Control of Documents and Records

Internal Audit

Control of Non-Conformity, Corrective and Preventive Action
Control of Documents and Records

Internal Audit

Control of Non-Conformity, Corrective and Preventive Action
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Control of Documents and Records
1.0 Objective

To establish proper flow, handling and control of essential documents and records affecting the products/service quality of the quality management system of Batangas State University

2.0 Scope

This procedure covers all documents that will be subject for initiation, review, approval, issuance, revision, control and maintenance such as quality manual, procedure manuals, work instructions, standard operating procedures (SOPs) for equipment, syllabus, curriculum, applicable statutory and regulatory requirements contained in CHED and CSC requirements, ISO Standards, and applicable records.

3.0 Reference Documents

BatStateU-QM : Quality Manual
BatStateU-PM-02 : Internal Audit
BatStateU-PM-03 : Control of Non-Conformity, Corrective and Preventive Action

All documents as reflected in the Document Masterlist (Internal and External).

4.0 Procedure

4.1 Identification and Control of Documents and Records

4.1.1 Each internal document shall have a unique identification title, control number and revision number such as

Quality Manual, BatStateU-QM
Institution Name - Quality Manual

Procedure Manual, BatStateU-PM-01 to 03
Institution Name - Procedure Manual - Control #

Work Instruction, BatStateU-WI-YYY-01 to XX
Institution Name - Work Instruction - Dept or Sect - Control #

Quality Objective, BatStateU-QO-YYY
Institution Name - Quality Objective - Dept or Sect

Operational Manual, BatStateU-OM-YYY
Institution Name - Operational Manual - Dept or Sect

For forms: BatStateU-FO-YYY-XX
Institution Name - Forms - Dept or Sect - Control #

For logbooks: BatStateU-LB-YYY-XX
Institution Name - Logbook - Dept or Sect - Control #

Revision, Rev. 00, 01, 02, 03…
4.2  Review, Approval and Issuance

4.2.1  Upon initiation of a new procedure and form, the originating department shall prepare the document and conduct review for adequacy.

4.2.2  For Quality Manual, Procedure Manuals and Quality Objectives, the Executive Committee shall conduct final review and shall be approved by the University President. For Work Instructions and forms, these should be reviewed by the originating department’s immediate superior and approved by the next higher supervisor. For new forms, this shall be reflected on the “Review and Approval Form” (No.: BatStateU-FO-DC-01).

4.2.3  Approved new document (including form) shall be endorsed to the Documents Controller and stamped “MASTER COPY” on each page (except for manuals/book – form materials which shall be stamped on the first page only) and stamped “RECEIVED” (first page only) with the affixed date of receipt, and register in the Document Masterlist (BatStateU-FO-DOC-03).

4.2.4  The Document Controller or the originating department shall determine the necessary distribution that will be indicated in the “Distribution and Retrieval Form” (No.: BatStateU-FO-DC-02). The document shall be reviewed against the Document Masterlist by the Document Controller to check any affected document/s. New documents which are not yet in the masterlist, shall be temporarily noted and be reflected in the next issue.

4.2.5  Updating of the Document Masterlist shall be done every new or revised document is received. All documents’ current revision status shall be identified in the masterlist and shall be used as a guide to prevent unintended use of obsolete document.

4.2.6  The Document Controller shall reproduce and issue the document as indicated in the distribution list.

4.2.7  All distributed copies shall be stamped with “CONTROLLED” on all pages except for manuals/book - form materials which shall be stamped on the first page only and stamped “ISSUED” (first page only) with affixed date of issue of the Controller. Forms to be used by the end user are not stamped “Controlled”.

4.2.8  All controlled (new and revised) documents shall be affixed with a “Document Revision Record” (No.: BatStateU-FO-DOC-02) for its revision description history.

4.3  Document Review, Revision and Reapproval

4.3.1  Controlled documents shall be reviewed regularly, or every internal audit, for adequacy and suitability. Results of review will be carried over on the audit report.

