


PHILIPPINE FISHERIES DEVELOPMENT AUTHORITY

QUALITY PROCEDURE

CONTROL OF DOCUMENTS



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	PFDA-QP-02	Quality Procedure	Effectivity:	

1.0 PURPOSE:

This document aims to define and provide the controls needed in the use, maintenance, and disposal of records.


- 1.1 This procedure aims to ensure that documents of external origin are identified and their distribution, controlled.

2.0 POLICY

It is the policy of PFDA to ensure that pertinent documents are properly identified, updated, approved, and made available at points of use. Also, it is the policy of PFDA to ensure that documents of external origin are identified and controlled during distribution.

3.0 DEFINITION OF TERMS:

- 3.1 Controlled Copy – Reproduced copy of the original document, latest issued document; indicated by blue “Controlled Copy” stamp.
- 3.2 Documents – as referred to in this procedure, are QMS quality procedures, standard operational instructions, the Quality Manual, and other procedures/standard/form indicated in the Document Masterlist.
- 3.3 Document Controller (DC) – Individual/s assigned to oversee the implementation of the Document Control procedure.
- 3.4 Document Custodian – Officer or staff assigned to maintain controlled copies of documents
- 3.5 Document Masterlist – A list of the documents being controlled by a Document Controller in terms of creation, approval, revision, distribution, access, and use.
- 3.6 DFF – Document Feedback Form. A form used to suggest any revision to an existing document or manual.
- 3.7 External Documents – Documents generated from external sources.
- 3.8 Internal Documents – Documents generated from QMS implementation and relevant PFDA operations.
- 3.9 Obsolete Copy – Superseded document, indicated by red “Obsolete Copy” stamp.
- 3.10 Original Copy – Original document bearing approvals in blue ink, maintained by the DC and indicated by green “Original Copy” stamp.

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3.11 Originator/Process Owner – Person who initiated document creation/revision who shall fill-out the “Prepared by” portion of the document.

3.12 Uncontrolled Copy – Reproduced copy of a controlled copy document strictly for reference use, indicated by black “Uncontrolled Copy” stamp.

4.0 SCOPE:

4.1 This procedure applies to all documents required by the PFDA’s Quality Management System as indicated in the Document Masterlist.

4.2 This procedure also covers the monitoring and/or distribution of externally generated documents.

5.0 RESPONSIBILITIES:

5.1 Quality Management Representative – Reviews the established procedures in line with the requirements of the PFDA Quality Manual and approves the same for implementation.


5.2 Document Controllers – Ensure that all documents are properly identified, updated, approved and made available at relevant areas for use. The DC is also responsible for the maintenance and implementation of this procedure on Control of Documents.

5.3 Document Custodians – Coordinate the implementation of this procedure within their respective group or center. Ensure that obsolete documents are identified and prevented from unintended use.

5.4 Unit Manager – Reviews and approves internal documents needed by his unit, process or function: approves the distribution of copies of external documents pertaining to his process.

6.0 PROCEDURE DETAILS:

Ref. No.	Key Activities	Responsibilities
6.1	Creation/identification of documents	Originator
6.2	Review and acceptance of draft documents	Concerned Officer/ Process Owner
6.3	Approval of documents	QMR
6.4	Registration and stamping of documents	Document Controller
6.5	Distribution of approved documents	Document Controller
6.6	Maintenance of Controlled Copies	Document Custodians
6.7	Document Revision/Updating	Originator
6.8	Control of External Documents	Document Custodians
6.9	Control of Electronic Document	Document Controller

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6.1 Creation/Identification of Documents

If a need to create a document arises, the Document Feedback Form (DFF) is used. An Originator prepares the DFF, together with the draft document. Draft documents shall be labeled (watermark, if possible) with the word “DRAFT” and should not be used in operations unless it is officially approved. The Originator may obtain a document code from the DC to initially identify/classify the document according to the established document coding system.

