1.1.5	Acceptance criteria of training / training report.
15.1.1.6	Regulatory requirements if any.
15.1.2	***In case of IRMRA' proposed training requirement :-***
15.1.2.1	Objectives of the proposed training
15.1.2.2	Acceptance criteria of the conducted training / training report.
15.1.2.4	Regulatory requirements if any
15.1.2.5	Related literature survey if required
15.1.3	***In case of internal Training : -***
15.1.3.1	Objectives of the proposed training
15.1.3.2	Identified training need to be achieved.
15.1.3.3	Raw material, technical / back up literature
15.1.3.4	Environmental regulation & safety aspects
15.1.4	**The broad design inputs consists of the following activities**
	(a) Compilation of course/study material including power-point slides, case studies after receipt of the same from the concerned faculty towards the allotted topic against each scheduled course (b) Administrative arrangement for imparting the training including air conditioned and spacious training hall, comfortable seating arrangement, power-point projector, board, Flip charts, marker pen, stationery requirements for trainees including scribbling pad, pen, pencil, eraser, sharpener and study material;

15.1.5	Design input parameters are reviewed for the adequacy of the requirements and possibilities of the collecting input requirements are worked out and approved. Record is maintained for this activity.
15.2	**Training Work:**
15.2.1	After completion of the above activities, the original training work starts and special attention is given for the following aspects as per the requirement for execution of the training.
15.2.1.1	Content of the training course as required
15.2.1.2	Purchase of required training materials.
15.2.1.3	Supervision of actual training.
15.3	**Preliminary Activities**
15.3.1	The customer approaches IRMRA with a request for development of any training services
15.3.3	In case of external customers a contract is established through letter correspondence with the customer. Capability of IRMRA is considered and the project is accepted and handed over to well-qualified & competent personnel who will act as project leader/ co-ordinator.
15.3.4	Aims and objectives of the design / development of the training are established in a meeting between the Director, training head and may also be with the Customer. Records of the relevant documents are kept.
15.3.5	Training head will then open up a new file for this job, and give an identification number.
15.4	**Design output** :
15.4.1	Based on the project input & aim of the project/design activity, Training head shall identify the form in which the design output is to be generated.
	Design output will be for the following activities
15.4.1.1	**Course material:-** The training head/Course Co-ordinator checks the prepared course material w.r.t contents of the course , sequential order of the topics as per the schedule, printing of course material and he also checks that all the printed material are readable and the diagrams, images and the graphs, if any are clear and readable
15.4.1.2	**Practical Observation:-**
15.4.1.3	**Examination**
15.4.1.4	**Training Certificate:-** Issuance of the certificate after the end of the course
15.5	**RECORDS** :-
15.5.1	Design input & Output lists.
15.5.2	Minutes of meeting

Title of the procedure	Procedure for design & development input & outputs
Purpose	To establish a documented procedure for design inputs & outputs
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 - Cl. No. 8.3.3 & 8.3.5
Responsibility	1. Director for total control. 2. Project Leader for collection of design inputs and output requirements. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/15

Procedure:

15.1 The design input for the development work is obtained from: -

15.1.1 In case of the customer proposed projects: -

15.1.1.1 Scrutinizing the customer requirements thoroughly.

15.1.1.2 Referring Specification, standards or customer supplied specification.

15.1.1.3 Related literature survey if required.

15.1.1.4 Customer specified technical requirements, Drawing etc.

15.1.1.5 Acceptance criteria of the developed product / project report.

15.1.1.6 Regulatory requirements if any.

15.1.2 In case of IRMRA' proposed project :-

15.1.2.1 Objectives of the proposed project.

15.1.2.2 Customer's agreement and specified requirements made by customer at the time of sanctioning project.

15.1.2.3 Acceptance criteria of the developed product / project report.

15.1.2.4 Regulatory requirements if any

15.1.2.5 Related literature survey if required

15.1.3 In case of internal project: -

15.1.3.1 Objectives of the proposed project & Market requirements.

15.1.3.2 Technical data specification required to be achieved.

15.1.3.3 Raw material, technical / back up literature

15.1.3.4 Environmental regulation & safety aspects

15.1.4 Design input parameters are reviewed for the adequacy of the requirements and possibilities of the collecting input requirements are worked out and approved. Record is maintained for this activity.

15.2 **Project Work:**

15.2.1 After completion of the above activities, the original project work starts and special attention is given for the following aspects as per the requirement for execution of the project.

15.2.1.1 Drawing / sketch as required

15.2.1.2 Purchase of required quality materials.

15.2.1.3 Fabrication of die, moulds etc. if required

15.2.1.4 To arrive at suitable formulation for proper controlling.

15.2.1.5 Supervision of actual work.

15.2.1.6 Testing & Inspection of the developed product / chemicals / ingredients

15.2.1.7 Process control parameters

15.2.2 Here, prototype materials are produced based on the objectives and are tested for its verification.

15.3 Preliminary Activities

15.3.1 The customer approaches IRMRA with a request for development of any rubber product.

15.3.2 IRMRA's own department/section wants to undertake a development project through proper channel for their own purposes to show the IRMRA's technical competence and infrastructure with respect to the market requirements by publishing technical paper.

15.3.3 In case of external customers a contract is established through letter correspondence with the customer. Capability of IRMRA is considered and the project is accepted and handed over to well-qualified & competent personnel who will act as project leader/ co-ordinator.

15.3.4 Aims and objectives of the design / development of project are established in a meeting between the Director, project leader and may also be with the Customer. Records of the relevant documents are kept.

15.3.5 Project leader will then open up a new file for this job, and give an identification number.

15.4 **Design output** :-

15.4.1 Based on the project input & aim of the project/design activity, Project leader shall identify the form in which the design output is to be generated.

Design output may be in the form of

15.4.1.1 Specification

15.4.1.2 Product

15.4.1.3 Drawings

15.4.1.4 Process instructions

15.4.1.5 Or Detailed project report or publication in reputed journals.

15.5 **RECORDS** :-

15.5.1 Design input & Output lists.

15.5.2 Minutes of meeting

Title of the procedure	Procedure for design and development review
Purpose	To establish a procedure for review of design & development.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 - Cl. No. 8.3
Responsibility	1. Director for total control. 2. Project Leader for organizing review meeting. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/16 (a)

Procedure: -

16.1.	Design review of the training activities is carried out at end of every phase/stage. Design reviews are carried out training head and one or more group leaders who are handling sub activities of the design along with subordinates if any. Design review team will take the following guidelines for discussion and further approval for any design activity.
16.1.1	Ease of the job with the existing facilities.
16.1.2	Inspection requirements and acceptance specification with respect to the customer requirements.
16.1.3	Reliability and administrative requirements
16.1.4	Study materials is relevant and appropriate to the course
16.1.5	Training is delivered effectively and evaluated thoroughly
16.1.6	Attendance of the participants is checked
16.1.7	Availability of faculty/ laboratory person as per the schedule.
16.1.8	Alternatives arrangements in case of failure.
16.1.9	Smooth conduction of training sessions as per scheduled time
16.1.10	Easy way of handling training participants by way of their feedback on content of the program, course material, venue and administrative arrangements.
16.2	Design review is done at the following stage and records of the same are kept:
16.2.1	Completion of the Input parameters.
16.2.2	Completion of the design plan.
16.2.3	Outputs as per planning and input parameters.
16.2.4	During verification stage of the total project.
16.3	**Design review records are kept which includes the following information:**
16.3.1	Date of review

16.3.2 16.3.3 16.3.4	Topic reviewed Persons present & Signature Out put of the review.
16.4	RECORDS: - Review meeting record.

Title of the procedure	Procedure for design and development review
Purpose	To establish a procedure for review of design & development.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015, Cl. No. 8.3
Responsibility	1. Director for total control. 2. Project Leader for organizing review meeting. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/16

Procedure: -

16.1. Design review of the developmental activities is carried out at end of every phase/stage or every six months period of time if the project is long-term basis or as per MoU with the customer. Design reviews are carried out with the team having Project leader and one or more group leaders who are handling sub activities of the design along with subordinates if any. Design review team will take the following guidelines for discussion and further approval for any design activity.

