



# Alinion Sentinel

## Complaint Management and Monitoring

### Making Your Complaint Procedures Efficient, Effective and Documented

Complaints provide vital feedback about how a product is performing. They are an increasingly important focus of the Food and Drug Administration.

Quality and compliance managers are finding that point-solutions and spreadsheet-based systems are inadequate to manage the complaints handling process. Incomplete records, delayed investigations, poor status tracking, limited data analytics, and inefficient regulatory reporting are major hindrances for a growing organization. Organizations must find ways to streamline the complaint management process while, at the same time, ensuring its effectiveness.

Alinion Sentinel includes “Tickets,” a powerful complaint handling system that integrates your quality program directly to the way you manage and respond to complaints. It ensures that complaints are managed properly and regulatory requirements are met.

### Introducing Sentinel “Help Tickets”

Alinion Sentinel provides for the dynamic management of exception processing and compliance. Complaints are a key issue addressable by Sentinel. Sentinel

is user-configurable to process issues, e.g. complaints, from receipt of the complaint

communication to the final resolution, collection of evidence and documentation, communication and reporting.

Sentinel’s Ticket functionality is ideally suited for the recording, assessment, assignment and resolution of complaints. With Sentinel, organizations can establish and maintain procedures for receiving, reviewing and evaluating complaints and ensure that all complaints are processed in a uniform and time manner.

### Management Dashboard for Enhanced Visibility and Status

Easily monitor status and performance at any level in the entire enterprise.

### Dynamic Reporting

Comes with a powerful reporting engine that can provide complaint management activity and history.

### Complaint Management and Monitoring

Assign all complaints to one or more individuals, easily allowing for tracking of status and disposition.

### Evidence Collection and Support

Directly integrates documents to the specific complaint under management, Attach documents, work papers and other objects directly to the complaint record.



### Help Tickets

Viewing help tickets.

Command and Control Software  
for Document and Process Management



## Complaint Management Overview

Simple complaints can be received and responded to within the context of the Help Ticket Management Process. The Ticket can be assigned to a resource for resolution. The assignment can include any range of detail with priority and due date. Details can include the attachment of documents, e.g. emails and analysis documents.

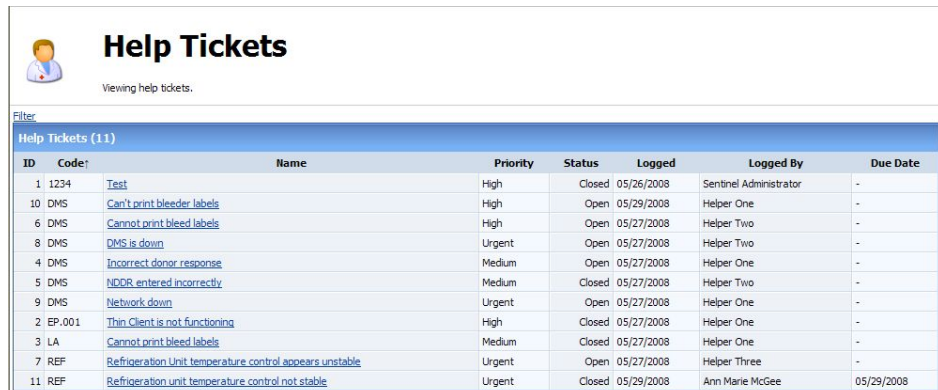
Sentinel also provides tracking and audit trails (Change Logs) that ensure the monitoring and documentation of complaints and other issues. At the

process level, help and complaint issues can be easily segregated by process, organization and ownership. The Help Ticket library enables authorized managers to monitor, filter and analyze all or any sub-group of tickets.

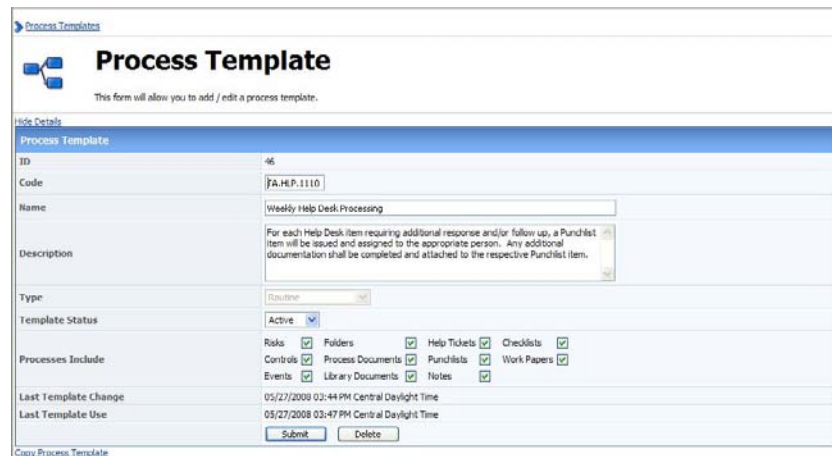
In addition, authorized persons can create reports, using a combination of parameters, to monitor up-to-the-minute help ticket / complaint data. All of this is done within an easy-to-implement, easy-to-use automated processing platform.