6.2 Review and Approval of Documents

Upon preparation of the DFF and Draft Documents, these are routed to the concerned officer/process owner for review and acceptance. After the Unit Manager reviews and approves the draft document, together with the accomplished DFF, it will be endorsed to the QMR for approval. Approved documents bear the signature of approving authorities in blue ink.

6.3 Registration and Stamping of Documents

6.3.1 Upon approval of the document, the DC confirms the revision of the document or assigns a new unique identification number according to the following classification:


- | | |
|-------------------------------------|-----------------------|
| a. Quality Manual | - PFDA-QM |
| b. Quality Procedure | - PFDA -QP-XX |
| c. Standard Operational Instruction | - PFDA -SOI-XX |
| d. Form | - PFDA -SOP/QP-XX Fnn |

note: xx and nn are series numbers starting with 01

6.3.2 Project-related policies follow the existing numbering system supplied by the PFDA.

6.3.3 The DC enters the details, of the document, in the Document Master list and keeps the master copy. The DC reproduces the master copy according to the number of custodians specified in the Distribution List. All copies of the document are stamped with “Controlled Copy” in blue ink prior to distribution.

6.3.4 Document Control Stamps are maintained and used by the Document Controller.

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6.4 Distribution and Maintenance of Controlled Copies


- 6.4.1 Distributed controlled copies of documents are recorded in the Document Distribution List by the DC. Upon receipt, the Document Custodian initials the controlled copy of document, in blue ink, and signs on the Distribution List.
- 6.4.2 If other than the controlled copy, a copy of the document is requested, said request is approved by the Document Controller. If approved, the Document Custodian may reproduce a “controlled copy” and stamp the copy with “Uncontrolled Copy”, in black ink, prior to release or distribution. The recipient initials the uncontrolled copy in blue ink.

6.5 Document Modification/Revision/Update

- 6.5.1 If there is a need to update, modify, or revise a QMS document, the DFF is used. Changes made to the document are typed in italics for easy identification. The nature of revision is reflected in the “Nature of Revision” portion of the document page. If about 50% or more of the pages is affected by revision/change, the revision/change is classified as “Complete Rewrite”. In such case, the revision number of all pages of the document shall follow the highest revision number of that document.
- 6.5.2 Review and approval of a revised document follow the guidelines set under Section 6.2 of this procedure. The Document Controller updates the Revision History page, which forms part of each document.
- 6.5.3 Upon distribution of the revised/updated document, obsolete copies are retrieved and stamped with “Obsolete Copy” in red ink. The Document Controller maintains the latest original copy of the obsolete document. Obsolete controlled copies are disposed of in accordance with the procedure on Control of Records.

6.6 Control of Externally-Generated Documents

- 6.6.1 Document Controller/s use the External Document Distribution List to register and monitor the receipt and distribution of externally generated documents.
- 6.6.2 Recording is done immediately upon receipt and turnover of documents to concerned unit and/or individual. The responsibility for the maintenance and updating of the External Document Distribution List is entrusted to the PFDA Group/Division/Unit. Externally generated documents received through e-mail are likewise recorded in the External Document Distribution List.

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6.7 Electronic Copies of Documents

6.7.1 Electronic copies of documents are not used as a reference for implementation since there is no assurance of being the latest version of the document. Electronic files of Original Copies are edited, copied, and printed only by the Document Controller to protect from unauthorized copy and use.

6.7.2 The Document Controller authorizes uploading and downloading of documents onto and from the intranet. Access to controlled documents available on the intranet is regulated through the use of an access code and password provided by the Information Technology Division (ITD-CPMISD). Access to controlled documents available on the intranet may be extended to other users.