16.1.1 Ease of the job with the existing facilities.

16.1.2 Inspection requirements and acceptance specification with respect to the customer requirements.

16.1.3 Assuring the less rejection or avoiding more repetition of the testing.

16.1.4 Reliability and maintenance requirements

16.1.5 Easy way of handling operation.

16.2 Design review is done at the following stage and records of the same are kept:

16.2.1 Completion of the Input parameters.

16.2.2 Completion of the design plan.

16.2.3 During verification stage of every phase or the total project.

16.3 Design review records are kept which includes the following information:

16.3.1 Date of review

16.3.2 Topic reviewed

16.3.3 Persons present & Signature

16.3.4 Out put of the review.

16.4 RECORDS: - Review meeting record.

Title of the procedure	Procedure for design verification & validation
Purpose	To establish a procedure for verification and validation activities of design & development.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015
Responsibility	1. Director for total control. 2. Project Leader for implementing. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/17(a)

Procedure: -

17.1 **Design verification** :

17.1.1 IRMRA assigned competent personnel for verifying the design activities. Design verification shall ensure that design output meets input requirements by means of design control measures such as

17.1.1.1 Recording design reviews

17.1.1.2 Undertaking feedback from the participants on

- Course content,
- Course material
- Presentation made by the faculty
- Relevance of the course topics
- Extent of coverage
- Adequacy of communication,
- Venue and administrative arrangements

17.2 **Design validation:**

17.2.1 Design validation of training service is done by: -

17.2.1.1 By question & Answer session during the training program.

17.2.1.2 Performance evaluation of the trained person

17.2.1.3 By examination in LMS courses.

17.2.1.4 Third party approval, if demanded by customer.

17.3 RECORDS:-

17.3.1 Technical data of verification & validation process.

17.3.2 Review – meeting minutes.

Title of the procedure	Procedure for design verification & validation
Purpose	To establish a procedure for verification and validation activities of design & development.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015
Responsibility	1. Director for total control. 2. Project Leader for implementing. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/17

Procedure: -

17.1 Design verification:

17.1.1 IRMRA assigned competent personnel (Mostly project leader themselves) for verifying the design activities. Design verification shall ensure that design output meets input requirements by means of design control measures such as

17.1.1.1 Recording design reviews

17.1.1.2 Undertaking quality tests and demonstrations

17.1.1.3 Doing Inspection & Testing (Physical, Chemical & Instrumental testing) as per customer requirements – to match with the performance / specification of the developed product / compound.

17.1.1.4 Carrying out alternate calculations or comparative results:

17.1.1.5 Comparing the prototype product with the existing product or imported product or customer supplied sample in terms of technical parameters, which are helped to decide the design input parameters. A test plan may be prepared by Project leader to ensure that the comparison on both the products is done in the similar type of test conditions. This type of job is assigned to the technically competent person along with the test procedure or standard.

17.2 Design validation:

17.2.1 Design validation of the product is done by: -

17.2.1.1 Trials can be taken from customer's end and approval is obtained by sending the product to the customer along with the internal technical data.

17.2.1.2 Evaluating the developed ingredients / chemicals in suitable rubber formulation.

17.2.1.3 Third party inspection for testing and final approval, if demanded by customer.

17.3 RECORDS:-

17.3.1 Technical data of verification & validation process.

17.3.2 Review – meeting minutes.

Title of the procedure	Procedure of identification & traceability
Purpose	To establish a procedure for identification & traceability of IRMRA test report / product.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 - Cl.no. 8.5.2 & 8.5.4
Responsibility	1. Director for total control. 2. HODs for guiding the Sectional Heads / supervisors. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/18

Procedure: -

18.1. IRMRA issues unique identification numbers for each assignment. The test reports are printed in an approved format / pre - printed Letter Head. IRMRA report will contain the following minimum information: -

18.1.1 Name and address & location of the lab.

18.1.2 Unique identification of the report i.e. report number with section code which is maintained through the complete testing activities.

18.1.3 Name and address of the client

18.1.4 Description & identification of the item tested or evaluated.

18.1.5 Characterization and condition of the test items where appropriate.

18.1.6 Date of receipt of sample / item to be tested and date of performance of test where appropriate.

18.1.7 Test specification or standards followed where applicable.

18.1.8 Reference of sampling procedure where relevant.

18.1.9 Deviation of test procedure if any.

18.1.10 Support results by table, parameter sheets, graphs etc.

18.1.11 Signed by approved signatories.

18.2 Unique lot or batch number is given for every product is being dispatched to the customers. The traceability record is maintained through the product reliability.

18.3. Records: Report Number Allocation Register, & Customer correspondence file.

Title of the procedure	PROCEDURE FOR IMPROVEMENT
Purpose	The purpose of this Procedure is to continually improve the effectiveness of the management system through the use of quality policy, objectives, audit results, analysis of data, corrective and preventive actions and management review.
Scope	This procedure is applicable to all aspects of the documented management system, which is implemented in the laboratory in accordance with ISO/IEC 17025:2017 (Cl. No. 8.6.1) and ISO 9001:2015 QMS at IRMRA, Thane and regional centers at Kolkata and Sri City.
Responsibility	The Director, Quality Manager, Technical Manager, HODs, SHs and Supervisors are responsible for continually improving the effectiveness of the management system at appropriate levels.
Procedure Number	IRMRA/QP/19

Procedure:

19.1 For the effective implementation of the management system, documents including Procedures and Work Instructions are prepared as per ISO/IEC 17025:2017/ISO 9001:2015 and the same are made available to the concerned laboratory personnel for use.

19.2 Further, formats, checklists and plans are also prepared and used for various activities including the following:

19.2.1 Formats for the generation of different quality and technical records.
19.2.2 Check-list for conducting vertical and horizontal internal audit

19.3 Plan for the following activities is prepared:

19.3.1 Internal audit of different sections of the laboratory.
19.3.2 Calibration and maintenance of various equipments and accessories.
19.3.3 Participation in Inter Laboratory Proficiency Testing (ILPT) or Inter Laboratory Comparison (ILC) incorporating all the mechanical and chemical test parameters covered in the NABL scope of accreditation.
19.3.4 Re-testing of retained samples covering the scope of NABL accreditation.

19.4 The Director, Quality Manager, and Technical Manager ensure continual improvement in the effectiveness of the management system by (i) scrutinizing the various quality and technical records generated in the laboratory, (ii) verifying

whether the various activities are carried out as per the plan and also through the following means:

19.4.1 Analysis of the feedback received from the customers to ensure customer satisfaction as stated in the Quality Policy through calculation and monitoring of customer satisfaction Index as per the Process no. IRMRA/QPROC/07, by CSC Head / HOD.

19.4.2 Review of the achievement of each of the objectives stipulated in the Quality Manual by QM / MR.

19.4.3 Review of the adequacy of the Objectives stipulated in the Quality Manual and modifying the same if required by QM / MR.

19.4.4 Review of the type and number of NCs encountered in the internal / external audits and **their non recurrence** in subsequent audits by HODs.

19.4.5 Participating in Inter Laboratory Proficiency Testing (ILPT) or Inter Laboratory Comparisons (ILC) programmes for different mechanical and chemical test parameters and if necessary organising inter laboratory comparisons with other labs who are interested to participate by TM / QM.

19.4.6 Conducting trend analysis whenever the laboratory participates in more than one programme of ILPT/ILC for the same parameter and thereby ensuring the maintenance of good performance of the laboratory. The trend analysis is also carried out by HOD for the reference samples checks results to verify the performance of the equipments and other factors which might influence the results as per cl. 5.1 of ISO 17025.

19.4.7 Ascertaining repeatability of the test results by re-testing of retained samples in a planned manner by TM.

19.4.8 Verifying the effectiveness of the corrective action taken on the complaints received from the customers, non conforming testing work, NCs encountered in the internal and external audits of the laboratory by HODs.

19.4.9 Preparing a preventive action plan covering management system requirements and technical activities to reduce the likelihood of occurrence of non conformities by HODs.

19.4.10 Obtaining feedback, both positive and negative from the customers, analyzing the same and taking necessary follow up action (if required) by HODs / PLs / SHs.

19.4.11 **Evaluating external service providers** periodically to ascertain their competence by HOD.

19.4.12 **Evaluating the critical consumable received and services availed** to ensure their adequacy by HOD.

19.4.13 **Management review** as per the agenda

19.5 Reference Documents:

(i) Quality Manual for NABL
(ii) Process for selection & evaluation of supplier- IRMRA/QPROC/08.
(iii) Process for Customer handling - IRMRA/QPROC/02.
(iv) Process for handling customer complaints - IRMRA/QPROC/06.
(v) Procedure for control of nonconforming testing work- IRMRA/QP/04.
(vi) Procedure for corrective & preventive action - IRMRA/QP/05.
(vii) Procedure for conducting internal audit - IRMRA/QP/03.
(viii) Procedure for conducting management review - IRMRA/QP/12.
(ix) Procedure for assuring the quality of test results - IRMRA/QP/10.

19.6 Records:

(i) Complaints Record
(ii) Non-conformity report (internal/External)
(iii) Calibration and maintenance of equipment/accessories record
(iv) Preventive action record
(v) Evaluation of suppliers and service providers record
(vi) Minutes of the Management review
(vii) Analysis of feedback received from customers
(viii) Verification of purchased products

Title of the procedure	New installation / transfer / scrap of machines / instruments
Purpose	To establish a procedure for Equipment/Instrument History.
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025: 2017
Responsibility	1. Director for total control. 2. HODs for guiding the Sectional Heads. 3. Scrap disposal committee for recording disposal activities & records. 4. MR for prepare, Issue, Control & Amendments
Procedure Number	IRMRA/QP/20

Procedure: -

20.1 New Installation of Machine / Instrument.

20.1.1 IRMRA receives new machines / instruments through Administrative Dept. The delivery note received along with the machine / instrument is brought to the notice of the Director.

