

ISO 9001:2015

QUALITY MANAGEMENT SYSTEM

ICAR – National Research Centre on Pig

DOCUMENTED INFORMATION

[LEVEL - 1]

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ABBREVIATION
Section No. NRCP/QMS/02

NRCP	ICAR – National Research Centre on Pig		
QMSM	Quality Management system Manual	QA	Quality Assurance
SEC	Section	MR	Management Representative
SL.	Serial	NO.	Number
REV	Revision	SER	Service
QP	Quality Procedure	QC	Quality Control
EFF	Effective	INSP	Inspection
QAP	Quality Assurance Plan	NC	Non Conformance
QS	Quality System	EQPT	Equipment
QMS	Quality Management System	DT	Date
QM	Quality Manual	BS	British Standards
DC	Document control	BIS	Bureau of Indian Standards
MRM	Management Review Meeting	IS	Indian Standard
IA	Internal Audit	CAR	Corrective action Request
IR	Improvement	SIGN	Signature
MNT	Maintenance	DSP	Dispatch

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DISTRIBUTION LIST
Section No. NRCP/QMS/04

Sl. No.	Authorized Holders	Copy	Address
01	Management Representative	00 Master Copy	ICAR (NRCP) Rani (Near Airport), Guwahati – 781 131
02	Director	01 Control Copy	ICAR (NRCP) Rani (Near Airport), Guwahati – 781 131

Note for Users:

- a) This documented information must be strictly controlled and maintained as an Organization-wide document.
- b) Uncontrolled current versions of this document are circulated to customers and clients on request from Marketing wing for providing information on Organization's Quality Policy, Quality System and Quality Management System Procedure.
- c) This documents is also used for General Training purpose on Quality Management System.

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FORWARD
Section No. NRCP/QMS/05

Quality Manual is the document that has been prepared to provide guidelines for the Quality Management system ISO 9001:2015 - Quality Management Systems- Requirements for regulatory purpose.

Common requirements are addresses in the same section under the clausal requirements. The manual, its copies or extract from it must not be passed on to unauthorized persons or organization without the written permission of the **Director**.

This Document forms part of Quality Management Systems- Requirements **ICAR – National Research Centre on Pig** and adherence to its requirements is mandatory. Unnumbered/uncontrolled copies may be given to customer/outside agencies, purely for information purpose only.

Management Representative is responsible to review and revise this manual with the approval of top management in accordance with the requirements of the Quality System from time to time.

It is the responsibility of Management Representative to maintain and incorporate all revisions on receipt and keep it up-to-date. **Company Brief profile** is available as a separate documented information in NRCP/DOC-05.

Changes to the documents of this manual are not permitted except with the approval of **Director** as detailed in this Manual. The persons responsible for issue and approval appear here below with their signature and date.

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SCOPE & APPLICABLE CLAUSES
Section No. NRCP/QMS/06

SCOPE OF CERTIFICATION

RESEARCH AND TRAINING IN THE FIELD OF PIG PRODUCTION

The Quality Management System address all the clauses of the ISO 9001 : 2015 version.

This QMS Manual applies to all activities of the organization and also applicable to all products and services and the necessary internal and external processes that are defined and controlled.

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NORMATIVE REFERENCES
Section No. NRCP/QMS/07

Normative References

The following document is used as references for establishing Information Security Management System in ***ISO 9000:2015 (Quality management systems — Fundamentals and vocabulary)***

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

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TERMS AND DEFINITIONS
Section No. NRCP/QMS/08

Terms and definitions used in the quality management system documentation are followed as per the ISO 9000:2015 Quality Management Systems- Requirements for regulatory purpose.

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ORGANIZATIONAL CONTEXT
Section No. NRCP/QMS/09

4 Context of the Organization

4.1 Organizational contexts

ICAR (NRCP) is committed to defining the position in the marketplace and understanding how relevant factors arising from legal, political, economic, social and technological issues influence our strategic direction and the Organizational context.

ICAR (NRCP) identifies, analyses, monitors and reviews factors that may affect our ability to satisfy our customers and stakeholders, as well as; factors that may adversely affect the stability of our process, or our management system's integrity.

To ensure that our QMS is aligned with our strategy, whilst taking account of relevant internal and external factors; we initially collate and analyse pertinent information in order to determine potential impact on our context and subsequent business strategy.

ICAR (NRCP) then monitors and reviews this information to ensure that a continual understanding of each group's requirements is derived and maintained. To facilitate the understanding of our context, we regularly consider issues that influence our context during management review meetings and are conveyed via minutes and business planning documents.

The output from this activity is evident as an input to the consideration of risks and opportunities, and the actions that we take to address them. Refer to Section 6.1 for more information about our risk and opportunity management framework.

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NEED AND EXPECTATION OF THE INTERESTED PARTIES
Section No. NRCP/QMS/10

4.2 Understanding the needs and expectations of interested parties

The effect or potential effect on our organizations ability to consistently provide products and services that meet our customer and applicable statutory and regulatory requirements, **ICAR (NRCP)** had determined the following:

- The interested parties relevant to the Quality Management System;
- The requirements of the identified interested parties relevant to the QMS;

ICAR (NRCP) is committed to continually monitoring, reviewing and analyzing information and relevant requirements of the interested parties to assure their requirements are effectively managed in the QMS.