7.0 REFERENCES:

- | | | | |
|-----|-----------------|---|-------------------------------------|
| 7.1 | PFDA -QP-02 | - | Control of Records |
| 7.2 | PFDA -QP-01 F01 | - | Document Masterlist |
| 7.3 | PFDA -QP-01 F02 | - | External Document Distribution List |
| 7.4 | PFDA -QP-01 F03 | - | Document Distribution List |
| 7.5 | PFDA -QP-01 F04 | - | Document Feedback Form |

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QUALITY PROCEDURE CONTROL OF RECORDS



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	PFDA-QP-02	Quality Procedure	Effectivity:	

1.0 PURPOSE:

This document aims to define and provide the controls needed in the use, maintenance, and disposal of records.

2.0 POLICY

To ensure conformity to the requirements and ensure the effective operation of the agency's quality management system, it is the policy of the **PFDA** to ensure that pertinent records are established, organized, maintained, and properly disposed of in accordance with the guidelines provided in the control of records.

3.0 DEFINITION OF TERMS:


- 3.1 Active Records - Records within the active retention period
- 3.2 Inactive Records - Records within the inactive retention period
- 3.3 Records Custodian - Identified individuals from each unit held responsible for the maintenance, filing and safekeeping of records, as indicated in the Records Matrix.

4.0 SCOPE:

- 4.1 This procedure applies to all records related to QMS and agency operations, which are indicated in the Records Matrix.
- 4.2 This procedure also covers the handling of externally generated data during execution of SOP/SOIs, as well as, those data provided by clients/customers.

5.0 RESPONSIBILITIES

- 5.1 Quality Management Representative – reviews and approves the records retention schedule for records pertaining to mandatory procedures on control of records and ensures that the Records Custodians adhere to the requirements of this procedure.
- 5.2 Unit Manager – reviews and approves the records retention schedule for records pertaining to the process.
- 5.3 Document Controller – ensures that the controls provided in this procedure are effectively implemented throughout the PFDA. Maintains the Central Records Retention Schedule.
- 5.4 Designated Officers – ensures that the data and information provided are sufficient, as required in the relevant document or form.
- 5.5 Unit Document Controller – ensures that records needed by the Unit are properly maintained and are readily available. Maintains that Unit's Record Retention Schedule and Record Masterlist, listing all the records held by the Unit.

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- 5.6 Unit Records Custodian – classifies records needed by his process: recommends retention periods for these records. Maintains active files needed by his process; turns-over inactive records to the Record Center, as needed; disposes obsolete records in his area.
- 5.7 Records Officer – ensures that active records relative to PFDA/Unit’s operation are properly maintained, and is also responsible for the maintenance and disposition of inactive records.

6.0 PROCEDURE DETAILS:


Ref. No.	Key Activities	Responsibilities
6.1	General procedure	Record Section, ASD, NFPC
6.2	Collection and identification	Records Custodian
6.3	Review and/or approval of records, as appropriate	Concerned designated officer
6.4	Storage and protection	Records Custodian
6.5	Retrieval and retention	Records Custodian
6.6	Disposition of current/active records	Records Custodian
6.7	Maintenance and disposition of inactive records	Records Section, ASD, NFPC

6.1 General

- 6.1.1 Records are legible, identifiable and easily retrievable.
- 6.1.2 Records can be in the form of any type of media such as hard copy or electronic file.
- 6.1.3 If necessary, records are reviewed and/or approved prior to issue.
- 6.1.4 Records indicate the person/s who authorizes its use.

6.2 Collection and Identification

- 6.2.1 Records are identifiable through any or combination of the following information, as appropriate:
- Title of Record
 - Date(s)
 - Name of signatory (ies)
 - Document Code
 - Revision status
 - Reference Document
 - Control number

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6.2.2 Records are collected upon availability from their source, for appropriate filing by the Records Custodian or concerned process owner. Only marking pens are used on records. Pencil markings are avoided and may be considered unofficial.

6.2.3 In case of erasure or correction, the corrected data bears the initials of the person who corrected it.

For example: ~~6312~~ 7564 ADK

6.3 Review and Approval of Records

6.3.1 Some records require the signature of authorized individuals. The reviewer ensures that said records are legible and contain sufficient information as basis for its endorsement or approval. Hence, some records without the signature of approving authorities may be treated “unofficial.”