20.1.2 As per the Director's direction, then the Machine / instrument is officially allotted to the section SH through proper channel.

20.1.3 A separate file maintained by section SH/HOD for individual machine / instruments. Steps are initiated by maintenance Engineer for getting the machines / Instrument installed.

20.1.4 After installation information is forwarded to Director, Management Representative, Administrator, Training Co-ordinator, HODs, Destination section SH, for the respective record / follow up action.

20.1.5 Maintenance Section prepares a history card for the machine/Instrument.

20.1.6 Training co-ordinator / SH will arrange a training programme after discussion with the person who has been trained by the experts of the machines / instruments for the benefit of organization in order to explain the features, limitations and application / utilities of the new installed machine / instrument. TC / SH maintains record of such training activities.

20.2 **Internal transfer of machine / instruments**

20.2.1 IRMRA follow a systematic procedure for transferring the instruments / machines from one section / dept. to the other section / dept..

20.2.2 Need and justification note for the internal transfer is forwarded to Director through proper channel. The note is scrutinised by Director and further action

initiated as follows.

20.2.3 Formal order in the prescribed format: IRMRA / FT / Internal Transfer - machine /01 is filled by A.O /MR/HOD as per the direction of the Director and forwarded to the concern persons through proper channel.

20.2.4 The copy of internal transfer is forwarded to the MR, TC, HODs, Administrator, and Director for the necessary record up gradation.

20.2.5 The machines / instruments along with the details of catalogues, operating manuals, calibration certificates etc. are transferred safely with the help of both side personnel's.

20.2.6 The necessary training for the new operator is given and ensured of its proper functional. A record of such training is maintained.

20.2.7 Administrator changes the necessary access of the system. MR upgrades the related documents of ISO.

20.3 **Scrap of machines / instruments**

20.3.1 IRMRA has appointed a scrap committee consisting of Director as chairman and Finance Officer as member Secretory and two of the senior scientists as committee members.

Those machine / instruments / measuring devices can not perform its operations as per the requirements and which are beyond repairs are classified as scrap. This classification verified by a competent service engineer who gives a certificate to that effect or otherwise where such certificates are received the machines / instruments are taken out of system immediately and notified to the higher authority for further course of action. Such items are labelled as "**SCRAP ITEM**" and segregated. Then Scrap disposal Committee reviews the items and then further action is initiated to scrap or replacement.

20.4 Records:-

20.4.1 Machine Installation Certificate.

20.4.2 Internal transfer records.

20.4.3 Scrap disposal committee report.

Title of the procedure	Allocation of manpower/ internal transfer of employees
Purpose	To establish a procedure for control of allocation of manpower/ internal transfer of employees
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025 : 2017; Cl. No. 6.2
Responsibility	1. Director for total control. 2. HODs / SHs for implementation. 3. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/21

21.1 **New manpower Allotment: -**

21.1.1 Any newly joined person reports to the Director. Then he / she is being directed to meet the AD (Admin) for completing the necessary administrative formalities.

21.1.2 AD (Admin) will send him/her to the Training Co-ordinator for arrangement of orientation programme.

21.1.3 The orientation programme includes ISO-9001 Quality awareness, Technical and administrative procedural aspects of IRMRA, Software training etc. The schedule may be of one-week time/ or more as per the requirement.

21.1.4 AD(Admin) sends an intimation to Director, Management Representative, Training Co-ordinator, HODs, Administrator and the concern reporting authority for records and necessary steps.

21.1.5 Reporting authority / A.O / any other authorised person will then introduce the employee to all HODs/ Section SHs / staff members.

21.1.6 After formal introduction, the person undertakes the orientation training as per schedule.

21.1.7 On completion of orientation training, the person is given on job training for understanding the job requirements and then he is placed on job.

21.1.8 Training Co-ordinator maintains a record of Orientation training & on job training.

21.2 **Internal transfer**

21.2.1 IRMRA follow a systematic procedure for transferring the employees from one section / dept. to the other section / dept..

21.2.2 Need and justification note for the manpower requirements / possible suggestion for internal transfer (if any) is forwarded to Director through proper channel. The note is scrutinised by Director and further action initiated as follows.

21.2.3 As per the direction of the Director the note is forwarded to the concern persons through proper channel.

21.2.4 The copy of such internal transfer is forwarded to the MR, TC, HODs, and software Administrator, and Director for the necessary record up gradation.

21.2.5 On completion of orientation training, the person is given on job training for understanding the job requirements and then he is placed on job.

21.2.6 A record of on job training is maintained.

21.2.7 Administrator changes the necessary access of the system. MR upgrades the related documents of ISO.

21.2.8 Training Co-ordinator upgrades the training records including on job training record of such transfers.

Title of the procedure	**Procedures for security & maintenance of software and hardware**
Purpose	To establish a procedure for security & maintenance of software and hardware
Scope	This procedure is applicable to all sections / Departments of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015 Cl. No. 7.5.1 & ISO/IEC 17025:2017
Responsibility	1. Director for total control. 2. IT incharge for implementation & control 3. IT / Service engineer to control and maintain of IT facilities. 4. MR for prepare, Issue, control & amendments
Procedure Number	IRMRA/QP/22

Procedure: -

22.1.1 IRMRA has established a system for maintaining its hardware and software system.

22.1.2 IRMRA has made annual contract with competent IT premises towards facilities maintenance of Hardware and software of IRMRA, as required.

22.1.3 IRMRA has employed a dedicated trained service engineer either directly or through contractor at IRMRA for the above said purpose.

22.1.4 Service engineer will interact with each and every one at IRMRA towards the maintenance of hardware and software.

22.1.5 He interacts with hardware related vendors towards repairs / replacements of spares etc.

22.1.6 He also interacts with the software towards update / debug of any software operations etc.

22.1.7 He takes care of security of data processing part of testing module by way of taking back up of the data every week, every month and every quarterly and yearly. And preserving the same with the proper label with easy & safety data retrieval as required.

Title of the procedure	**Procedure for uncertainty in measurement**
Purpose	To establish a documented procedure for calculation of uncertainty in measurement
Scope	This procedure is applicable to activities related to uncertainty measurements at IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025: 2017; Cl. No.: 7.6
Responsibility	1. Section head for calculation and implementation. 2. HOD for verification and approval. 3. QM / MR for issue, control and amendments. 4. Director for total control.
Procedure Number	IRMRA/QP/23

Procedure: -

23.1.1 Identify the parameters contributing uncertainty in result of given test

Take appropriate number of readings for given parameter

23.1.2 Calculation of Type A uncertainty:

Take mean of readings of given parameter(t). Calculate standard deviation of readings taken. Standard uncertainty (type A) of instrument is calculated by following formula:

$$\text{Standard uncertainty} = \sqrt{(\text{std. dev.})^2 / n}$$

Calculate % of standard uncertainty with respect to mean value of readings taken

23.1.3 Type B uncertainty: list out uncertainty of each and every uncertainty parameter of the instrument

23.1.4 Combined standard unceratainty is calculated by following formula

$$Uc = \sqrt{\text{Sum of squares of \% of all type B uncertainties+ type A uncertainty}}$$

23.1.5 Expanded uncertainty is calculated by formula:

$Ue = k^* Uc$

at 95% confidence level, coverage factor k=2

Title of the procedure	**Procedure for" Project Management"**
Purpose	To establish a documented procedure for project management
Scope	This procedure is applicable to activities related to projects handled at IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015
Responsibility	1. MR for issue and control. 2. Project Leader to plan, execute & manage the project. 3. Director for approval
Procedure Number	IRMRA/QP/24

Procedure: -

24.1 All scientists/officers of IRMRA are designated as "Project Leaders" to execute various projects of IRMRA and he will select his team.

24.2 As a first step, all projects (both internal & sponsored) are registered with Director and a unique project number is allotted for the project. Their record established in the format no. **IRMRA/FT/Design-approval/03** after receipt of confirmed project from parties.

24.3 Project No. is allotted as per the following order :
e.g. **IRMRA** / / / /
((name of institution) (Sponsor) (PL) F.Year S.No. for the year.

24.4 Project Leader and team members shall quote the project no. in all the project related documents including purchase, testing etc.

24.5 The purchase order is issued for purchasing any items related to the project with PO number having reference to the project no. without any reference to the customer identity.

24.6 Payment release order also shall contain the Project no. in order to manage and maintain separate accounting for the project and payment advice & material receipt voucher will be routed through store incharge.