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DETERMINING THE SCOPE & PROCESS OF QMS
Section No. NRCP/QMS/11

4.3 Determining the scope & process of the Quality Management System

ICAR (NRCP) has determined the boundaries and applicability of the Quality Management System to establish its scope when considering the following:

- a) The external and internal issues,
- b) The requirements of relevant interested parties,
- c) The products and services of **ICAR (NRCP)**,
- d) The compliance obligation,
- e) Organizational units, functions and physical boundaries,
- f) Authority and ability to exercise control and influence.

ICAR (NRCP) is committed to applying all applicable requirements of the International Standard to the intent and Scope of our Quality Management System.

The Scope of our QMS shall always be available to internal and external parties and maintained as documented information. The QMS was determined, designed and implemented to cover and support for the Scope “Research and training in the field of pig production”.

4.4 Quality management system and its processes

ICAR (NRCP) has established, implemented and maintained the quality management system including improve through,

- a) By determining the input of the process like customers requirement, purchase requirement and other requirement reflect in the process interaction .
- b) The organization has decided to determine the sequence and interaction of all the process through verify the training, production, customer requirement, purchase requirement, resource requirement and other requirements as an when it is needed.
- c) NRCP has established the process for verifying of product requirement through quality assurance plan for research and training in the field of pig production.
- d) NRCP has established the resource planning through KPIs.
- e) The organization has assigned the responsibility to all the sectional head / process owner which has been reflect in Roles and responsibility of individual – NRCP/DOC-04
- f) Risk assessment has been defined as per doc. Ref. NRCP/RAO-01.
- g) The organization has established sectional KPIs and objective analysis and used to review at least once in six month and discussed in the Management Review.
The Top management and Managers of the MRM decide any changes needed in any of the process to ensure the achievement of intended results.

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- h) The organization used to verify the improvement to proceed and QMS through internal audit which is conducted at least once in a six month by external auditor to all of the process of the organization and finding are discussed in the management review meeting which conducted at least once in a six months.

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LEADERSHIP & COMMITMENT
Section No. NRCP/QMS/12

5 - Leadership

5.1 Leadership and commitment

5.1.1 General

Director is committed towards the leadership as per the process requirement of the QMS.

- a. The Director has taken accountability for the effectiveness of the quality management system.
- b. The Director has already established the quality policy & objectives which are suitable to organization goal.
- c. The Director also established the requirement in to the organization's business process.
- d. The Director has also established the process risk and review once in at least six months and if any changes found to be discussed in MRM.
- e. The Director has established resource planning .
- f. The Director has established internal communication to continue the effectiveness of quality management system.
- g. The Director has ensured to achieve the intended results through the quality inspection record
- h. The organization has engaged all the qualified and active man power to each process to get the QMS effectiveness results.
- i. The Director is also committed towards the improvement of the quality management system.
- j. The Director has also defined the roles & responsibility of each process head.

5.1.2 Customer focus

ICAR (NRCP) ensures customer requirements and expectations are clearly defined, understood and achieved at all levels of the organization. We are committed to achieving 100% customer satisfaction and will accomplish this by understanding and mitigating risks and opportunities that may affect the conformity of products and services and to assure Statutory and Regulatory requirements are identified and achieved according to the applicable Clauses of the QMS Manual, Procedures and Forms.

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QMS POLICY
Section No. NRCP/QMS/13

5.2 Policy

QUALITY POLICY OF THE ORGANIZATION

National Research Centre on Pig is committed to undertake Research and Training in the area of pig production , health and product processing through innovative research in order to provide technology backstopping for enhanced pork production , employment generation and poverty reduction among socially and economically weaker sections through the medium of pig husbandry . To fulfil this commitment , the institute has adopted ISO 9001 : 2015 standard and continually improving our Quality Management System.

Date:

Director

The Quality Policy statement defines the organization's quality policy. Employees are fully briefed about this policy on joining the organization & during planned training. All Employees are responsible to implement the quality policy. The quality policy is displayed at prominent places within the organization & is controlled.

Director of NRCP considers the following while are defining quality policy

- It is appropriate to the purpose of the organization.
- It reflects commitment to meet the requirements & continually improvement the effectiveness of QMS.
- It is communicated & understood by all concerned and relevant interested parties of the organization as appropriate consider by the MR / Director
- It is regularly reviewed for continuing suitability.

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ROLES, RESPONSIBILITY & AUTHORITY
Section No. NRCP/QMS/14

5.3 Organizational roles, responsibilities and authorities

The director has defined responsibility and authority for the individual process owner and it has been communicated training, through display board in a suitable place to easily readable.

- a) The quality policy has been established confirming the requirements of the International Standard.
- b) The intended output is also considered in the policy.
- c) The performance of the quality management system and opportunities for improvement of products to meet the requirement including the further requirements and expectation correcting & preventing or reducing undesired results, including the improvement of performance and effectiveness of the quality management system.
- d) The organization has established, documented and maintained the customer focus through the organization structure. Ref. doc. NRCP/DOC-3.
- e) The director has documented procedure for change control to maintain the integrity of quality management system. The procedure has been established, documented and maintained in the change requirement in a planned condition. Ref. doc. NRCP/QP/10.