6.4 Storage and Protection

6.4.1 Records are kept in appropriate locations to minimize physical deterioration, damage, and loss. As such, records may be protected in accordance with the following:

- Use of expanded folders, protective sheets, and/or ring binders;
- Stored on shelves or steel cabinets to prevent from deterioration;
- Regular backups of e-files; and,
- Access restriction, through password to prevent from unauthorized use.

6.5 Retrieval and Retention


6.5.1 To ensure easy retrieval, filing cabinets, shelves, boxes, folders, and envelopes are labeled according to the established filing system. Likewise, a Records Matrix is maintained indicating information, such as: Record Title, Retention Period and Record Custodian for both active and inactive records.

6.5.2 Records, borrowed by other offices or workgroups, are traced using logbooks or log sheets.

6.6 Maintenance and Disposal

6.6.1 Maintenance and disposal of records are done in accordance with the Records Matrix. Turnover of inactive records is scheduled on and recorded in a specific logbook of the concerned individual or office.

6.6.2 Permanent records bearing authentic signatures can be converted to e-files; but the hard copy should be retained or maintained (the e-files can serve as back-up files)

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7.0 REFERENCES:

7.1 See 8.0 Records Matrix

8.0 RECORDS MATRIX

TITLE	RETENTION		CUSTODIAN	
	Active	Inactive	Active	Inactive
Sample only				
TOR	Upon Closure (+2yrs)	Permanent	PM	Records Office/ COO
Invitation to BID	Upon Closure (+2yrs)	Permanent	PM	Records Office/ COO
Letter of Intent	Upon Closure (+2yrs)	Permanent	PM	Records Office/ COO
Letter of Inquiry from client	Upon Closure (+2yrs)	Permanent	PM	Records Office/ COO
Client Referral Acceptance & Monitoring Form	Upon Closure (+2yrs)	Permanent	PM	Records Office/ COO
Inquiry Receipt and Endorsement Form	Upon Closure (+2yrs)	Permanent	PM	Records Office/ COO
Contact Report	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO
Client Profile/ Background Info	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO
Project Proposal	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO
Prescribed Project Proposal from the client	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO
Logframe	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO
Workplan	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO
Finplan	Upon Project Closure (+2yrs)	Permanent	Finance Center/ Accounting	Records Office/ COO
Transmittal letter	Upon Project Closure (+2yrs)	Permanent	PM	Records Office/ COO

"usefulness is worthy of preservation because of administrative, legal, historical and/or significance in the lifetime of the agency."

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QUALITY PROCEDURE CONTROL OF NON- CONFORMITY



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	PFDA-QP-03	Quality Procedure	Effectivity:	

1.0 PURPOSE

This document defines the policies and guidelines to identify and control nonconforming products/services during PFDA operations and QMS scope.

2.0 POLICY

The PFDA shall provide services to its clients in accordance with their specified requirements. As such, it is the policy of the PFDA to ensure that all services that do not conform to requirements are identified, evaluated, and resolved in accordance with the guidelines as provided in this document.

3.0 DEFINITION OF TERMS:

- 3.1 NC - Nonconformity. Deviation from a specified requirement that need immediate action.
- 3.2 OFI - Opportunity for Improvement. A lapse in the system that causes minor errors or may cause potential problems in PFDA operations and therefore may need to be improved.
- 3.3 RFA - Request for Action form. This is used to initiate and record the identified NC/OFI and monitor the status and actions taken relative to the NC/OFI.
- 3.4 Disposition - Actions to be taken on nonconformities
- 3.5 Control Measures - Actions to be taken to prevent occurrence of an identified Nonconformity

4.0 SCOPE

This document applies to all services provided by the PFDA for its clients, where nonconformities may arise during Harbor and Market operations.