4.3.2  In case of any change/s in the content of the controlled document or form, the originating department should request for “Document Change Notice” (No.: BatStateU-FO-DOC-01) for review and re-approval by the same persons who performed original review and approval, unless otherwise specifically designated in the Document Change Notice form.
4.4 Filing, Availability, Retrieval and Storage

4.4.1 Every department is responsible in filing and properly storing their forms, documents and records.

4.4.2 All forms, documents and records shall be available at anytime at point of use and shall be filed accordingly in binders/ folders with proper labels for easy retrieval and to prevent damage, deterioration and loss.

4.4.3 The Document Controller should randomly check documents annually to ensure their availability at point of use. Results of checking shall be registered in a “Document Monitoring” logbook (No.: BatStateU-REC-LB-01)

4.5 Legibility

4.5.1 All documents and records shall be ensured of its legibility.

4.5.2 Controlled documents and records of any form should not use thermal paper.

4.5.3 The use of correction fluid/tape or pencil is not permitted.

4.5.4 To correct documents, the proper authority should draw a horizontal line across the entire word/s, number or alphanumeric series and write his/her name, initial and signature as well as the date the correction was made.

4.6 External Documents

4.6.1 External Documents are documents coming from external source such as international standards, statutory and regulatory requirements, specifications, drawings, equipment manuals, material safety data sheets, reference books, etc.

4.6.2 All external documents received by the Document Controller shall be stamped “CONTROLLED” on each page and “RECEIVED” (first page only) with affixed date of receipt/signature of the recipient except for reference equipment manuals/books which shall be stamped “CONTROLLED” on the first page only.

4.6.3 The Document Controller shall register the external document received in the Document Masterlist (No.: BatStateU-FO-DOC-03).

4.6.4 Distributed documents shall be stamped “CONTROLLED” on each page and “ISSUED” (first page only) with affixed date of receipt/signature of the recipient except for reference equipment manuals/books which shall be stamped “CONTROLLED” on the first page only.

4.6.5 Documents in electronic form (e.g. soft copy) will not be stamped controlled but will only be registered in the Document Master list.

4.6.6 The receiving department or the Document Controller shall identify the distribution of the received document and shall be reflected on the distribution list.
4.6.7 The Document Controller is NOT required to maintain a copy of any external document in book or manual form unless needed.

4.6.8 The “NO RETRIEVAL, NO DISTRIBUTION” Policy will be implemented.

4.7 Obsolescence and Retrieval

4.7.1 All obsolete documents must be retrieved or recalled by the Document Controller upon issuance of the newly revised or updated documents and will be stamped “OBSOLETE”.

4.7.2 Obsolete original documents must be stored for reference purpose and will be disposed as per 4.9.

4.7.3 Records for archive shall be endorsed to the Document Controller by the department owner for processing as per National Archives of the Philippines.

4.7.4 Documents and records must be properly labelled such as name of records, date covered (month and year) and are placed in the cabinets to ensure easy retrieval and to protect it from damage, deterioration and loss.

A logbook is provided for the control of all documents and records being archived (No.: BatStateU-REC-LB-11)

4.8 Retention

Please refer to BatStateU-REC-QMS-01 (Master Matrix of Records).

4.9 Disposition

4.9.1 All records/documents intended for disposition as per 4.8 shall be recycled, shred or sold.

5.0 Records

Records are filed and maintained as per 4.5 to 4.8.