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ADDRESSING RISK & OPPORTUNITIES
Section No. NRCP/QMS/15

6 Planning

6.1 Action to address risk and opportunities

6.1.1 Director has established, documented and maintained the procedure for addressing risk and opportunities as per doc. ref. NRCP/QP/01 to achieve the following,

- a. To achieve the intended results through risk assessment and opportunities.
- b. The director is committed to enhance the desirable effect through internal audit. Doc. Ref. for Internal Audit procedure – NRCP/QP-06.
- c. To prevent or reduce undesired effects through quality assurance plan and its performance analysis of data, objectives and sectional KPIs.
- d. To achieve improvement.

6.1.2

- a. The organization has documented procedure to identify the risk and opportunities including the new product, process, new customer and using new technology.
- b. And how to
 - i. Integrate and implement to determine the inputs and outputs expected from these procedures to determine the sequence and interaction of these process etc.
 - ii. The organization has also established, documented and maintained the effectiveness of the action done by the process owner through evaluation of effectiveness of the process. Doc. Ref. NRCP/QP/01.

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QMS OBJECTIVES AND CHANGE PLANNING
Section No. NRCP/QMS/16

6.2 Quality objectives and planning to achieve

6.2.1 ICAR (NRCP) has established, documented and maintained the quality objectives through,

- a) The objectives taken by the organization's quality policy.
- b) Which is measurable.
- c) Which maintain the applicable requirement of the QMS Standard.
- d) Which are conforming the products and consider to enhance the customer satisfaction level.
- e) Can be monitor through objective analysis record and
- f) Which is communicate to all the interested parties.
- g) Which is also appropriate and up-date once in a year through MRM.

It is ensured that the objectives are SMART (Specific, Measurable – where practicable, Achievable, Realistic, Time bound) and are consistent with the Quality policy, including the commitments to qualityat workplace, compliance to legal and other requirements and continual improvement.

When setting objectives and targets, our organization ensures that they are consistent with the needs and expectations of our interested parties, as defined in Section 4.2, . In addition, technological options, financial, operational and business requirements are considered.

6.2.2 The organization has determined the planning of objective achieves its quality objectives and documented, implemented and maintained through,

- a) The objectives are analysis once in at least six month and the audited. The findings is discussed in the MRM.
- b) The director has allocated resource for competent human, plant & machinery, infrastructure, measuring instruments.
- c) Secondary responsibility lies with the sectional head and director will be the primary responsible.
- d) The establishment of objectives will be done in the beginning of the implementation of the QMS and
- e) The results will be analyzed to evaluated the objectives achievement once in at least six months and it will be verify through internal audit and review will be done in the MRM which is also at least once in six month.

6.3 Planning of changes

The director has documented, implemented and follow the need of changes at least once in year to verify the need to any changes to be taken place after discussion in the management review meeting, considering the report of internal audit. The changes will be carried out after considering the following,

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- a) The changes are made whenever there is possibility to improve of system.
- b) To improve the integrity of quality management system.
- c) Considering the resource available and
- d) To consider whether the responsibility and authorities to be re-allocated considering the failure of previous responsible persons.

Quality Objectives of ICAR (NRCP)s are the followings,

Sl. No.	Quality Objectives	Target
1	Strengthening frontier research identified areas and quality pig seed production	Production of 1000 piglets / year
2	Improving reproductive efficiency in pigs through Artificial Insemination (AI) in the institute farm and farmers' field	Minimum 500 AI / year
3	Monitoring and surveillance of pig diseases and development of disease diagnostics	Evaluation of 600 biological samples / year
4	Post harvest management and value addition of pork	Development of 2 new products or processes / year
5	IP management and commercialization of technologies	
6	Awareness creation and capacity building amongst stakeholders	Training of minimum 100 farmers and / or entrepreneurs / year

Note: The objectives will be reset based on the following points,

- a) The purpose of the changes and their potential consequences;
- b) The integrity of the quality management system;
- c) The availability of resources;
- d) The allocation or reallocation of responsibilities and authorities.

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RESOURCE REQUIREMENTS
Section No. NRCP/QMS/17

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resource need to establish implement and maintained continual improvement of the quality management system by considering the following,

- a) Whether the present internal resources are capable enough to continue the present constraints.
- b) The present external provider are capable enough to provide improve services as per requirement of the organization's requirements such as timely and specific require of purchase products, considering the market rate.

7.1.2 People

ICAR (NRCP) identifies personnel training needs, provides required training, and evaluates the effectiveness of the training provided. Personnel assigned to perform specific tasks, operations and processes are qualified on the basis of appropriate education, experience or training. Assessment of research achievement and organization effectiveness based on fulfillment of institute goals. Scientists operate with current and harmonized evaluation criteria . Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives. Records of personnel qualifications and training are maintained.

7.1.3 Infrastructure

ICAR (NRCP) is responsible for planning, providing and maintaining the resources needed to achieve product and process conformance, including buildings, workspace and associated utilities, laboratories, library, green areas; process equipment (hardware and software); and supporting services and other associated services such as equipment for the research – learning process this includes accessories, supplies and consumables. The Maintenance In-charge is overall responsible for managing the entire machine maintenance services.