5.0 RESPONSIBILITIES

- 5.1 Unit Staff - Identify the nonconformity and initiates the control and disposition measures, in coordination with assigned Supervisor or authorized officer. He or she Records the information/data related to nonconformity as per Corrective and Preventive Action Procedure
- 5.2 Unit Manager - Identifies nonconformities, establishes the control methods, defines responsibilities and authorities, and reviews and approves the necessary action to address the identified nonconformity.
- 5.3 Agency Head – Authorizes actions involving high level risk to PFDA.

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6.0 PROCEDURE DETAILS

Ref. No.	Key Activities	Responsibilities
6.1	Identification of nonconformity	Unit Staff
6.2	Verification	Unit Manager
6.3	Resolution	Unit Manager
6.4	Implementation of Appropriate Action	Refer to Control of Nonconformity Matrix
6.5	Verification of Action Taken	IQA Team/Department Head / Agency Head

6.1 Identification of nonconforming products/services

Nonconforming products/services may arise, from agency operation or QMS scope, when deviation(s) from the following project documents happen during execution:

- Financial Plan
- Work Plan
- Contract with suppliers, including resource persons/consultants
- Code of Conduct

Upon identification, such nonconformity is recorded using the RFA form. Refer to PFDA -QP-04 Corrective and Preventive Action Procedure.

6.2 Verification of Nonconformity

All documented nonconformities are referred to the Unit Manager, for verification and analysis of the nonconformity, using appropriate problem solving tools/techniques. The Unit Manager, depending on the nature of the nonconformity, may initiate a meeting with concerned individuals to facilitate the verification and identification of root cause.

6.3 Resolution of nonconformity

After problem analysis, the necessary corrective/preventive action is formulated and recorded in the RFA form. Whenever possible, the target date for completion of "Action to be Taken" are indicated in the RFA, as a basis for the subsequent follow-up and verification of action taken and results.

6.4 Follow-up on Action Taken

With reference to the submitted RFA, the Unit Manager, may conduct follow-ups on "action to be taken" and perform some verification to ensure that appropriate action have been taken to address the identified nonconformity. If the implemented

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resolution or control measure, to address the identified nonconformity, is found to be more effective and/or efficient, such approach may be adopted to update the established Control of Nonconformity Matrix. Revision of such Matrix follows the Document Control Procedure.

6.5 The matrix below describes the disposition and/or control measures applicable to identified NCs.

CONTROL OF NONCONFORMITY MATRIX

Nature of Nonconformity	Disposition/Control Measures	Responsibility
Delays on target dates for deliverables	<ul style="list-style-type: none"> • Inform Client • Revise Workplan 	
Billing errors	<ul style="list-style-type: none"> • Retrieve the Billing Statement • Reissue BS with covering explanation 	
Inability to notify customer re changes in planned arrangements	<ul style="list-style-type: none"> • Issue written explanation/apologies 	
Errors in publication	<ul style="list-style-type: none"> • Publish errata 	
Deviation from established Code of Conduct	<ul style="list-style-type: none"> • Investigate • Refer to superior/ manager for immediate appropriate action 	
Documentation errors <ul style="list-style-type: none"> • Reports • Certificates • Handouts • Correspondence 	<ul style="list-style-type: none"> • Retrieve • Revise • Resend 	

7.0 REFERENCES:


- | | | |
|-------------------------|---|--------------------------------------------|
| 7.1 PFDA -QP-01 | - | Control of Documents |
| 7.2 PFDA -QP-04 | - | Corrective and Preventive Action Procedure |
| 7.3 PFDA -QP-04 F01 | - | Request for Action Form |
| 7.4 PFDA Code of Ethics | | |

PHILIPPINE FISHERIES DEVELOPMENT AUTHORITY

QUALITY PROCEDURE

CONTROL OF CORRECTIVE AND PREVENTIVE ACTION



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	PFDA-QP-04	Quality Procedure	Effectivity:	

1.0 PURPOSE

This document provides the policies and procedure to initiate and record corrective and preventive actions taken by the PFDA to eliminate causes of nonconformities and support the intention of continual improvement.