24.7 Project leader shall submit a Progress report to the Director regularly with details of the project status alongwith budget planning for the next quarter / of the financial year so as to plan & manage the accounts of the organisation.

24.8 The status of all projects are reviewed on monthly basis with Director to update

latest position of project.

24.9 All projects shall be subjected to a techno-commercial audit with respect to :

a. Cost and purchase management of project.
b. Time management of project
c. HR management of project
d. Technical outcome of the project
e. Billing and payment

24.10 All completed projects will be taken up for the review and audit in the upcoming quarterly meeting of PRC meeting.

24.11 The above audit is done by a project review committee (PRC) comprising of :

a. PL
b. Accounting person
c. Another independent PL
d. Any other invitee as deemed necessary

24.12 The final audit report will be prepared by the PRC and finally approved by Director.

24.13 After approval of the Director, the project is officially declared to be completed and certified.

24.14 A review report (write-up) along with the commercial and final billing details of project will be handed over to office for further action.

24.15 All internal R&D activities must also be identified by separate project No. and the same finding will be audited and the outcome of technical finding must be documented and handed over to the office.

24.16 A copy of thesis/report/publication shall also be furnished alongwith the report for reference purposes.

24.17 The audit will take place once in quarter and the review of audit report will be done in MRC.

24.18 RECORDS:

1) Project file.
2) Audit Review Report.
3) Final Project Report.
4) Project completion certificate.

Title of the procedure	**Procedure for" Project Account Management"**
Purpose	To establish a documented procedure for project account management
Scope	This procedure is applicable to activities related to projects at IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015
Responsibility	1. MR for issue and control. 2. Project leader to maintain records & documents. 3. SH (F&A) financial audit & records. 4. Director for approval.
Procedure Number	IRMRA/QP/25

Procedure: -

25.1 Finance and Accounts Section is responsible for account management of all projects and overall expenses of organisation.

25.2 As a part of project management, the account of financial income and expenditures of all individual projects are maintained separately with unique project No. as approved by Director.

25.3 To ensure the accounting of project funds, all expenditures related payment release orders are insisted to co-relate the respective project number.

25.4 All sectional expenses related to section maintenance activities also accounted separately towards financial accountability and also to be maintained through internal project No.

25.5 Financial & Accounting Section Head prepares a comprehensive project wise report on every month with details of the budget like billed, expenses etc. for discussion in monthly meeting.

25.6 Finance & Accounting section shall prepare a comprehensive budget plan.

25.7 All planned fund accounts shall be managed in a project under the project lead by Admin personal.

25.8 The finance / account of individual project are audited by the PRC (auditors) and reproduced for the approval of Director.

25.9 Records are maintained for all above activities and also subjected to Finance audit as per the Govt. / statute for final audit certification.

25.10 Records:

(i) Tally generated records w.r.t. the created accounting master codes in Tally software.

(ii) MIS reports.

(iii) Audit completion report.

Title of the procedure	**Procedure for" Business Development"**
Purpose	To establish a documented procedure for Business Development.
Scope	This procedure is applicable to all activities of IRMRA related to a) Testing, b) Training c) New Proposal, d) Seminars/workshop at Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015
Responsibility	1. MR for issue and control. 2. HOD (BD & QM) responsible for plan & approval of visit. 3. BDG – Identification of Advisory on new business potential in the core area. 4. Dept (BD & QM) – To Plan & execute the planned activities. 5. Marketing section – To organize & execute various marketing activities to promote awareness on facilities of IRMRA. 3. Director for approval
Procedure Number	IRMRA/QP/26

Procedure: -

Strategic Planning:

26.1 Business Development Group (BDG) will identify the sources of business within the scope of IRMRA's core competency.

26.2 Business Development Group will meet at least once in month to identify such business opportunities and explore the same.

26.3 BD Department person will plan and execute the plan of activities towards new business development.

26.3 Any new enquiries received as a result of effort made by BDG, will be handled by BDG until the firm order is received from client.

26.4 All SHs/HODs who are also responsible for sending the Business potential enquiries to customer shall send a copy to BDG to keep a follow up on the same to create the business.

26.5 BDG will also plan to visit to potential customers towards the new business opportunities and existing/old customer towards continuation of business.

26.6 BDG will be seeking necessary technical support from the technical sections with regard to the feasibility study charges and other activities like creation of facilities and technical interpretations etc. as deemed necessary.

26.7 Any officer/SH/HOD visiting any major cities of India/ abroad, will be requested to meet the important existing or potential client towards business opportunities (and also recovery of old outstanding if any).

Business Development & Marketing activities:

26.8 Website of IRMRA:

26.8.1 Business Development & QM Dept. is responsible for periodic review & upgradation of website in order to keep the latest information available in the website.

26.8.2 Any information related to the workshops/training/seminars / conferences organized by IRMRA are promptly displayed in the website.

26.8.3 The website are kept updated and the enquiries / feedback received through website are processed appropriately to convert then into the business.

26.9 Customer Visits: B/D personal and SH/HODs shall visit the potential customers as well as the existing customers to develop the relationship and establish rapo to create more business.

26.10 Workshops/Seminars/Conferences

26.10.1 One or two days workshops or seminars are organized at different location in India and abroad towards promotion of Business of IRMRA.

26.10.2 Different topics are included as per need.

26.10.3 Jointly or on its own once in 3 years.

Business Development Output Management :

26.11 The testing assignment received from client as the result of BDG activities will be diverted to CSC for further processing.

26.12 After receipt of firm order, on projects, Director & Head of Business Development Group jointly decide to hand over the order to the respective project leader depending on the thrust area of work. Business development will explore the possibilities of getting more business on the same area without breach of any confidentiality clause as deemed necessary.

26.13 Visit reports are made and follow up / queries are taken by Dept .of BD & QM for business exploration.

26.14 Records:

a) Visit Reports.
b) Monthly reports (summary report)
c) Introductory letters sent to customer.
d) Minutes of meeting.

Title of Procedure	Procedure for " Transportation, Receipt, Handling, Storage, Retention and Disposal of test samples "
Purpose	To establish a documented procedure for "Transportation, Receipt, Handling, Storage, Retention and Disposal of test samples"
Scope	This procedure is applicable to CSC, testing and admin department of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025: 2017; Cl. No. 7.4 ISO 9001:2015
Responsibility	1. QM / MR for issue and control 2. HOD (Tyre & Non Tyre Testing) responsible for plan and implementation of disposal of tested samples from Department 3. CSC – Preservation of tested samples for a period of 03 months 4. Admin--Disposal of test sample after 3 months of preservation period. 5. Scrap committee – For final approval of disposal. 6. Director for approval.
Procedure Number	IRMRA/QP/27

Procedure:-

27.1 Sample Receipt and Processing

27.1.1 Test Samples are received in a designated area (i.e. Customer Service Cell).

27.1.2 Upon receipt of the sample, the following will be done:

27.1.2.1 The person who is authorized to receive the sample verifies that packages received are consistent with the description on the test sample

27.1.2.2 He or she observes and records the condition of the sample and compares it with the test request letter for the following items:

a. Number of units, sample identification number, if any, requested analyses, and storage conditions.

b. If a test request letter and its samples are received and found to be incomplete, notify a supervisor.

c. If the sample ID does not match with the ID mentioned in the test request letter, the sample is held pending and the clarification is sought from the Customer. If clarification cannot be satisfactorily obtained, the samples are stored temporarily or returned.

27.1.2.3 If the sample is rejected, the reason for rejection is informed to the customer and the record for the same is maintained.

27.1.2.4 Other information will also be checked and or verified such as:

a. if applicable, presence of seal and seal integrity (NOTE: Seals are not needed on all samples.

b. seal quotation, including date and signature or initials are to be consistent with test request letter

27.1.2.5 Any records or documentation received with the sample are to accompany the sample and are included with the administrative package that accompanies the lab reporting of results.

27.1.3 Unique Code is assigned to the Sample and is forwarded to respective Testing Sections as per the test requirements described by the customer along with test conditions, unit of measurement, test method etc.

27.2 Sample Storage and Sample Transfer

27.2.1 Sample Storage

27.2.1.1 Samples awaiting analyses are placed in the designated storage locations by the Customer Service Cell.

27.2.1.1 Samples are stored frozen, refrigerated or at room temperature.

27.2.1.1 The sample storage areas are organized to prevent contamination or cross contamination and are monitored. Each testing department is to have a local procedure for monitoring the storage of samples.

27.3 Sample Transfers Within the Laboratory

27.3.1 Sample transfers between the Customer Service Cell and test lab document the chain of custody. Samples received from the CSC are recorded in the web application

27.4 Sample Storage During Analysis

27.4.1 Samples are kept under lock and key while in the analyst's possession.

27.5 Sample Reserve Portions

27.5.1 Sample reserves are returned to the CSC upon completion of the analysis and documented on the handwritten worksheet /web application.

