OBJECTIVE

To define the Incident Investigation Procedure (IIP) which is used to investigate, correct, and prevent problems and complaints.
The purpose of the IIP is to:

- identify the root cause of problems (including non-conforming product), and
- identify corrective and preventive actions needed to prevent recurrence.

The IIP includes an investigation conducted in cooperation with the area involved, and any other necessary experts to determine what went wrong and what its most basic causes were. The report includes a list of planned corrective and preventive actions both short term and long term with responsibilities and estimated timing for each item. Each action item identified in the investigation shall be documented as complete either in the initial IIP Report, or in later updates.

Status of open Incident Investigations will be reviewed periodically and every quarter, by the Quality Manager..

Procedure

IIP Incident Investigation shall be conducted for follow incident triggers:

Trigger points for Production Investigations
Investigation if more than 2 days of a greater than 10% production loss
Investigation if more than 25% of production loss in one day

Trigger points for Quality Investigations
Internal - An incident that produced a non-conforming product
External - A complaint that could result in a loss of customer, volume or cost to Giles Chemical

Trigger points for mechanical failure investigations
4 hour unexpected down time for the following equipment:

- Filter Press
- Digesters
- Crystallizers
- Centrifuges
- Dryers
- Bagger
- Palletizer
- Boilers
- Air Compressors

Investigations

The goal of each IIP Incident investigation is to uncover root cause of the problem, and to decide appropriate action which will correct and prevent recurrence. To understand the root cause, investigations should make use of appropriate information from employees, customers, suppliers, internal, and external records.

Quality Assurance issues a number for each IIP Incident.

IIP Incident Reports

IIP Incident Reports shall be written using form provided. The report may be written by anyone participating in the investigation.

Each IIP Incident Report shall be approved by the Manger, Quality Assurance and the Manager of the area involved. They shall ensure that reports are accurate, corrective and preventive actions are clearly stated, and that responsibilities and estimated completion dates are appropriate.

Each corrective and preventive action item shall list the persons responsible for completing the item and an estimated completion date. Unless the action item is complete with the original report, leave room below the item for updates.

Each action item shall be completed and reported as complete unless it is later found to be unnecessary. Items found to be unnecessary shall be identified in updates to the IIP Incident Report.

TRAINING DOCUMENTATION

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Revision Number	Revision Date	Revision Author	Revision Description
00	09/09/2005	CM	New Document
01	06/08/2009	PT	-Placed procedure on new format -Made Minor Revisions- CAPA replaced with IIP (Incident Investigation Report)