2.0 POLICY


The delivery of PFDA's products and services necessitates that specified requirements of customers/clients are satisfied in accordance with the service agreement. It is the policy of the PFDA to identify, control and prevent recurrence/occurrence of products/services that do not conform to specified requirements. It is likewise the policy of the PFDA to implement corrective and preventive actions to continually improve the effectiveness of the established quality management system.

3.0 DEFINITION OF TERMS:

- | | |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1 NC | - Nonconformity. Deviation from a specified requirement that need immediate action. |
| 3.2 OFI | - Opportunity for Improvement. A lapse in the system that causes minor errors or may cause potential problems in PFDA harbor and market operations and therefore may need to be improved. |
| 3.3 Corrective Action | - Action to eliminate the cause of a detected NC/OFI or other undesirable situation. Corrective action is taken to prevent recurrence. There can be more than one root cause for a NC/OFI. |
| 3.4 Preventive Action | - Action to eliminate the cause of a potential nonconformity or other undesirable situation. Preventive action is taken to prevent occurrence. There can be more than one root cause for a NC/OFI. |
| 3.5 RFA | - Request for Action form. This is used to initiate and record the identified NC/OFI and monitor the status and actions taken relative to the NC/OFI. |
| 3.6 Initiator | - A PFDA officer or staff who initiated the RFA. |
| 3.7 IQA | - Internal Quality Audit. A procedure to evaluate the effectiveness of the QMS. |

4.0 SCOPE

This procedure covers all corrective and preventive actions identified when nonconformity is encountered/anticipated through internal audits, customer complaints, problems encountered/anticipated during PFDA market and harbor operations or QMS scope and any event that could affect the QMS.

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5.0 RESPONSIBILITIES

- 5.1 The Quality Management Representative is responsible for ensuring the proper implementation of this procedure.
- 5.2 The Unit Manager ensure that appropriate actions are carefully reviewed, approved, and implemented without undue delay to eliminate the causes of nonconformities. They are also responsible for ensuring the effectiveness of actions taken.
- 5.3 The Initiator is responsible for conducting follow-up activities to verify the completeness and the effectiveness of the actions taken.
- 5.4 The Unit Staff may initiate requests for actions upon identification of NC or OFI.
- 5.5 IQA Auditors are authorized to initiate RFA through their Audit Team Leader.
- 5.6 The IQA Team Leader maintains a registry of issued RFA.

6.0 PROCEDURE DETAILS

6.1 Identification of Nonconformities

Nonconformities are identified through or during conduct or as a result of the following:

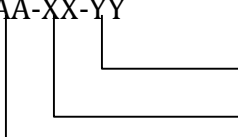
- 6.1.1 ---- operations;
- 6.1.2 Benchmarking;
- 6.1.3 Analysis of similar processes;
- 6.1.4 Evaluation of previous outputs/activities relative to the operations;
- 6.1.5 QMS audits;
- 6.1.6 Customer feedback; and,
- 6.1.7 Supplier evaluation.

6.2 Documenting and Reporting of Nonconformities

Identified nonconformities should be recorded on the RFA Form.

6.2.1 Prior to issuance of RFA, the form is assigned a serial number as follows:

AAA-XX-YY



Sequence number
Year
Origin
CDDSSS - SSSD department

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6.2.2 RFA form contains information that includes, but not limited to:

- Description of potential or actual nonconformity/nonconformance/OFI;
- Root-cause analysis, if applicable;
- Proposed action;
- Individuals responsible for initiating and implementing action;
- Target completion date; and,
- Follow-up action date.

6.3 Corrective and/or Preventive Action Implementation

6.3.1 The individual or unit/group responsible for the identified nonconformity identifies its root cause and implement appropriate action in a timely manner. The identified root cause is recorded in the appropriate section of the RFA.