6.0 Responsibility

It is the responsibility of the Document Controller that the above procedure is properly implemented.
7.0 References

BatStateU-REC-QMS-01: Master Matrix of Records
BatStateU-FO-DOC-01: Document Change Notice
BatStateU-FO-DOC-02: Document Revision Record
BatStateU-FO-DOC-03: Document Masterlist
BatStateU-FO-DC-01: Review and Approval Form
BatStateU-FO-DC-02: Distribution and Retrieval Form

Prepared by:
Prof. Rogelio A. Antenor
Quality Management Representative
Date: DEC 27 2016

Reviewed by:
(See attached Certification)
The Executive Committee
Date: DEC 2 8 2016

Approved by:
Dr. Tirso A. Ronquillo
University President
Date: DEC 2 9 2016
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**Document Title:** CONTROL OF DOCUMENTS AND RECORDS

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PROCEDE MANUAL

Document Reference No.: BatStateU-PM-01

Document Title: CONTROL OF DOCUMENTS AND RECORDS

Reference No.: BatStateU-FO-DC-01 Effectivity Date: January 03, 2017 Revision No. 00

Title: REVIEW AND APPROVAL FORM

Authored by: ___________________________ Doc. Control No.: ________________

☐ Internal Document ☐ External Document ☐ Soft Copy ☐ Hard Copy

Name or Title of Document:

If applicable: Ref. No.: ___________ Effectivity Date: ___________ Revision No.: ___________

Type or Classification of Document:
☐ Form ☐ Syllabus ☐ Curriculum ☐ SOPs For Equipment ☐ IQA Documents
☐ Others ________________

Brief Description of the Document:

Review Comments / Recommendations (include an attachment if necessary):

Inclusive Date of Review:

Reviewed by: ___________________________ Approved by: ___________________________

Signature Over Printed Name Of Official Signature Over Printed Name Of Official
Designation: ___________________________ Designation: ___________________________
Office: ___________________________ Office: ___________________________
Date Signed: ___________________________ Date Signed: ___________________________

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Internal Audit
1.0 Scope

The procedure covers the internal quality audit process from audit planning and scheduling to follow-up audits and reporting.

2.0 Objective

To document, establish, implement and maintain an internal audit procedure for an effective implementation of the established quality management system.

3.0 Reference Documents

- BatStateU-QM: Quality Manual
- BatStateU-PM-01: Control of Documents and Records
- BatStateU-PM-03: Control of Non-Conformity, Corrective and Preventive Action

4.0 Procedure

4.1 Planning and Scheduling

4.1.1 All quality system process elements shall be audited at least once a year as per Audit Master Schedule (No.: BatStateU-FO-IQA-01) which shall be approved by the Quality Management Representative (QMR). The schedule shall be formulated on the basis of the status and importance of the activity. However, a particular area of the entire quality system may be audited more frequently, when deemed necessary.

4.1.2 The Lead Auditor shall furnish the auditors with the objectives and scope of audit, the names of the team members, the department to be audited and other pertinent details before the scheduled audit date. This is to ensure the effectiveness of the audit.

4.1.3 The Lead Auditor shall ensure that all copies of the necessary documents such as quality manual, procedures, previous audit results and all other relevant documents are available during audit.

4.1.4 The Audit Plan (No.: BatStateU-FO-IQA-02) should include but not limited to the audit date, audit scope, audit objectives, criteria, audit team/auditors, time of audit, elements and areas to be audited and auditees.

4.1.5 The audit team shall prepare the necessary audit checklists to ensure that all the important items/elements are covered.

4.1.6 The audit checklist shall be referenced on the ISO standards, the quality manual, quality procedures and necessary work instructions, where applicable.

4.1.7 The section clauses or elements in the audit checklist shall be based from the audit plan.
4.1.8 The Lead Auditor shall discuss the necessary preparations, formulations of the audit plan and other audit activities, timetable and preparation and review of the audit checklist.

4.2 Selection of Auditors/Audit Team

4.2.1 Selection of lead auditor and auditors will be based on the competence of the auditors from the “List of Qualified Auditors”. Independence in conducting of audits shall be ensured by the QMR and the lead auditor for objectivity and impartiality to avoid conflict of interest and bias in opinion during audit.

4.2.2 The QMR shall maintain the integrity of the audit by ensuring that neither the lead auditor nor any member of the audit team is/are member/s of the department or function to be audited. They shall have no direct responsibility on the activity being audited.