27.5.2 The CSC will store the reserve in the designated storage area and under proper storage conditions.

27.6 Sample Disposition

27.6.1 The sample remnant shall be deposited to the Customer Service Cell immediately (same day) after the testing. The deposited samples in the Customer Service Cell shall not be allowed to be taken out except by authorized persons

27.6.2. Tested sample shall be retained for 3 months by the Customer Service Cell

27.6.3 The untested samples, samples received for Inter Laboratory Comparison test program and samples received for R & D testing shall be returned back to customer on the receipt of the request for the same for their further course of action

27.6.4 After 3 months of the retention period, tested samples shall be forwarded to Administration department for safe disposal.

27.6.5 The scrap committee reviews details and arranges for disposal.

27.6.6 After review, balance sample/ tested sample is cut into pieces and sold to the approved scrap dealers after proper approval from scrap committee.

27.6.7 Records are established with regard to the scarped items.

27.6.8 Dispatch notes are made available at Administration Department.

27.7 Records: Scrap File no. IRMRA/SCRAP-TEST ITEMS/01

Title of Procedure	Procedure for "Organization Knowledge"
Purpose	To establish a documented procedure for "organization knowledge"
Scope	This procedure is applicable to all department of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015, Clause No. 7.1.6
Responsibility	1. QM / MR for issue and control 2. All dept. responsible for implementation 3. Librarian is responsible for keeping all the records
Procedure Number	IRMRA/QP/28

Procedure:-

IRMRA shall maintain the following knowledge pertaining to the existing operation of its processes.

The following knowledge from the internal sources shall be maintained

S. N.	Internal Sources of knowledge	Responsibility for updation & re-accessibility
	Patents, Publications, Transfer of Technology (ToT)	All Scientific Staff & Librarian
	Newsletter issued by IRMRA	HOD Chemical & Librarian
	Technical articles published in National & International Rubber Journals / Magazines.	All Scientific Staff & Librarian
	Knowledge gained from experience: ➢ New product / process developed ➢ New test method development ➢ Product / process improvement ➢ New facility created	All Scientific Staff & Librarian
	In specific cases a power point presentation will be made before concerned management person by the attendee	ALL HOD / Librarian

	Students coming at IRMRA for Internship, project, training from the different academic / research institution ➢ Name & contact details of student (one page resume) ➢ Letter from parent organization ➢ Supervisor form parent organization & IRMRA ➢ After completion of project student shall make power point presentation before key technical personnel of IRMRA and detailed project report to be submitted to the library.	HOD, Training & HR Admin Project Supervisor & Librarian

The following knowledge from the external sources shall be maintained

S. N.	External Sources of knowledge	Responsibility for updation & re-accessibility
	Standard copies: ASTM, IS, ISO, BSI etc	MR & Librarian
	Joint Intellectual property: patents, publications, transfer of technology (ToT)	All Scientific Staff & Librarian
	Knowledge gained from experience: ➢ Proceedings of Conference/ Seminar/ Workshop attended by any of employees of IRMRA. ➢ Training material & Certificates of attended trainings ➢ Visit report after visit to any industry, lab, institute comprising of o Customer visited with name & address o Person contacted name & designation, contact details o Outcome of the visit o Follow up / future course of action	Attendee, Concerned HOD & Librarian Attendee, HR & Librarian Concerned HOD, Director, HOD, Accounts

Title of Procedure	Procedure for " Post Delivery Activities"
Purpose	To establish a documented procedure for "Post Delivery Activities"
Scope	This procedure is applicable to CSC, testing and admin department of IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO 9001:2015, Clause No. 8.5.5
Responsibility	1. QM / MR for issue and control 2. All HOD
Procedure Number	IRMRA/QP/29

Procedure:-

IRMRA shall meet the following post-delivery activities associated with its products & services as and when required.

SERVICES: (Testing, Training, Consultancy)

- IRMRA abides by rules & regulation laid down by applicable Govt. bodies, Accreditation bodies, Certification bodies, Recognition bodies, Approving authorities.
- IRMRA analyses the feedback received from different customer periodically for the various services received by them.

PRODUCTS: (Product Development)

- Warranty – Products supplied are liable for replacement in case of non-conformity observed during warranty period.
- Performance bank guarantee – To guarantee the performance of the supplied product for the period specified in the contract.
- Validation of the supplied products at the customer end.

Title of Procedure	Procedure to ensure impartiality in the laboratory activities
Purpose	To establish a documented procedure to ensure impartiality in the laboratory activities
Scope	To avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity and to ensure impartiality in testing activities.
Reference	ISO/IEC 17025:2017; Clause No. : 4.1
Responsibility	Quality Manager/Technical Manager is responsible for supervision of staff during any activity carried out regarding testing and Director is responsible for taking necessary action if required.
Procedure Number	IRMRA/QP/30

The management of IRMRA including the Director, Quality Manager and Technical Managers are committed to maintaining impartiality in the laboratory activities. Manager/Technical Manager(s), take care that the staff carry out the testing in impartial manner and they are not involved in any activity that would diminish customer's confidence in the laboratory's competence, impartiality, judgment or operational integrity. If any such activity is detected during day-to-day work, cross verification of the test results, internal audit, management review, the same is brought to the notice of General Manager. General Manager takes suitable action so that confidence in laboratory's competence, impartiality, judgment or operational integrity is maintained.

The laboratory staff is not made aware of the identity of the customer from whom sample is received for testing. Samples are given code numbers and sample code No. is only mentioned in the log (raw test data) sheet. Technical Manager(s) specifies the tests to be carried out on the log sheet.

IRMRA is responsible for the impartiality of its laboratory activities. IRMRA ensures that no undue pressure is created on the technical staff to skip the test procedural steps for faster results delivery or to overlook the adverse results which affects a customer. Further no monetary incentives are offered to the employees for the number of tests conducted or the results of test. The testing staff and officers of the laboratories are recruited on a specific scale of pay as per the rules framed by the institute. The remuneration of technical staff is not influenced by the quantum of samples tested or number of tests carried out or on results of the tests. Further, the samples are identified by suitable means of codification to maintain the confidentiality of the Customer. It is ensured that managers and other personnel are free from any undue internal and

external commercial, financial and other pressures and influences that may adversely affect the quality of their work. The identification of any possible risks to impartiality is carried out on an on-going basis as well as once in a year during annual management review. The staff members are made to sign an appointment letter containing following clauses when he/she joins this organization:

- He/she shall not at any time or times, without the consent of the institute, disclose, divulge or make public except under legal obligations, any project, investigation or research schemes carried out at the institute which ought not to be disclosed, divulged or made public whether the same may be confided or become known to him in the course of his service or otherwise, and not to use or otherwise take advantage in his private capacity of special knowledge so obtained, or put into operation any invention or process of which he/she shall have obtained knowledge as aforesaid except as regards a member of the institute and then only to the extent to which, as and when he/she shall be entitled so to do in common with the other members of the institute in accordance with the prescribed rules and regulations.

- He/she shall not engage himself directly or indirectly to work for any political party with or without remuneration nor attempt to impede the institute in its functions nor divulge any of the secrets, information or connections to any other person whatever.

IRMRA has identified risks to its impartiality, on an on–going basis, that arises due to customers, employees and other external personnel including suppliers and service providers. This includes those risks that arise from IRMRA's various activities, or from its relationships, or from the relationships of its personnel. As regards external risks to impartiality, the following possibilities that may cause the bias are duly considered:

a) Business relationships between IRMRA and the customer;
b) Family or personal relationships between persons of IRMRA who is involved in laboratory activities and the customer.

The procedure for dealing with risks is given in IRMRA/QP/34.

ASSOCIATED DOCUMENTS:

IRMRA /QMS/CON/01 – Undertaking for maintaining confidentiality

IRMRA/QP/34- Procedure for Actions to Address Risks

Title of Procedure	Procedure to Protect Customers Confidential Information and Results
Purpose	To establish a documented procedure to protect Customers Confidential Information and Results
Scope	This procedure covers the protection of customer's confidential information and proprietary rights and protection of electronic storage and transmission of results and applicable to IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025:2017; Clause No. : 4.1
Responsibility	Respective Technical Manager(s) and Laboratory Officers are responsible for protecting the customer's confidential information.
Procedure Number	IRMRA/QP/31

Procedure

When the samples are received for testing, they are identified by suitable means of codification and then sent to respective departments. Any document generated during testing is treated as confidential document and it is ensured that these documents are not seen by other customers. Customers are allowed to enter the laboratory if required with prior permission of Laboratory Officer or Technical Manager. If the customer desires to impose legally enforceable commitments while undertaking testing work for them, the same is done in the form of contract / agreement / work order between IRMRA and its customer. Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) is treated as confidential by IRMRA and is not disclosed to the concerned customer. The provider (source) of this information is confidential to IRMRA and is never shared with the customer, unless agreed by the source. During the visit of customers it is ensured that information related to other customers are not discussed, revealed or made available to them.

