Documented procedure «Procedure for performing corrective and preventive actions»

DP.10.06/2021

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CONTENTS

1 PURPOSE AND SCOPE OF APPLICATION

This documented procedure of the quality management system has been developed in accordance with the requirements of the ST RK ISO 9001:2016 and regulates the procedure for analyzing non-compliances, assessing the need to develop, implement and verify the effectiveness of corrective and preventive actions based on the results of all types of inspections, internal audit in the structural divisions of the university. The original of this documented procedure is a paper medium.

The requirements of this documented procedure apply to all divisions of the university.

2 REGULATORY REFERENCES

The following regulatory documents were used in the development of this documented procedure:

ISO 9000:2017 Quality Management Systems - Basic provisions and vocabulary.

ST RK ISO 9001:2016 Quality Management Systems - Requirements.

DP.10.02/2021 Documentation management procedure

DP.10.03/2021 Procedure for managing quality records

DP.10.04/2021 Procedure for the management of non-compliant products

DP.10.05/2021 Procedure for conducting internal audit

3 DOCUMENTS RELATED TO THE PROCEDURE

Plan of corrective and preventive actions - Form F 03 -DP.10.05/2021

4 DEFINITIONS OF TERMS, DESIGNATIONS AND ABBREVIATIONS

4.1 Terms and definitions

The terms and their definitions from ISO 9000- 2017 Quality Management Systems. Basic provisions and vocabulary. are used in this documented procedure.

Procedure - an established way of carrying out an activity or process.

Process - a set of interrelated and interacting activities that transform inputs into outputs.

Corrective action - an action taken to eliminate the cause of a detected non-compliance or other undesirable situation.

A corrective action is taken to prevent the recurrence of an event; a preventive action is taken to prevent the occurrence of an event.

Preventive action - an action taken to eliminate the cause of a potential non-compliance or other potentially undesirable situation.

A preventive action is taken to prevent the occurrence of an event, while a corrective action is taken to prevent the recurrence of an event.

Release - permission to move to the next stage of the process.

Products - the result of the process.

4.2 Abbreviations

HD - The head of the division in this documented procedure, unless otherwise specified, the head of the division responsible for the development and implementation of corrective actions;

RD - regulatory documentation.

5 DESCRIPTION OF THE PROCESS

5.1 This description of the procedure for developing, conducting and verifying the effectiveness of corrective actions regulates the requirements for the content of the documented procedure "Procedure for performing corrective and preventive actions" DP.10.06/2021.

5.2 Procedure for the development and implementation of corrective and preventive actions.

The beginning for the development of corrective and preventive actions is a documented deviation from the established criteria.

The norms and criteria by which a decision is made to develop corrective actions should cover:

- results of internal audit (inspection);
- process indicators;
- non-compliances of products with established standards;
- information about the presence and frequency of occurrence of similar deviations.

The reason for the development of corrective and preventive actions is also the systematic deviation of the same parameter of product quality in the same direction from the nominal.

Typical non-compliances in the main processes are given in the Classifier of typical non-compliances F 01-DP.10.04/2021 (Documented procedure "Procedure for the management of non-compliant products").

The procedure for dealing with products that do not meet the established requirements is defined in the documented procedure of DP.10.04/2021 "Procedure for managing non-compliant products".

The person responsible for the analysis enters non-compliances in the "Plan of corrective actions" (Form F 03 - DP.10.05/2021), together with the head of the divisions identifies the reason for the rejection and develops proposals for actions on the process.

The result of the non-compliance analysis is formalized in the " Checklist for conducting an internal audit" F 02 - DP.10.05/2021. The procedure for filling out the Protocol is described in detail in the documented procedure DP.10.05/2021 "Procedure for conducting internal audit".

When developing corrective and preventive actions, the person responsible for the development first of all checks the assessment of the necessity and adequacy of

the costs of corrective and preventive actions, the severity of the deviation made by the person responsible for conducting an internal audit. The content of corrective and preventive actions is entered in the Form F 03 - DP.10.05/2021.

The plan of corrective and preventive actions is approved by the rector of the university.

An authorized representative of the university's quality management checks the nature and degree of influence of the developed actions on the quality of the final result.

The result of the implementation of corrective and preventive actions is noted in the plan of corrective and preventive actions. The implementation of corrective or preventive actions is carried out by responsible persons. The control of the timeliness and completeness of the implementation of corrective and preventive actions is assigned to the person responsible for their development.

The effectiveness of corrective and preventive actions is checked by the person responsible for the inspection during the internal audit.

If the reason for the non-compliance established during the internal audit has not been eliminated, the person responsible for the audit informs the university management about it in the form of a memo.

If the cause of the non-compliance is eliminated, the person responsible for the audit puts a mark on the implementation of the plan of corrective or preventive actions.

6 DOCUMENTATION AND ARCHIVING

6.1 The original of the documented procedure is kept in the Department of Academic Affairs.

6.2 Quality records are maintained in accordance with the requirements of the documented procedure DP.10.03/2021 "Quality records management procedure".

7 INFORMATION ON THE PROCESS

7.1 Incoming information

№	Document name	Responsible person for compiling	Term of provision	Note
1	Plan of corrective and preventive actions	Responsible person for inspection	As the non-compliance is identified	
2	QMS documentation required for process management or the functioning of a structural division	Process Owner Head of the structural division	After identifying the non-compliance	

7.2 Outgoing information

№ пп	Document name	Responsible person for providing	Term of provision	Note
1	2	3	4	5
1	Internal memo	RP Responsible person for the analysis of non-compliances	After identifying the non-compliances	

8 CHANGE REGISTRATION SHEET

Form of the document change registration sheet and its copies

Se-quence number of the change	Section, para-graph of the doc-ument	Type of change (replace, cancel, add)	Number and date of notification	The change was made	
				Date	Surname and initials, signa-ture, position