4.2.3 The audit team shall be composed of qualified and trained internal quality auditors. The minimum qualification for the internal quality auditors must at least be a college graduate, a permanent employee with a total work experience of at least three (3) years and have attended an IQA training/seminar of at least 24 hrs.

Refer to Internal Quality Auditors Qualification Matrix.

4.2.4 The audit team consisting of the qualified auditors shall be nominated by the Lead Auditor prior to the audit.

4.3 Opening Meeting

4.3.1 An opening meeting shall be conducted by the lead auditor prior to proceeding with the audit; to be participated by the audit team, auditees and involved departments if necessary. The objective of the meeting is for familiarization and awareness of the participants on the mechanics of the entire audit process.

4.4 Conducting the Audit

4.4.1 Using the applicable documents and the prepared audit checklists, the lead auditor and the team members shall conduct the audit by interviewing the auditee at the area being audited or desk audit (review of the applicable documents), and/or checking of actual implementation against documented procedures.

4.4.2 The auditor shall note down on the checklist all the necessary findings during the time of audit, including the objective evidences of conformances and/or non-conformances.

4.4.3 The QMR should evaluate the competence of the lead auditor while the lead auditor and/or the QMR will evaluate the competence of the internal quality auditors. Refer to Auditor’s Performance Evaluation (No.: BatStateU-FO-IQA-04).

4.4.4 All findings whether major or minor non-conformances shall be classified as Non-conformity (NC) and Improvement Potential (IP) for those which can lead to potential non-conformance or can still be improved.
4.4.5 a) Non-Conformity (NC)

- Absence of procedure required by the standard.
- Non-implementation of a procedure required by the standard.
- A lapse in the implementation of the management system.
- An isolated lapse in an implemented management system requirement.
- Health and safety requirement not implemented.

b) Improvement Potential (IP)

- All areas of concern that would lead to non-conformities.
- Suggestions or recommendations of best practices.
- Improvement possibilities of the system.

4.4.6 The lead auditor shall discuss with the auditee the results of the audit.

4.4.7 The audit team shall evaluate their findings and deliberate on the nonconformity found during the audit. Final decision as agreed upon by the audit team must be reflected on the audit report. Unresolved issue by the team shall be decided by the QMR or the Lead Auditor.

4.5 Closing Meeting

4.5.1 Closing meeting shall be conducted as soon as the audit has been finished. Similar participants during the opening meeting are expected to attend the closing meeting.

4.5.2 The lead auditor will discuss the results of the audit. For the findings called-out during the audit, non-conformance reports are issued to the concerned department. Unresolved issues with the auditee are elevated to the department head. They will likewise agree to the follow-up action to be taken as scheduled.

4.6 Reporting

4.6.1 The final basis for the results of the audit shall be formalized through internal audit report which will be prepared by the lead auditor for review and approval of the QMR.

4.6.2 All auditees with findings shall be issued with a Non-conformity, Corrective and Preventive Action Report (NCPAR) but distribution of audit report will be as per discretion of the QMR.

4.6.3 Correction as necessary, corrective and preventive action shall be initiated and implemented by the auditee/Department Head to be documented through the NCPAR and coordinated with the lead auditor. For details on the investigation, refer to control of non-conformance, corrective and preventive action procedures.

4.6.4 All results of the internal quality audit shall be an input to the management review meeting for continuous improvement.

4.6.5 Corrective actions not implemented on the committed date shall be elevated to the QMR for further disposition.
4.6.6 Corrective actions are then declared “closed” once verified to be effective upon approval of the QMR.

4.7 Follow-up Audit

4.7.1 A follow-up audit shall be conducted minimum of two (2) days after implementation of the corrective action even without prior announcements to verify if the committed action is implemented and preferably minimum of one (1) month after another follow-up audit will be done to verify the effectiveness of the implemented action. This must be recorded in the Corrective and Preventive Action Monitoring Log (No.: BatStateU-FO-NCP-02).

4.7.2 To maintain the continuity of the audit, preferably, the same audit team may be assigned to do the follow-up audit if necessary.