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7.1.4 Environment for the operation of processes

Management identifies and manages the human and physical factors of the work environment considered to be important to control processes and to achieve conforming of products and services. Evaluations include:

- a) **ICAR (NRCP)** never engage in or support discrimination in hiring, remuneration, access to training, promotion, termination or retirement based on religion, cast, birth, gender, sexual orientation family responsibilities, marital status, union membership, political influence, age or any other condition that could raise to discrimination. **ICAR (NRCP)** offer equal pay for equal work.
- b) **ICAR (NRCP)** always support the employees those who become to mental or emotional as opposed to physical in naturals with applicable laws in the country and provide support and do the use of various techniques to demoralize or intimidation enemy.
- c) **ICAR (NRCP)** also having well define procedure to safe guard environmental & health work place to prevent potential accident and injury at work place. The organization also provide all facilities considering their working impact on health due to hazardous or occupational illness that could occurred in work place.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

ICAR (NRCP) has maintained a well define procedure to ensure valid and reliable results while monitoring, measuring to verify the conformity of products and services to meet the requirement of intended use through,

- a) **ICAR (NRCP)** has defined the requirement of qualified personnel, machinery and measuring instruments to achieve the desire results and,
- b) **ICAR (NRCP)** are maintaining all the trained technical man power, machinery and measuring instruments through preventive maintenance, proper work environment, timely calibration of measuring instrument to maintain to ensure their continuity fitness of their purpose.

7.1.5.2 Measurement traceability

ICAR (NRCP) has maintained a well define procedure to ensure the traceability of measuring equipment prior to use through the following,

- a) The organization use to verify prior to use the instrument against the standard traceability to international or national measurement standard. The organization also follow when no such standard are exist, the basis use for calibration or verification are retained as documented information.
- b) The Q.C. In-charge used to identify in order to determine the status of instruments.

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- c) The Q.C. In-charge use to safe guard the measuring instrument from adjustment, damage or deterioration, which could invalidate the calibration status and subsequent measurement of results.

The QC in-charge also should determine if the validity of previous measurement result had been adversely affected when measuring instrument is found to be unfit for its intended purpose. The QC in-charge should take the appropriate action to modified the equipment for used of measuring, so that to achieve the expected results.

7.1.6 Organizational knowledge

ICAR (NRCP) recognises that organisational knowledge is a valuable resource that supports our quality management activities and ensures continual product and service conformity. There is a strong link between Organisational knowledge and the competence of our people, the latter being peoples' ability to apply knowledge to their work.

To ensure that Organisational knowledge is retained and transferred. Organisational knowledge is recorded in documented information, and is embedded in our processes, products and services.

Examples of Organisational knowledge include:

1. Documented information regarding a process, product or service;
2. Previous specifications and work instructions;
3. The experience of skilled people and their processes and operations;
4. Knowledge of technologies and infrastructure relevant to our Organisation.

Sources of internal knowledge also include our intellectual property; knowledge gained from experience and coaching; lessons learnt from failures and successes; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services.

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COMPETENCY & AWARENESS
Section No. NRCP/QMS/18

7.2 Competence

ICAR (NRCP) ensure the competency is the main criteria for maintaining of performance and effectiveness of the quality management system. The organization has identified the competency through,

- a) The organization has established, documented and maintained the competency criteria through competency matrix as per the process requirement. As per the criteria, the interview will be taken and appointment will be issued.
- b) After that the employee will be place on duty as per selection criteria to the department as skill will be judge through interview and,
- c) If found,not as per the satisfaction level, further training will be provided by competent person to upgrade the knowledge and evaluation will be done. If needed, further re-training will be provided, otherwise he/she will be appointed permanently.
- d) All the records are maintained as per the followings,
 - Competency matrix with training need identification - NRCP/HRD-01
 - Training plan and schedule - NRCP/HRD-02
 - Training record & evaluation - NRCP/HRD-03

7.3 Awareness

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of our policies and objectives. The company operates a formal system to ensure that all employees within the Organization are adequately trained to enable them to perform their assigned duties.

Where required; awareness training and monitoring is conducted in-house, although for more specialist skills, external courses are utilized. The effectiveness of awareness training is evaluated and recorded. The company induction includes an introduction to our Organization's QMS policy statements and objectives. Future training needs are identified as part of the management review process.

ICAR (NRCP) ensures through the defined procedure for Training that employees and members at each relevant function and level aware of:

- a) The importance of conformance with the QMS policy, procedures and to requirements of the Quality management system;
- b) Their roles and responsibilities in achieving conformance with QMS policy and procedures and with the requirements of Quality management systems; and
- d) The potential consequences of departure from specified operating procedures.

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COMMUNICATION
Section No. NRCP/QMS/19

7.4 Communication

7.4.1 General

ICAR (NRCP) has established, implemented, maintained the process how to implement internal and external communication relevant to the organization's quality management system through the following,

- a) The organization will internally communicate the quality policy, objectives, work instructions as per the requirement of the process through display in an easily readable place. The product specification, requirement to be communicated through office corresponding or hard copy of specification and any other instructions or information through phone or verbally.

All external communication will be done through email, carrier or over phone.

- b) As and when information is required to pass out to the person whether internal or external to be communicated as weekly, monthly, half yearly and annually.
- c) All the communications will be done through, training, notice board, periodic meeting, letter, feedback, electronic media (E-mail) etc.
- d) The process owner will be communicate regarding their related information.

