

Title: CLIENT ISSUE MANAGEMENT PROCEDURE

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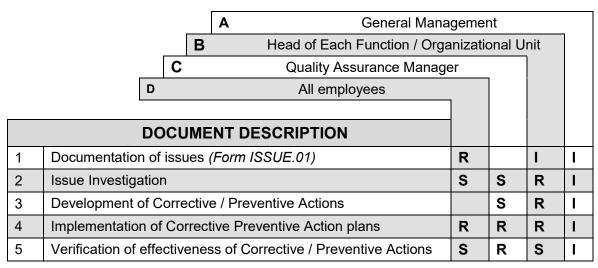
1. PURPOSE

1.1 This Procedure describes the process of documenting, investigating, and resolving Client issues.

2. GLOSSARY

- 2.1 Issue refers to a statement of dissatisfaction or recommendation that is expressed by a Client and received by the 12PM CONSULTING. Whenever a Client lodges a issue, a response is either explicitly or implicitly required.
- 2.2 Root cause analysis is a method of problem solving used for identifying the root causes of faults or problems. A factor is considered a root cause if removal thereof from the problem-fault-sequence prevents the final undesirable event from recurring; whereas a causal factor is one that affects an event's outcome, but is not a root cause. Though removing a causal factor can benefit an outcome, it does not prevent its recurrence with certainty.

3. RESPONSIBILITIES



R: Responsibility, I: Informed, S: Support

4. PROCEDURE

4.1 The manner in which the **12PM CONSULTING** manages client issues is defined in the table in the following page.

Note: The Table's first column shows the steps (actions) followed in order to perform the tasks described in this procedure. As required, the second column includes comments, identifies related documents associated with carrying out the particular activity, and (where required) the records and forms which are generated from the activity.



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ACTION Receipt of Issue Documentation Notify General Forward Issue to management and the Department (Function **Quality Assurance** Manager) Manager Issue Investigation Is the Issue YFS valid? NO NO Inform Person that filed the issue s the person that filed the issue Satisfied? YES **Notify General** Document the issue & Management closure **END**

COMMENTS

All employees are responsible for receiving and documenting issues.

Issues and recommendations are documented on standardized Form ISSUE.01, being careful to include as much detail as possible which will allow for throughout investigation and implementation of corrections / corrective actions, as circumstances warrant.

Following its documentation the issue is forwarded to the Department (function) manager responsible for the key processes associated with the issue.

The Department (function) Manager notifies the Company's General Management and the Quality Assurance Manager, and investigates the issue in an effort to verify the validity of the issue.

Note: Issues are considered "non-valid" when the nature of the issue does not include action (in-action) / responsibilities / activities on part of 12PM CONSULTING.

All non-valid issues need to be addressed immediately.

In the event that the issue is categorized as non-valid, the person that filed the issue is informed and the rational is documented in form ISSUE.01.

In the event that the issue is characterized as a valid issue, the actions defined below are followed.



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Investigate issue (Root cause analysis) / Develop Corrective / Preventive Actions (CAPAs) Inform person that filled the issue Satisfied? Implement CAPAs Document the issue

COMMENTS

All issues are investigated for the purpose of discovering the <u>root causes</u> of the undesirable situation. The investigator may retrieve related documents, including contracts, agreements, action plans, policies, and or other related quality documents which may assist in the investigation.

Following the completion of the investigation phase, corrections to remedy the undesirable situation are identified and (were circumstances warrant) implemented.

The person that filled the issue is informed of the actions implemented to remedy the situation. In the event that the selected corrections do not satisfy the person that filled the issue, alternate corrections are explored and (were circumstances warrant) implemented.

Throughout the investigation and correction phase, the Quality Assurance Manager as well as General Management are consulted and informed.

In the event that corrective actions intended to prevent recurrence of the undesirable situation are identified, these actions are implemented following agreement with the Quality Assurance Manager as well as General Management

All actions related to the issue's investigation and corrections are documented on the standardized Form ISSUE.01.

5. FORMS

6.1 Form: ISSUE.01: Client Issue Form

and closure

6. QUALITY RECORDS

FILE	MAINTAINED BY	MEDIA	RETENTION TIME
Form: ISSUE.01: Client Issue Form & all communications with Client	Quality Assurance Manager	Paper or electronic	For a period no less than three years



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REVISION HISTORY

VERSION	DATE	REVISION DESCRIPTION	REVISED BY
1	2/2/2017	First Issue	-