5.0 Records

5.1 List of Qualified Auditors
   BatStateU-FO-IQA-01: Audit Master Schedule
   BatStateU-FO-IQA-02: Audit Plan
   BatStateU-FO-IQA-03: Auditors Evaluation Checklist
   BatStateU-FO-IQA-04: Auditor’s Performance Evaluation

5.2 Internal quality audit records will be maintained and filed by the lead auditor in accordance to control of documents and records procedure.

6.0 Responsibility

It is the responsibility of the QMR and the Lead Auditor to ensure that the above procedure is implemented.

Prepared by: Prof. Rogelio A. Antenor
Quality Management Representative
Date: DEC 27 2016

Reviewed by:
(See attached Certification)
The Executive Committee
Date: DEC 28 2016

Approved by: Dr. Tirso A. Ronquillo
University President
Date: DEC 29 2016
Control of Non-Conformity, Corrective and Preventive Action
1.0 Scope
This procedure is applicable to all products/materials, process and system non-conformances including customer feedbacks/complaints and unmet quality objectives’ targets.

2.0 Objective
To establish and maintain documented Control of Non-conformance, Corrective and Preventive Action procedures to ensure effective implementation of the actions.

3.0 Reference Documents
- BatStateU-QM: Quality Manual
- BatStateU-PM-01: Control of Documents and Records
- BatStateU-PM-02: Internal Audit
- BatStateU-WI-PO-03: Handling Customer Complaints
- BatStateU-WI-OSAS-01: Student Grievance Process

4.0 Procedure

4.1 All non-conformances detected as a result of defective product/material, unmet goals/objectives and targets, customer complaints, unsatisfactory results of customer survey, audit findings and service related non-conformances, must be recorded and identified. Investigation of the cause must define the nature and extent of the non-conformance.

4.2 Any affected personnel upon observance of a non-conformance as stated in item 4.1 can raise a Non-conformance Report or inform any member of the involved department about the non-conformance observed.

4.3 The involved department shall record the non-conformance into the Non-Conformity, Corrective/Preventive Action Report (NCPAR) (No.: BatStateU-FO-NCP-01).

4.4 For product or material he/she shall identify and segregate the non-conforming product/material and dispose as follows:
   a) Condemned or
   b) Reject and return to supplier

4.5 Disposition must be reviewed, agreed and implementation must be verified through inspection and/or test as applicable. Records of accepted non-conforming product or material must be recorded.

4.6 Correction and Corrective Action

4.6.1 Correction shall be taken to eliminate a detected nonconformity. This can be made in conjunction with corrective action.

4.6.2 Corrective action shall be taken to eliminate the cause of a detected nonconformity to prevent the non-conformity recurrence. This can be initiated by any staff responsible for the non-conformance/s as a result described in item 4.1.

The department concerned of the non-conformance shall be responsible for the timely investigation on the probable root cause of the problem, the formulation of correction as necessary and implementation of corrective action needed to eliminate its recurrence. Application of controls to ensure the effectiveness of the action taken shall be determined. These shall be recorded in the Non-conformity, Corrective/Preventive Action Report (NCPAR).
4.7 Preventive Action

The determination of preventive action to eliminate the cause of potential non-conformities in order to prevent their occurrence may be done through the following but not limited to results of meetings, internal and external audits, customer satisfaction surveys and analyzed data.

4.7.1 Proposed preventive action and controls to be applied to ensure its effectiveness shall be discussed by the Department Heads. Relevant Information on preventive actions taken shall be discussed during the regular Management Review meetings. The finalized preventive action shall be recorded in the Non-conformity, Corrective/Preventive Action Report (NCPAR) (No.: BatStateU-FO-NCP-01).

4.8 Customer Complaints

4.8.1 Any report or feedback from the customer which is treated as complaint shall be handled by the respective department or an Investigation Committee, and shall be recorded through the Non-conformity, Corrective/Preventive Action Report (NCPAR).