After completing the testing of samples, the request letter from customer, data generated during testing and copy of the test report issued to the customer are filed together and preserved month-wise with Laboratory Officer, in customer care section. The testing personnel observe professional secrecy with regard to all the information gained while carrying out tests. Staff members are not allowed to take any file / report / register out of department without the permission of Laboratory Officer to ensure that no records are viewed by other customers.

Protection of electronically stored information is ensured by giving password so that these documents are accessed by authorized personnel only. When the results are conveyed electronically by means of fax or e-mail, the identity of the customer intended to receive is ascertained. All the staff of IRMRA have signed an undertaking for maintaining confidentiality of the customer information and results.

ASSOCIATED DOCUMENTS:

IRMRA /QMS/CON/01 – Undertaking for maintaining confidentiality

Title of Procedure	Procedure for use of decision rule while reporting statement of conformity
Purpose	To establish a documented procedure for use of decision rule while reporting statement of conformity
Scope	The scope covers the procedure adopted by IRMRA for the use of decision rule while stating conformity for a test with the specification stipulated by the customer at IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025:2017; Clause No.: 7.1.2
Responsibility	Technical Manager(s), authorized signatories are responsible for using this procedure as and when statement of conformity is requested by the customer.
Procedure Number	IRMRA/QP/32

Procedure

When the customer requests a statement of conformity to a specification or standard for the test (e.g. pass/fail, in-tolerance/out-of-tolerance), IRMRA ensures that the specification or standard and the decision rule is clearly defined. Unless inherent in the requested specification or standard, the decision rule selected is communicated to, and agreed with, the customer.

While issuing test report, if the statement of conformity is requested by the customer, the following procedure is adopted.

During the contract review stage, necessary clarification is obtained from the customer regarding the specification or standard against which statement of conformity is to be given. It is ensured that the specification required for each and every test parameter is explicitly defined in the standard or specification. If the same is not available, the required specification is obtained from the customer. Further, it is made clear to the customer that the measurement uncertainty evaluated or estimated by IRMRA for the concerned parameter will be duly considered while stating statement of conformity. This is finalized during the contract review stage.

The decision rule used in such cases is documented below and the same is in line with ILAC G8-Guidelines on the reporting of compliance with specification & EURACHEM/ CITAC 2007- Use of Uncertainty Information in Compliance Assessment for more details.

Decision rule used for statement of conformity in test results:

IRMRA evaluates / estimates measurement uncertainty for each test parameter as a percent for quantitative parameters in accordance with the procedure IRMRA/QP/23. Both type-A and type-B components are taken in to account in the evaluation or estimation.

The statement of conformity is made in the test report as given in the following example:

Quantitative parameters:

Test parameter: Tensile strength

Measurement uncertainty estimated for IRMRA for this parameter = 6%

Test result reported for a particular sample is 546 Newton. Thus the estimated uncertainty in this case works out to 32.8 Newton (546 x 6/100). The result is reported in this case as 546 ± 32.8 Newton. i.e If the same sample is tested in IRMRA laboratory, the results can be between 513.2 (546.0 – 32.8) and 578.8 (546 + 32.8) at 95% confidence level.

CASE 1: If the requirement as per the standard /specification as stipulated by the customer is ">= 500 Newton", then the same is reported as "Compliance" or "Pass". This is because both 513.2 and 578.8 (minimum and maximum values that can be obtained in IRMRA, if retested) are meeting the minimum requirement stipulated.

CASE 2: If the requirement as per the standard /specification as stipulated by the customer is ">= 600 Newton", then the same is reported as "Non-compliance" or "Fail". This is because both 513.2 and 578.8 (minimum and maximum values that can be obtained in IRMRA, if retested) are not meeting the minimum requirement stipulated.

CASE 3: If the requirement as per the standard /specification as stipulated by the customer is ">= 520 Newton", then the same is reported as "Compliance can't be specified clearly". This is because,

a) Although the reported result 546 is meeting the requirement,

b) 513.2 (minimum value that can be obtained in IRMRA, on retesting) is not meeting the requirement, and,

c) 578.8 (maximum value that can be obtained in IRMRA, on retesting) is meeting the requirement.

CASE 4: If the requirement as per the standard /specification as stipulated by the customer is ">= 560 Newton", then the same is reported as "Compliance can't be specified clearly". This is because

a) although the reported result 546 is not meeting the requirement,

b) 513.2 (minimum value that can be obtained in IRMRA, on retesting) is not meeting the requirement, and,

c) 578.8 (maximum value that can be obtained in IRMRA, on retesting) is meeting the requirement.

Similar methodology is used for all quantitative test parameters.

The statement of conformity is made in the test report as given in the following example in respect of qualitative or semi quantitative parameters:

Qualitative or semi quantitative parameters:

Test parameter: Colour Fastness to washing. Here the test result can be 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5 or 5.

Here measurement uncertainty is not calculated. But, as the test is conducted subjectively, the result can vary by half a grade. i.e if the sample is tested and reported as 3.0, and if the same sample is retested a number of times in IRMRA, the result can be between 2.5 and 3.5. i.e half a grade less or more than the reported value. Hence, half a grade is considered as measurement uncertainty for the purpose of decision rule while reporting statement of conformity of the results.

Thus, if the test result is reported as 3.0, then the statement of conformity is specified as given below under different circumstances:

CASE A: If the requirement as per the standard /specification as stipulated by the customer is ">= 2", then the same is reported as "Compliance" or "Pass". This is because both 2.5 (minimum value that can be obtained in IRMRA, if retested) and 3.5 (maximum value that can be obtained in IRMRA, if retested) for the tested sample are meeting the minimum requirement stipulated.

CASE B: If the requirement as per the standard /specification as stipulated by the customer is ">= 4", then the same is reported as "Non-compliance" or "Fail". This is because both 2.5 (minimum value that can be obtained in IRMRA, if retested) and 3.5

(maximum value that can be obtained in IRMRA, if retested) for the tested sample are not meeting the minimum requirement stipulated.

CASE C: If the requirement as per the standard /specification as stipulated by the customer is ">= 3", then the same is reported as "Compliance can't be specified clearly". This is because

a) Although the reported result 3 is meeting the requirement,

b) 2.5 (minimum value that can be obtained in IRMRA, on retesting) is not meeting the requirement, and,

c) 3.5 (maximum value that can be obtained in IRMRA, on retesting) is meeting the requirement.

CASE D: If the requirement as per the standard /specification as stipulated by the customer is ">= 3.5", then the same is reported as "Compliance can't be specified clearly". This is because

a) . Although the reported result 3 is not meeting the requirement, and

b) 2.5 (minimum value that can be obtained in IRMRA, on retesting) is not meeting the requirement, but,

c) 3.5 (maximum value that can be obtained in IRMRA, on retesting) is meeting the requirement.

However, if the customer explicitly stipulates not to take measurement uncertainty in to account while stating the statement of conformity, IRMRA incorporates a disclaimer in the test report as "Measurement Uncertainty is not taken into consideration while stating conformity with the specified requirements, as requested by the customer".

ASSOCIATED DOCUMENTS:

IRMRA /QP/7.1.1 - Procedure for Review of Request, Tender and Contract
IRMRA /QF/7.1/01 – Test request form
IRMRA /QF/7.4 /01 – Sample/item Receipt Record

Title of Procedure	Procedure for use of NABL symbol
Purpose	To ensure the use of NABL symbol in the Test reports in accordance with the policy of NABL enunciated in the document NABL 133
Scope	Applicable to all the test reports issued by the laboratory
Reference	ISO/IEC 17025:2017; Cl. No. 5.5
Responsibility	Technical Manager(s), authorized signatories are responsible for using this procedure
Procedure Number	IRMRA/QP/33

Procedure: The laboratory is accredited for compliance with ISO/IEC 17025 by NABL in respect of mechanical and chemical testing of rubber and rubber products. The laboratory is complying with the requirements of ISO/IEC 17025 and NABL requirements stipulated in specific criteria NABL 165 and other documents including NABL 133 which stipulates "NABL policy for use of NABL symbol/ claim of accreditation by accredited laboratories".

5.1 The laboratory uses NABL symbol – i.e NABL logo along with the certificate No. issued to the concerned laboratory of IRMRA while issuing test reports containing accredited test parameters to related only to the specific CAB location and not with any other non-accredited locations.

The laboratory complies with the requirements of ISO/IEC 17025 as well as NABL requirements even if the laboratory is not using NABL symbol on the test reports, Separate report/certificate be issued for non-accredited parameters. Asterisk mark or any other symbol is not allowed / not permitted to use in the report / certificate containing accredited parameters.