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DOCUMENTED INFORMATION
Section No. NRCP/QMS/20

7.5 Documented information

7.5.1 General

ICAR (NRCP) ensures that our QMS includes the documented information that is required to be maintained and retained by ISO 9001:2015 and additionally, any documented information identified by our Organization that demonstrates the effective operation of our QMS. Refer to the Register of Documented Information.

ICAR (NRCP) maintains a documented QMS as a means to ensure that products and services conform to specified requirements. The QMS consists of the following four levels of documented information:

Level 1	QMS Documented Information – defining the scope of the Quality Management System, QMS Policy, Scope of Implementation; Description of the main elements of the QMS as per the requirements of the various Clauses and their interaction and reference to related documents)
Level 2	QMS Procedures – defining how the required procedures of the various Clauses are being established.
Level 3	Work Instruction –documented procedures for controlling operations activities.
Level 4	Forms, Formats, Records & Registers as required by the Standard and determined by ICAR (NRCP) to be necessary to ensure the effective planning, operation and control of processes.

7.5.2 Creating and updating

ICAR (NRCP) ensures that when we create documented information it is appropriately identified and described (e.g. title, date, author, reference number) and is available in an appropriate format (e.g. language, software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy

7.5.3 Control of documented information

7.5.3.1 & 7.5.3.2

Documented information is retained to provide evidence of conformity to the requirements specified by ISO standards, customer requirements and of the effective operation of our management system. An electronic document management system, which is backed up and updated as required, is used to retain documented information ensuring only the current versions are available to users. All management system documents are controlled according to the Procedure which defines the process for:

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1. Approving documents for adequacy prior to issue;
2. Reviewing and revising as necessary and re-approving documents;
3. Ensuring that changes and current revision status of documents are identified;
4. Ensuring that relevant versions of applicable documents are available at points of use;
5. Ensuring that documents remain legible and readily identifiable;
6. Ensuring that documents of external origin are identified and their distribution controlled;
7. Preventing the unintended use of obsolete documents;
8. Ensuring that documents of external origin are identified and their distribution controlled.

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OPERATIONAL PLANNING & CONTROL
Section No. NRCP/QMS/21

8 Operation

8.1 Operational planning & control

ICAR (NRCP) establishes and implements documented plans and procedures that describe the processes and the controls required for the provision of services in awareness to the objectives, the potential for planned or unintended change, and the risks and opportunities identified. During this planning phase, management or other responsible personnel identify the following parameters:

- Objectives and requirements for the service;
- Verification, validation, monitoring, inspection and test requirements;
- Documented information to demonstrate conformity;
- Document information to demonstrate process effectiveness;
- Necessary resources; or outsourced processes and their controls;
- Criteria for process performance and product/service acceptance;
- Potential consequences and mitigation to change affecting input requirements;
- Resources necessary to support the ongoing operation of the service.

The output of planning activity includes documented plans, resource schedules, process, requirements and procedures.

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REQUIREMENT FOR PRODUCT & SERVICES
Section No. NRCP/QMS/22

8.2 Requirements for products and services

8.2.1 Customer communication

ICAR (NRCP) has implemented an effective system for communicating with customers the system includes but is not limited to:

- a. Information relating to product and service information;
- b. Inquiries, contracts and order handling, including amendments;
- c. Customer feedback, including customer complaints;
- d. Specific requirements for contingency actions, when relevant.
- e. Non dealing or control of customer properties.

8.2.2 Determining the requirements for products and services

ICAR (NRCP) develops appropriate requirements to ensure that we satisfy the needs and expectations of our customers or relevant interested parties. **ICAR (NRCP)** ensures that customer requirements are clearly articulated and that their requirements are captured and understood before the acceptance of an order. Customer requirements include the following:

1. Previous customer requirements;
2. Statutory and regulatory requirements related to the product;
3. Other non-customer specified performance requirements;
4. Any additional requirements determined by **ICAR (NRCP)**;

8.2.3 Review of the requirements for products and services

Prior to committing to the customer, **ICAR (NRCP)** ensures and confirms our capacity to supply the required product or service. Pre-acceptance reviews are conducted to ensure that:

1. Product requirements are defined and are appropriate;
2. Any additional requirements determined by **ICAR (NRCP)** are appropriate;
3. Contract or order requirements differing from those previously expressed are resolved;
4. **ICAR (NRCP)** has the ability to meet the defined requirements;
5. Documented information is retained and maintained showing the results of the review.

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Customer requirements are confirmed before acceptance by the exchange of contracts, purchase orders via appropriate electronic or hard copy formats. In case the customer does not provide any specific requirements for the services, the organization selects the general requirements for the service based on experience previous orders executed and thereby conveys it to the customer for their approval

8.2.4 Changes to requirements for products and services

ICAR (NRCP) ensures that all relevant documented information; relating to changes in product or service requirements, is authorized and amended where necessary, and that all relevant personnel are made aware of the documented requirement changes.

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DESIGN AND DEVELOPMENT OF PRODUCT & SERVICES
Section No. NRCP/QMS/23

8.3 Design and development of products and services

8.3.1 General

ICAR (NRCP) is establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. In designing and developing research and training plan NRCP follow research advisory committee meeting every year . Top management considered the design and development of research for the benefits of stakeholders.