Refer to BatStateU-WI-PO-03 : Handling Customer Complaints
BatStateU-WI-OSAS-01 : Student Grievance Process

4.9 Verification

4.9.1 Corrective and preventive actions implemented shall be logged by the assigned personnel in the Corrective and Preventive Action Monitoring Log (No.: BatStateU-FO-NCP-02) and will be monitored and regularly updated to verify its effectiveness. Refer to item 4.7 (Follow up) of Internal Audit Procedure, BatStateU-PM-02.

4.9.2 The Quality Management Representative or the Department Head shall approve the verification.

4.9.3 All necessary changes brought about by the implementation shall be reflected in the affected documented procedure or relevant work instructions as applicable.

5.0 Records

Records are filed and maintained as per Control of Documents and Records Procedure, BatStateU-PM-01.

6.0 Appendices

BatStateU-FO-NCP-01: Non-conformity, Corrective/Preventive Action Report (NCPAR)
BatStateU-FO-NCP-02: Corrective and Preventive Action Monitoring Log

Prepared by: Prof. Rogelio A. Antenor
Quality Management Representative
Date: DEC 2 7 2016

Reviewed by: The Executive Committee
(See attached Certification)
Date: DEC 2 8 2016

Approved by: Dr. Tirso A. Ronquillo
University President
Date: DEC 2 9 2016
# NON-CONFORMITY, CORRECTIVE/PREVENTIVE ACTION REPORT (NCPAR)

<table>
<thead>
<tr>
<th>NCPAR No.</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Department/College</th>
<th>Section Clause No. (for IQA only)</th>
</tr>
</thead>
</table>

1. Details: *Non-conformity raised as a result of:*

- [ ] Material, Product or Equipment
- [ ] Unmet Quality Objectives
- [ ] Customer Complaints
- [ ] Service Non-conformity
- [ ] Internal Quality Audit
- [ ] Potential Nonconformity
- [ ] Customer Satisfaction Survey
- [ ] Improvement

2. Description of: [ ] Non-Conformity  [ ] Potential Non-Conformity  [ ] Improvement

Detected by:  

3. Disposition: [Applicable for Material/Product or Equipment only]

- [ ] Rework/Repair
- [ ] Use as is
- [ ] N/A
- [ ] Reject & return to supplier
- [ ] Other

Proposed by:  

4. Correction (Immediate Action):  

Responsible Person/s:  

5. Root Cause Analysis: [ ] Non-conformity  [ ] Potential Non-conformity:

Investigated by:  

6. [ ] Corrective Action:  

[ ] Preventive Action:  

[ ] Improvement:

Responsible Person/s:  

7. Follow-up Implementation of Action:

- [ ] Satisfactory
- [ ] Not satisfactory (issue new NCPAR)

Remarks:  

Name & Signature:  

Date:  

8. Verification on the effectiveness of action: To be completed by the Department Head / Immediate Supervisor

- [ ] Satisfactory
- [ ] Not satisfactory (issue new NCPAR)

Remarks:  

Verified by:  

**Name of Department Head/Immediate Supervisor**  

Signature  

Date
# CORRECTIVE AND PREVENTIVE ACTION MONITORING LOG

<table>
<thead>
<tr>
<th>NCPAR No.</th>
<th>Date of Non-conformity Issued</th>
<th>Non-conformity</th>
<th>Root Cause Analysis</th>
<th>Corrective/Preventive Action</th>
<th>Target Date of Implementation</th>
<th>Date Action Verified as Implemented</th>
<th>Date Action Verified as Effective</th>
<th>Status</th>
</tr>
</thead>
</table>
Office of the Board and University Secretary

CERTIFICATION

This is to certify that the Procedure Manual (Control of Documents, Internal Audit and Control of Non-Conformity, Corrective and Preventive Action) has been reviewed by the Batangas State University Executive Committee prior to its approval.

Given this 28th of December 2016 at Batangas State University, Batangas City.

ENRICO M. DALANGIN
Board and University Secretary
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(043) 980-0385 loc. 1116