5.2 IRMRA can claim accreditation in narrative reference also for the claim of accreditation in publicity material, in such cases it shall be accompanied by the 'Accreditation Certificate number'.
For example, -
NABL accredited testing laboratory vide certificate number TC-XXXX –
Accredited by NABL vide Certificate number TC-XXXX –
ISO/IEC 17025 Accredited Testing Laboratory by NABL vide Certificate number TC-XXXX

The claim of accredited status is not to be done on any report / certificate / document, which contains non-accredited parameters.

5.3 IRMRA can use 'NABL Accredited CAB Combined ILAC MRA Mark' after obtaining a written approval from NABL and agreeing to the rules for the use of the Accredited CAB Combined ILAC MRA Mark.
IRMRA shall need to fill in the Appendix 'A'- Agreement for use of NABL Accredited CAB Combined ILAC MRA Mark given in NABL 133 document and submit it to NABL.

6.1 Laboratory have a documented procedure for - a) Use of NABL Symbol, and b) Claiming NABL accreditation in narrative reference.

6.2 Laboratory uses NABL symbols in all the reports for the parameters / tests covered under NABL accredited scope only. IRMRA does not use NABL symbol or claim NABL accreditation status in any form for the parameters, which are not covered under NABL accredited scope. The non-accredited parameters shall not be a part of the report / certificate intended to be issued under NABL symbol,

6.3 IRMRA ensures that the certificates and / or reports issued are under the valid accredited scope and meets the relevant requirements of ISO/IEC 17025 of NABL

6.4 IRMRA does not authorize the use of NABL Symbol by their customers, sub-contractors or any other third party.

6.5 IRMRA does not use the NABL Symbol and / or claim of accreditation for its franchisee / subcontractor, which are not accredited by NABL.
6.6 IRMRA uses the NABL Symbol and / or claim of accreditation during the period when it holds valid accreditation only.

6.7 While claiming NABL accreditation, IRMRA uses NABL symbol and / or narrative reference to the claim of NABL accreditation only.

6.8 IRMRA uses the NABL Symbol and / or claim of accreditation only under the name and address, on which it holds valid accreditation.

6.9 When providing proof of accreditation, IRMRA uses the Accreditation Certificate along with the scope of accreditation

6.10 IRMRA does not use NABL Logo or NABL Symbol or any claim of accreditation on the products or items, which a CAB has tested / calibrated or produced.

6.11 IRMRA does not use NABL Symbol and / or any claim of accreditation in such a way as to imply that NABL accepts responsibility for activities carried out under the scope of accreditation.

6.12 Where the claim of accreditation is used by IRMRA in a narrative reference to accredited status, it is always be accompanied by the 'Accreditation Certificate number', granted by NABL.

6.13 IRMRA ensures that there is nothing in report and/or certificate or in any attachment or other material, which implies or may lead any user of the results or any interested party to believe / made to believe, that the work is accredited when in fact it is not.

6.14 IRMRA does not issue a calibration certificate

7.1 IRMRA can use pictorial representation of NABL Accredited CAB Combined ILAC MRA Mark to where TC-7719 is the Accreditation Certificate Number after written approval from NABL.

8. IRMRA can use NABL Accredited CAB Combined ILAC MRA Mark after written approval from NABL whenever required and will maintain a documented procedure for the use of NABL Accredited CAB Combined ILAC MRA Mark on its test report.

9.1 IRMRA uses "NABL Symbol" in the appropriate legible and displayed form and proportion. The image of NABL Symbol is to be obtained from NABL secretariat.

9.2 IRMRA can use the electronic reproduction of "NABL Symbol" with permission from NABL, complying all the requirements of NABL 133, integrity of NABL symbol is maintained and distortion of graphic is avoided.

9.3 IRMRA can to use NABL Symbol as well as "NABL Accredited CAB Combined ILAC MRA Mark" with prior written permission from NABL as per NABL 133.

9.4 IRMRA ensures that the NABL symbol is positioned such that it is not combined with any other logo / symbol / mark. If the ILAC MRA Mark is to be used it shall be positioned such that the NABL symbol shall be on right side of the ILAC MRA Mark, but shall appear in close proximity to each other.

9.5 IRMRA ensure that the NABL symbol and/or "NABL Accredited CAB Combined ILAC MRA Mark if used " is reproduced in black and white color only. Embossed, relief, or die-stamped versions are allowable.

9.6 IRMRA ensures that the NABL symbol and/or ILAC MRA Mark is always used in its original, designed proportions. As a general guideline, one dimension of the NABL symbol, preferably the height, should be within approximately 5% of the size of the ILAC MRA Mark, if ILAC MRA Mark is used.

9.7 IRMRA ensures that the NABL symbol and/or ILAC MRA Mark shall not be distorted or stretched in any way.

9.8 IRMRA ensures that the NABL symbol and/or ILAC MRA Mark shall not appear in size that is unreadable.
9.9 IRMRA ensures that the if ILAC MRA mark is used it shall be maintained in similar proportions to the NABL symbol (within the Accredited CAB Combined ILAC MRA Mark)
9.10 IRMRA ensures that the NABL symbol and/or ILAC MRA Mark shall only be used in its normal horizontal orientation and not be rotated.
9.11 IRMRA ensures that the NABL symbol and/or ILAC MRA Mark shall be used on a background that will not impede readability.
9.12 IRMRA ensures that the NABL symbol and/or ILAC MRA Mark photocopies from other documents shall not be used.

10 IRMRA may include the results of subcontracted tests in its endorsed report and / or certificate only if:
a) IRMRA takes full responsibility for the subcontracted test and / or calibration.
b) IRMRA shall take approval from the subcontractor to report excerpts from the subcontractor's report and / or certificate.
c) IRMRA ensures the subcontracted test result shall be clearly and unambiguously identified.

14.1 IRMRA ensures the use "NABL Symbol" and / or claim NABL accreditation in publicity and/or advertising materials for promotional purposes, including brochures, business reports & stationery, technical literature, websites or on proposal / quotation for testing, work only
14.2 IRMRA ensures that the accreditation claim is related to or associated only with the services for which it is accredited by NABL, and not with any other activities in which the IRMRA is involved.
14.3 IRMRA ia well aware that the NABL accreditation is location specific. The accreditation claim shall be related only to the specific location that is covered under the NABL scope of accreditation, and not with any other non-accredited location. Once the accredited CAB shifts the premises, they shall immediately stop the use of NABL Symbol and / or any claim of NABL accreditation at the new premises till NABL verifies and approve the suitability of new premises.

14.4 In brochures, proposal or quotation, IRMRA distinguish the scope that is covered under NABL Accreditation from those that are not covered.

14.5 IRMRA ensures that where "NABL Symbol" and / or Claim of Accreditation is printed on letterhead and/or other corporate stationery, such stationery shall not be used for work proposal or quote, nor for reporting the results exclusively outside the NABL Scope of Accreditation, or for certifying a product or item,

Title of Procedure	Procedure for Actions to Address Risks
Scope	This procedure covers the actions taken by IRMRA as and when risks are encountered in the activities conducted by IRMRA at Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025:2017; Clause No. : 8.5 ; ISO 9001:2015 6.1.2
Responsibility	Quality Manager and Technical Managers are responsible for initiating the action and monitoring the implementation of the same, while encountering the risk. During the annual management review, Director and all the members of the management review are apprised of the risks encountered and the actions taken.
Procedure Number	IRMRA/QP/34

Procedure

IRMRA considers the risks and opportunities associated with the laboratory activities while conducting testing, design & development activities in order to: give assurance that the management system achieves its intended results; enhance opportunities to achieve the purpose and objectives of the laboratory; prevent, or reduce, undesired impacts and potential failures in the laboratory activities; achieve improvement.

IRMRA may encounter risks in the laboratory activities including testing. The risk may be due to personnel, equipment, facilities and environment conditions, system and supporting services. The probability of risk occurrence may vary from “rare” to “almost certain”. The consequence of risk occurrence may vary from “incidental” to “extreme”. Risk assessment is initially done by QM / TM in their respective area on the basis of experience and the risk assessment work sheet is prepared. Depending upon the assessment of each risk, the same is rated as “low”, “medium” and “high”. IRMRA ensures that the actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results while conducting mechanical, chemical and biological testing of textiles and other products. The flow chart for identification of risk and action taken to treat the same is given in ANNEX of this procedure. Some of the possible reasons due to which risk is encountered includes the following:

Due to impartiality: The identification risk in testing activities is assessed continuously by the QM and TM. If a risk to impartiality in testing is encountered/ identified, the IRMRA takes efforts to demonstrate how it eliminates or minimizes such risk.