8.3.2 Design and development planning

ICAR (NRCP) is consider in determining the stages and controls for design and development, including

- a) The nature, duration and complexity of the design and development activities,
- b) The required process stages, including applicable design and development reviews,
- c) The required design and development verification and validation activities,
- d) The responsibilities and authorities involved in the design and development process,
- e) The internal and external resource needs for the design and development of research and production of pork and pig seed.
- f) The need to control interfaces between persons involved in the design and development process,
- g) The need for involvement of customers and users in the design and development process,
- h) The requirements for subsequent provision of services,
- i) The level of control expected for the design and development process by customers and other relevant interested parties,
- j) The documented information needed to demonstrate that design and development requirements have been met.

ICAR (NRCP) manages the interfaces between different groups involved in design & development to ensure effective communication and clear assignment of responsibility by Design & Development review committee. Planning output is updated, as appropriate, as the design & development progresses.

8.3.3 Design and development inputs

ICAR (NRCP) has determined the requirements essential for the research work, production of pig seed and pork, improving reproductive efficiency in pigs through Artificial Insemination to be designed and developed. **ICAR (NRCP)** is consider,

- a) Functional and performance requirements,
- b) Information derived from previous similar design and development activities,
- c) Statutory and regulatory requirements,
- d) Standards or codes of practice that the organization has committed to implement,
- e) Potential consequences of failure due to the nature of the services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

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Conflicting design and development inputs is resolved.

ICAR (NRCP) is retaining documented information on design and development inputs.

8.3.4 Design and development controls

ICAR (NRCP) is apply controls to the design and development process to ensure that,

- a) The results to be achieved are defined,
- b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements,
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements,
- d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use,
- e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities,
- f) Documented information of these activities is retained.

8.3.5 Design and development outputs

ICAR (NRCP) is ensure that design and development outputs

- a) Meet the input requirements,
- b) Are adequate for the subsequent processes for the provision of products and services,
- c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria,
- d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

ICAR (NRCP) is retain documented information on design and development outputs.

8.3.6 Design and development changes

ICAR (NRCP) is identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

ICAR (NRCP) is retain documented information on,

- a) Design and development changes,
- b) The results of reviews,
- c) The authorization of the changes,
- d) The actions taken to prevent adverse impacts.

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CONTROL OF EXTERNAL PROVIDER
Section No. NRCP/QMS/24

8.4 Control of externally provided processes, products and services

8.4.1 General

ICAR (NRCP) maintains responsibility for the quality of all products purchased from external providers, including customer designated sources. Procedures ensure products and services being provided by external sources will conform to our customers' requirements.

- a) The organization has established, documented and maintained the requirement from the external providers has been established approved and evaluated before placing an order as per doc. ref. NRCP/QP-05.
- b) No external providers are engage to our core process.
- c) No process, or part of the process activities are provided by the external providers for research work , production and post harvest management.

8.4.2 Type and extent of control

The organization has established, implemented and maintained the external provider process to avoid the adversary affect the organization's ability to consistently deliver conforming products and services to their customer through the following,

- a) The external providers procedure are control by the team leader and by process owner.
- b) The organization ensure that the procedure so documented are confirmed the require output.
- c) The organization does not take any direct access of supply the product & services to the customers of the organization. If in future any service is taken all the statutory and regulatory requirement will be take care.
- d) External providers verification is carried out through evaluation process of the organization including risk assessment. Doc. Ref. Procedure for control of external provider - NRCP/QP-05

8.4.3 Information for external providers

ICAR (NRCP) has established, documented and maintained the purchase order / work order / agreement to clearly indicate the service / product required by the organization through external providers' criteria.

- a) The organization is using purchase order providing all the specific requirement including product / service specification, delivery schedule and other terms & condition and accordingly the material will be inspected and approved.
- b) The organization before issuing the purchase order used to approved the external provider on the bases of approval procedure.
- c) The competency use to measure as per external provider procedure.
- d) Interactions, Control & monitoring, Verification and validation will be carried out by purchase manager will comply all the activities as per control of external provider.

Ref. Doc.-

- Procedure for control of external providers – NRCP/QP/04

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PRODUCTION & SERVICE PROVISION
Section No. NRCP/QMS/25

8.5 Production and service provision

8.5.1 Control of production and service provision

ICAR (NRCP) is committed to control the production and service condition through,

- a) **ICAR (NRCP)** is plan to undertake research and training in the area of pig production and improving reproductive efficiency in pigs. The organization also comply with the statutory and regulatory requirement as per the norms of explosive section.

The result of the products are achieve through various processes like production planning considering the client requirement, quality control through various steps and maintained the following records,

- i. Production Planning,
 - ii. Incoming material inspection,
 - iii. In-process & final inspection,
 - iv. Instruments calibration record
- b) The organization has established, documented and maintained through various processes like competency of qualification, experience and skilled and to maintained the documented information. Use of measuring instrument through the calibration procedure of measuring equipment. Doc. ref. NRCP/QP-11.
- c) The organization used to implement the various appropriate stages to confirm the output of the products are acceptable to the clients,
- i. Qualification criteria,
 - ii. Stage wise inspection to get the conformity of the output,
 - iii. Calibration Result,
 - iv. Validation & Re-validation .
- d) The organization also considered to use of suitable infrastructure, friendly environmental condition for the operational process.
- e) The organization appoints the competent personnel to achieve the conformity of product.
- f) The validation and re-validation for control of production & service provision is not applicable in the production process.
- g) The organizational object is to prevent human error, so the competency matrix is established. Training, evaluation & re-evaluation is done as per training result.
- h) The Q.C. In-charge is responsible to release the final products.