6.3.2 For actions to be effective, they should be focused on addressing the root-cause rather than the detected NC/OFI.

6.3.3 The Unit Manager reviews and approves the actions indicated in the RFA, prior to their implementation.

6.4 Verification of Actions Taken

6.4.1 Details of the actions taken and the verification results are written on the follow-up portion of the RFA.

6.4.2 Once the target completion date is due, the IQA Team Leader/Initiator verifies the action taken and records this in the RFA.

6.4.3 If verification necessitates an additional action plan or follow-up, the next follow-up date is agreed upon.

6.4.4 To ensure that needed actions are prevented from unnecessary delays, follow-ups shall be limited to only three times wherein the PFDA Head conducts the third and final follow-up.

6.5 Effectiveness of Actions Taken

6.5.1 Effectiveness of actions taken is discussed and verified during Management Team meetings wherein information relevant to RFAs is considered.

6.5.2 Records of review of the effectiveness of actions taken are maintained per department.

6.5.3 Status of actions taken is included in the agenda and is discussed during management reviews.

7.0 REFERENCES:


- | | | |
|---------------------|---|--------------------------|
| 7.1 PFDA -QP-04 F01 | - | Request for Action Form |
| 7.2 PFDA -QP-03 | - | Control of Nonconformity |
| 7.3 PFDA -QP-05 | - | Internal Quality Audit |

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QUALITY PROCEDURE

CONTROL OF INTERNAL QUALITY AUDIT



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	PFDA-QP-05	Quality Procedure	Effectivity:	

1.0 PURPOSE:

- 1.1 To establish, document, and maintain a procedure for the PFDA's Internal Quality Audit (IQA).
- 1.2 To define the system for the planning, preparation, execution, follow-up, and reporting of IQA activities in determining whether:
 - 1.2.1 The QMS conforms to the planned arrangements, to the requirements of standard audit criteria and to the established PFDA quality management system; and,
 - 1.2.2 The QMS is effectively implemented and maintained.

2.0 SCOPE:


- 2.1 This procedure applies to the PFDA's quality management system whose processes directly affect the quality of services delivered to the customer.

3.0 DEFINITION OF TERMS:

- 3.1 Audit - Systematic, independent, and documented process for obtaining evidence and evaluating it objectively, to determine the extent to which criteria are fulfilled.
- 3.2 Audit Plan - Description of the activities and arrangements for an audit
- 3.3 Audit Scope - Extent and Boundaries of an audit
- 3.4 Audit Criteria - A set of policies, procedures, or requirements.
- 3.5 Audit Evidence - Records, statements of facts or other information which are relevant to the audit criteria and verifiable.
- 3.6 Audit Findings - Results of the evaluation of the collected audit evidence against audit Criteria.
- 3.6 NC - Nonconformity, non-fulfillment of requirement.
- 3.7 Disposition - Actions to be taken to address nonconformities
- 3.8 Control Measures - Measures to be taken to prevent occurrence of an identified problem
- 3.9 RFA - Request for Action form
- 3.10 OFI - Opportunity for Improvement – an area of the QMS which currently fulfills the requirement but which may be further enhanced to prevent a possible non-conformity.
- 3.11 QMR - Quality Management Representative

4.0 RESPONSIBILITY

- 4.0.1 The QMR is responsible for ensuring that a complete audit on the quality management system takes place at least once a year.
- 4.0.2 The IQA Team Leader is responsible for ensuring the proper implementation of this procedure.
- 4.0.3 The QMR is responsible for ensuring that appropriate actions, with regard to audit findings are taken without undue delay to eliminate their causes.
- 4.0.4 The auditor(s) who carried out the audit, which resulted in raising audit findings, is responsible for conducting follow-up activities to verify the completeness and the effectiveness of the actions taken. And are responsible for preparing the necessary tools and Audit Checklist to be used for the Audit.
- 4.0.5 Auditee provides audit evidence to the IQA team; responds to audit findings as needed.