Due to reporting statement of conformity: As and when a statement of conformity to a specification or standard is provided, IRMRA documents the decision rule employed,

taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule. The procedure for use of decision rule while stating conformity with specified requirements is described in Quality Procedure – IRMRA/QP/32.

Due to non conforming work encountered: Deficiencies in the testing related activities may be encountered by IRMRA and these are identified through complaints, negative feedback, NCs in internal audit & NABL assessment, poor performance in PT/ILC participated, non compliance with the pre defined criteria while performing internal quality checks and through supervision by QM and TM. In all such cases IRMRA takes actions (including halting or repeating of work and withholding of reports, as necessary) based upon the risk levels established as specified in this procedure.

IRMRA plans:

Actions to address the risks and opportunities that may be encountered; the actions taken (and to be taken) are duly incorporated in this procedure for their effective implementation; and, the effectiveness of these actions are duly evaluated during the annual management review. This includes the risk probability, risk consequence and risk index. As and when the risk index is found to be medium or high, appropriate actions are duly taken.

IRMRA deals with risk as per details given below:

Risk Probability: The "probability" of risk occurrence is rated as follows:

Risk probability	Rating	Criteria (Likelihood of risk occurrence)
Rare	1	Unlikely to occur, but possible
Unlikely	2	Unlikely but can be reasonably expected to occur
Possible	3	Will occur several times
Likely	4	Will occur frequently
Almost certain	5	Continually experienced

Risk Consequence: The "consequence" of risk occurrence is rated as follows:

Risk probability	Rating	Criteria (Impact of risk on laboratory activities)
Incidental	1	Negligible impact on laboratory results
Minor	2	Laboratory results are slightly affected
Moderate	3	Limited impact on laboratory results

Major	4	Serious impact on laboratory results
Extreme	5	Disastrous impact on laboratory results

The risk Index is calculated for each risk encountered using the formula as given below:

Risk Index = Risk Probability x Risk Consequence

Thus, the risk index can vary between 1 to 25. The risk assessment is done as "Low", "Medium" and High" on the basis of the following:

Risk Index	Risk assessment
1 to 8	Low
9 to 16	Medium
17 to 25	High

When the risk assessment is found to be "Medium" and "High", appropriate mitigation measures are taken by the concerned manager positively. As and when the assessment is found to be "Low", the concerned manager will monitor the situation from time to time for its possible recurrence.

The "mitigation type activities" taken on the risk encountered are as under:

Option	Type	Description
Avoid risk	1	Withdraw from the activity – i.e Do not perform the concerned test
Eliminate the risk	2	Eliminate the risk source that influences/ affect the results – It may be person, equipment, method/SOP, CRM, consumable, environment
Change risk	3	Change probability or consequence – Change the person, equipment etc., that affects the result
Share risk	4	Outsource risk – i.e resort to subcontracting to a competent laboratory
Retain risk	5	Accept the risk by informed management decision – But every time the test is performed examine all possibilities that affects the result

Each of the TM and QM explains the risk encountered by them during the last one year during the annual management review and update risks and opportunities determined. The results of risk identification are also reviewed during this management review.

Title of Procedure	Procedure for Review of Request, Tender and Contract
Purpose	To ensure the
Scope	This procedure covers the review of test request for testing of samples by IRMRA laboratories.
Reference	ISO/IEC 17025:2017; Clause No. : 7.1.1
Responsibility	Technical Manager/Officer(s) of Customer Care is responsible for review of the test request. Technical Manager(s) in the respective testing sections is responsible for allotting the samples to concerned testing staff.
Procedure Number	IRMRA/QP/35

Procedure

The Technical Manager/Officer(s) in the Customer Service Cell receives the sample along with request letter directly from customer or by post/courier. In case customer does not submit a request letter, IRMRA Test request form is given to the customer to specify the tests required. The laboratory manager/officer(s) reviews the request letter to ensure that:

Test parameter and appropriate test method is stated,
The laboratory has capability and resources to meet the requirements of customer.

When the customer requests a statement of conformity to a specification or standard for the test (e.g. pass/fail, in-tolerance/out-of-tolerance), IRMRA ensures that the specification or standard and the decision rule is clearly defined. Unless inherent in the requested specification or standard, the decision rule selected is communicated to, and agreed with, the customer. IRMRA takes in to account measurement uncertainty also while giving statement of conformity to a standard or specification. The procedure used for considering decision rule while reporting test results is described in Quality Procedure- IRMRA/QP/32. The decision rule to be used while stating the conformity with specified requirements is decided during the contract review stage.

If any deviation is to be done, consent is taken from customer either orally or in writing before starting the test. If consent is taken orally, laboratory manager/officer records it on customer's request letter. The sample/item code is allocated by KRITI LIMS system called as "Job Number". The number is allocated serially in every Financial year. This number is unique and has a format 0000 (a serial number), which is also assigned as URL number. Coded samples are sent along with the customer's request letter to Technical Manager of concerned laboratory. In case of testing, if the sample is to be sent to more than one Laboratory then accordingly, sample is cut into pieces and

sent to respective Laboratory by the Customer Care. The Technical Manager makes entries of the samples in their respective "Allotment Register".

Before starting the test, the technical staff ensures that the equipments are working properly, glassware are cleaned properly and quality of chemicals and reagents is appropriate for the test.

After accepting the test request, if any change is required from the laboratory, Technical Manager/Laboratory Officer communicates the same to the customer and if necessary gets his consent for the change.

If any change emanates from the customer, Laboratory Manager/Officer in the Customer Care section communicates the changes to the concerned Technical Manager who in turn ensures that the same is communicated to the concerned personnel.

The capability and resources available with IRMRA is ensured while making changes in the test request, irrespective of whether the change is requested by customer or by the laboratory.

The Laboratories of IRMRA resort to sub-contracting of testing work only in cases of exigencies. Sub-contracting may be done in case of unforeseen circumstances like pressure of excess work load or breakdown / maintenance of equipments, non-availability of trained personnel or non availability of expertise with IRMRA. Only ISO/IEC 17025 accredited testing Laboratories are used for this purpose. However, if accredited testing laboratories are not available, then sub contracting may be done to non accredited testing laboratories also. The customer is duly notified of the subcontracting arrangement and approval is obtained

Whenever, new or additional testing facilities are to be created based on the contract review with the customers, the Director has detailed and comprehensive discussions with the concerned Technical Manager and Quality Manager on the following:

- identification of the competent manpower,
- training to be imparted,
- suitability of existing accommodation or need for providing additional accommodation,
- necessity of maintaining suitable environmental conditions,
- need for procurement of new standard test methods,
- preparation of SOPs for the additional tests,
- equipments & accessories and reference standards to be procured,

- calibration of the new equipments & accessories and reference standards,
- procurement of chemicals, glassware, CRMs and other critical consumables required,
- internal quality checks to be carried out prior to commencing commercial testing
- participating in inter laboratory comparisons and / or Proficiency testing for some of the added tests

Commercial testing for the customers is undertaken for the newly added tests only after ascertaining the capability& competency of the concerned section of the laboratory. If required, additional internal audit of the concerned section is conducted also.

ASSOCIATED DOCUMENTS:

IRMRA /QP/27 - Procedure for Handling of test samples
IRMRA/CSC/FT/03– Test requisition
IRMRA /CSC/R-01 – Sample Inward Register

Title of Procedure	PROCEDURE FOR HANDLING, TRANSPORT, STORAGE, USE AND MAINTENANCE OF EQUIPMENT
Scope	The purpose of this procedure is to define handling, transport, storage, use and maintenance of equipment in order to insure proper functioning and to prevent contamination or deterioration at IRMRA, Thane and regional centers at Kolkata and Sri City
Reference	ISO/IEC 17025:2017; Clause No. : 6.4.3
Responsibility	Technical Manager of laboratory is responsible for safe handling, transport, storage, use and maintenance of equipment.
Procedure Number	IRMRA/QP/36

Procedure

1. Verification of equipment is carried out conforming to specified requirements before being placed or returned into service.
2. The transportation & commissioning of all the major equipment are done by the suppliers or by their representatives.
3. All equipment are stored at specified storage conditions as per manufacturer's instruction.
4. Due care is taken to use the equipment as per the manufacturer's operating instructions of respective equipment.
5. The maintenance or repair of equipment, if any, is carried out by authorized technical personnel / outside agencies. Preventive maintenance of the equipment is done on **half-yearly** basis by IRMRA authorized personnel from maintenance dept.
6. Only authorized testing personnel are permitted to use the equipment. The working instruction / manual are easily accessible to testing personnel.
7. Test equipments including hardware and software are safe guarded from adjustment which could invalidate the test results.
8. Care is taken to avoid overloading and mishandling of the equipment.

ASSOCIATED DOCUMENTS:

- Equipment's history cards (e.g. IRMRA/INS/REC/HIF/01)
- Preventive maintenance records (e.g. IRMRA/MN/PMS)