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8.5.2 Identification and traceability

In order to preserve the conformance of service provided to customer requirements during internal processing and delivery, **ICAR (NRCP)** identifies the product & service throughout the service realisation process in accordance with the Service Provision Procedure.

- Stored data and materials are identified as to job, description and compliance status;
- Research identification records;
- Subsequent orders are identified by contract number.
- Process to be clearly identify through proper documentation.
- Research contracts.

8.5.3 Property belonging to customers or external providers

ICAR (NRCP) has identified, verified, protected and safeguard customers' property provided for use or incorporation into the products and services.

ICAR (NRCP) has retained documented information for lost, damaged or otherwise found to be unsuitable for use of customer property and immediately report this to the customer.

8.5.4 Preservation

ICAR (NRCP) ensures proper handling, storage, preservation of lab records and printed or electronic materials under the responsibility of MR.

8.5.5 Post-delivery activities

ICAR (NRCP) meets requirements for post – delivery activities associated with the products and services.

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8.5.6 Control of changes

ICAR (NRCP) has reviewed and control changes for production or service operations to the extent necessary to ensure continuing conformity of customer or internal requirements. Changes for production / service may be initiated as a result of:

- modernization based on the context of the organization analysis results;
- needs of interested parties, or customer feedback ;
- design department when vulnerability is detected and (or) opportunities for improvement are identified.

Management reviews and monitors changes that affect manufacturing process or outside services and ensures change documentation and information is distributed and controlled. Records of results of the review of changes, the persons authorizing the change, and any necessary actions arising from the review are maintained in accordance with applicable procedures. Doc. ref. NRCP/QP-10

Ref. Doc.-

Procedure for Control of Change -NRCP/QP/10

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RELEASE OF PRODUCT & SERVICES
Section No. NRCP/QMS/26

8.6 Release of products and services

The QC In-charge has overall responsibility for planning and implementing the inspection and test activities needed to verify that product requirements are met at appropriate stages of the product realization process.

Documented information is retained to indicate the person authorizing the release of the service. Product delivery does not proceed until all compliance have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

Measurement and acceptance criteria that are necessary for service acceptance are retained as documented information; subsequent criteria for acceptance and rejection need to be documented in acceptance record;

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CONTROL OF NON-CONFORMING OUTPUT
Section No.NRCP/QMS/27

8.7 Control of nonconforming outputs

To detect, control and rectify any aspect of an output that does not conform as quickly and efficiently as possible. Where necessary, any service output that does not conform to requirements is properly identified and controlled to prevent unintended use. The non-conformity is analyzed and the cause(s) are investigated.

Improvement actions are implemented to ensure the non-conformance does not reoccur. Once the non-conforming outputs are corrected, the outputs are then verified for conformity against requirements. Documented information concerning the nature of any non-conformances, the resolving authority, and the resulting corrective actions is retained.

If any Non-conforming product is delivered, informed immediately to the client and the product will be recall as the product is not permissible to sale under any concession.

Ref. Doc.-

- Procedure for Control of Product Non-conformity – NRCP/QP/07.

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MONITORING, MEASUREMENT, ANALYSIS & EVALUATION
Section No. NRCP/QMS/28

9 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

ICAR (NRCP) has established, documented and maintained suitable methods for determining which aspects of the quality management system and its processes are to be monitored, measured and evaluated. The frequency and methods by which our processes for research and supporting process are monitored, measured and evaluated is determined through,

- a) Statutory and regulatory requirements to be reviewed once in six month;
- b) Customer feedback to be reviewed once in six month;
- c) Process and QMS requirements, to met the intended use;
- d) Process performance and audit results to be reviewed once in at least six month to evaluate the QMS results and to be discussed in the MRM;
- e) Risk to be identify as per process of QMS and to be review as per existing process and any new process included or any improve technology is being included in process;
- f) The non-conformity of product / services to be verified, root cause analysis to be done and corrective action to be taken to avoid further similar non-conformity. Whenever there is similar non-conformity is occur, the risk to be re-evaluated and accordingly process to be followed.

ICAR (NRCP) has ensured that monitoring and measurement activities are implemented in accordance with the determined requirements and have retained appropriate documented information as evidence of the results. **ICAR (NRCP)** has ensured that version control software tools are used and maintained, as appropriate.

ICAR (NRCP) has evaluated the quality performance and the effectiveness of the quality management system once in at least six months and to evaluate to results of processes.

ICAR (NRCP) has retained appropriate documented information as evidence of the monitoring, measurement, analysis and evaluation results.

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9.1.2 Customer satisfaction

ICAR (NRCP) has documented and maintained the following parameter to monitor the customer perceptions as,

- a) Customer feedback,
- b) Timely delivered of product & services,
- c) Customer visit / meeting with customer,
- d) Customer complaint,
- e) Customer visit reports.

9.1.3 Analysis and evaluation

ICAR (NRCP) performs necessary analyses and evaluates appropriate data and information initiated from monitoring and measurement and uses the results to evaluate conformity of products and services, customer satisfaction, the performance and effectiveness of the QMS, the performance of external providers, and the need for improvement of the QMS.