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4.1 Planning the Audit


- 4.1.1 An Annual Audit Plan is prepared by the IQA Team Leader before the start of a calendar year.
- 4.1.2 The Annual Audit Plan contains the schedule for a twelve-month period during which the whole of the quality management system will be audited, at least once.
- 4.1.3 In addition to the planned audits, unplanned internal audits may be initiated by the QMR, if deemed necessary. Decisions for initiating unplanned internal audits should be based on:
 - unusual increase of quality related problems,
 - introduction of new products and services,
 - changes on the quality system, function and processes, and,
 - customer's request.
- 4.1.4 The Annual Audit Plan is reviewed and approved by the President prior to its implementation.
- 4.1.5 Copies of the Annual Audit Plan are disseminated to all concerned departments through a memorandum prepared by the QMR.
- 4.1.6 Prior to conducting an audit, both planned and unplanned audit require a notification, to be given at least a week before the conduct of audit, to affected functions. Notification of an audit shall be in the form of an Audit Schedule prepared by the IQA Team Leader.
- 4.1.7 An Audit Schedule shall include the:
 - purpose of the activity;
 - audit scope;
 - departments to be audited with their designated representatives;
 - assigned auditors; and,
 - date and time of the audit.
- 4.1.8 Auditors, who are tasked to conduct the audit shall be selected from the pool of qualified personnel listed on the Special Order duly signed by the General Manager. Auditors registered on the list are trained and qualified in accordance with appropriate education, training, skill, and experience.

4.2 Preparation for the Audit

- 4.2.1 Upon notifying auditors and auditees, necessary documentation (e.g. Quality Manual, PAWIM, QMS and project management records) are reviewed by auditors.
- 4.2.2 Taking into account the audit scope, objectives, and the information gained from the review of various documents and records, Audit Checklists are developed.

4.3 Conducting the Audit

- 4.3.1 An opening meeting is conducted prior to actual audit to reconfirm audit schedule, basis for the audit, and audit participants.

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4.3.2 An Audit proper must have the following activities:

- Establishment of facts by interviewing personnel, reviewing documents, observing processes, and verifying records.
- Recording of facts as evidence of the audit.
- Evaluation of facts to determine the objective evidence of a nonconformity.
- Classifying audit findings as to NC or OFI.

4.3.3 Closing meeting is conducted to present audit findings to the Port Management the audited area. RFAs are issued to the Quality Management Committee after the closing meeting.

4.4 Reporting of Audit Findings

4.4.1 Audit findings, are documented on the Request for Action (RFA) form.

4.4.2 Audit follow-up is conducted on or after the target implementation/completion date, to verify whether the appropriate action is effectively implemented.

4.4.3 Details of the actions taken and the verification results are written on the follow-up portion of the RFA.

4.4.4 In case of a rescheduled follow-up, the auditor ensures that the new follow-up date is properly recorded in the RFA.

4.4.5 “Closed” RFAs are returned to the IQA Team Leader.

4.4.6 An Audit Summary Report is prepared by the IQA Team Leader and submitted to the QMR for approval.

4.4.7 To provide evidence of a systematic audit and for useful references, the IQA Team Leader maintains all relevant records of concluded internal audits.

4.4.8 Results of internal audits are discussed and presented during management review meetings.

4.5 Verification of Actions Taken

4.5.1 RFAs are forwarded to the IQA Team Leader, who assigns control numbers for monitoring purposes. The IQA Team Leader maintains a registry of all RFAs.

4.5.2 Corrective/preventive actions are implemented without undue delay. Guidelines are given on Corrective and Preventive Action Procedure.

4.5.3 Actions to address OFIs are recommended but not required.

4 REFERENCES:

- | | | | |
|-----|----------------|---|--------------------------------------------|
| 4.3 | PFDA -QP-04 | - | Corrective and Preventive Action Procedure |
| 4.4 | PFDA -QP-04 F1 | - | RFA form |
| 4.5 | PFDA -QP-05 F1 | - | Audit Checklist |