In order to identify strengths, weaknesses, threats and opportunities in our quality management system, **ICAR (NRCP)** monitors and analyses trends using the following quality data points:

1. Characteristics of processes, services and their trends to confirm the products / service;
2. Conformity to product, customer and legal requirements;
3. Customer satisfaction and perception data and to analysis to know the result;
4. Supplier and external provider performance data;
5. Results of actions taken to address risks and opportunities;
6. Effective implementation of QMS planning so as to achieve the planning result;
7. Improvement opportunities identified during internal audits and management reviews.

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INTERNAL AUDIT
Section No. NRCP/QMS/29

9.2 Internal audit

- a) The **ICAR (NRCP)** has established, documented and maintained a procedure for Internal Audit as per doc. Ref. NRCP/QP/05 and conduct the internal audit generally at least **once in a six months** cover all the processes. The internal audit results are critical inputs which help the process improvement also critical result findings. The audit frequency is also consider upon the process performance trends, results from previous audit, levels of customer satisfaction rates of non-conformity and corrective action etc. to ensure that our organization focus on the aspect that effect products and conformity.
- b) The organization has a define audit criteria, scope of each audit as,
 - i. Audit plan and schedule,
 - ii. Audit Notice,
 - iii. Audit checklist & observation record
 - iv. Audit Non-conformance report
 - v. Audit summary report
- c) The audit cannot be done by the process owner to his own process. He can do the other then his own process or the external experienced auditor can be provided through whom having an auditing knowledge on the process.
- d) All the audit documents will be submitted to process owner, MR and director. The audit findings will be discussed in the Management Review meeting.
- e) All the audit finding (NC) will be resolved within agreed time schedule by auditee and NC will be closed. The auditor will see if the root cause and correction is as per the NC raised, he will close the audit NC.
- f) The organization has established, documented and maintained and retained the documented information.

Ref. Doc.-

- Procedure for Internal Audit - NRCP/QP/05

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Approved by: Director	Signature: <i>VK Gupta</i>

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MANAGEMENT REVIEW
Section No. NRCP/QMS/30

9.3 Management review

9.3.1 General

To ensure the continuing suitability, adequacy and effectiveness of our Quality management system in meeting our organization's strategies, Director conducts formal management review meetings at planned intervals i.e. at least ONCE IN SIX MONTHS or as per the requirement of internal audit findings.

9.3.2 Management review inputs

The management review has been planned and carried out taking into consideration:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- c) Information on the performance and effectiveness of the quality management system, including trends in:
 - 1) Customer satisfaction and feedback from relevant interested parties;
 - 2) The extent to which quality objectives have been met;
 - 3) Process performance and conformity of products and services;
 - 4) Nonconformities and corrective actions;
 - 5) Monitoring and measurement results;
 - 6) Audit results;
 - 7) The performance of external providers;
- d) The adequacy of resources;
- e) The effectiveness of actions taken to address risks and opportunities;
- f) Opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review have included decisions and actions related to:

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system;
- c) Resource needs.

ICAR (NRCP) has retained documented information as evidence of the results of management reviews.

Ref. Doc.-

- Procedure for Management Review - NRCP/QP/06

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NON-CONFORMITY & CORRECTIVE ACTION
Section No. NRCP/QMS/31

10 Improvement

10.1 General

ICAR (NRCP) determines and selects opportunities for improvement and implements necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include :

- a) Improving the product and services that the input are meet with the output as per requirement of the client considering the further requirement which is required for the process to be review with the client.
- b) Correcting, preventing or reducing undesired effects and
- c) Improving the QMS by adopting the require process of product / services.

10.2 Nonconformity and corrective action

10.2.1

- a. The organization takes the action to eliminate the causes of the non-conformity in order to reduce recurring or occurring elsewhere by,
 - i. The QC In-charge always use to review the non-conformity if found.
 - ii. The root cause is always determine before doing the correction.
- b. The QC In-charge also finds out if any similar conformity is existing or any potentially non conformity can occur.
- c. The QC In-charge implement any action needed for solving any customer complaint,
- d. Review of effectiveness of the corrective action taken and
- e. Update the risk assessment carried out during the planning and
- f. The QCIn-charge makes the changes in the QA plan as per requirements of non-conformities.

10.2.2 The nature of non-conformities & any subsequent action taken and the result of corrective action have been retained as documented information as per rec. ref. NRCP/NCP-02.

Ref. Doc.-

- Procedure for Corrective Action – NRCP/QP/08

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CONTINUAL IMPROVEMENT
Section No. NRCP/QMS/32

10.3 Continual improvement

ICAR (NRCP) continually improves the effectiveness of its Quality management system through the effective application of the policies, objectives, auditing and data analysis, corrective and preventive actions and management reviews of the organization.

Customer satisfaction, internal audit data, process and product performance data and then compared against objectives to identify additional opportunities for improvement.

The overall effectiveness of continual improvement program, including corrective actions taken, as well as the overall progress towards achieving objectives, are assessed through our management review process.

If any opportunity is find out, the action and result to be address as part of continual opportunities.

Ref. Rec.-

Improvement Record– NRCP/IR/REC-01

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