### Step 1: Define Your Complaint/Help Process Template

Using Sentinel's Process Template function, design a process template that will be used to create the recurring, complaint management processes. Such processes will be typical defined as *Routines*. The process template can be defined with a variety of components, along with the standard *Events and Tasks*. Optional components include Folders, Work Papers, Checklists, Documents, Controls, Punchlists, Notes and, of course, Help Tickets.



ID	Code	Name	Priority	Status	Logged	Logged By	Due Date
1	1234	Test	High	Closed	05/26/2008	Sentinel Administrator	-
10	DMS	Can't print bleeder labels	High	Open	05/29/2008	Helper One	-
6	DMS	Cannot print bleed labels	High	Open	05/27/2008	Helper Two	-
8	DMS	DMS is down	Urgent	Open	05/27/2008	Helper Two	-
4	DMS	Incorrect donor response	Medium	Open	05/27/2008	Helper One	-
5	DMS	NDDR entered incorrectly	Medium	Closed	05/27/2008	Helper Two	-
9	DMS	Network down	Urgent	Open	05/27/2008	Helper One	-
2	EP.001	Thin Client is not functioning	High	Closed	05/27/2008	Helper One	-
3	LA	Cannot print bleed labels	Medium	Closed	05/27/2008	Helper One	-
7	REF	Refrigeration Unit temperature control appears unstable	Urgent	Open	05/27/2008	Helper Three	-
11	REF	Refrigeration unit temperature control not stable	Urgent	Closed	05/29/2008	Ann Marie McGee	05/29/2008



**Process Template**

This form will allow you to add / edit a process template.

**Hide Details**

**Process Template**

ID: 46

Code: JA.HEP.1110

Name: Weekly Help Desk Processing

Description: For each Help Desk item requiring additional response and/or follow up, a Punchlist item will be issued and assigned to the appropriate person. Any additional documentation shall be completed and attached to the respective Punchlist item.

Type: Routine

Template Status: Active

Processes Include:

- Risks
- Folders
- Help Tickets
- Checklists
- Controls
- Process Documents
- Punchlists
- Work Papers
- Events
- Library Documents
- Notes

Last Template Change: 05/27/2008 02:44 PM Central Daylight Time

Last Template Use: 05/27/2008 03:47 PM Central Daylight Time

Buttons: Submit, Delete

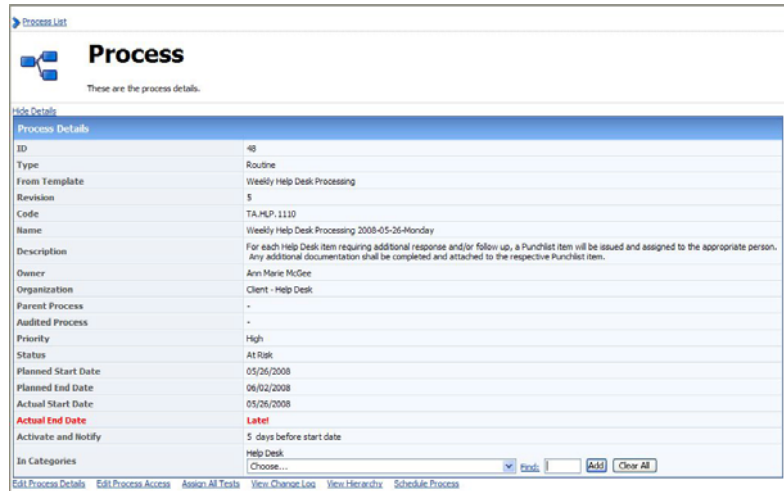
[Copy Process Template](#)

Once defined, the process template can be used as often as needed. It can be easily modified as a template and even copied and modified to create a similar template. For example, the template might be used in one organization to manage outside complaints and used in a different organization to manage internal help requests.

## Step 2: Create and Schedule the Complaint / Help Process

Create the Complaint management process from the template. This includes identifying the process owner, the managing organization, setting a priority and adding appropriate *Start* and *End* dates. In addition, the process can be linked as a child to another process within the appropriate organization.

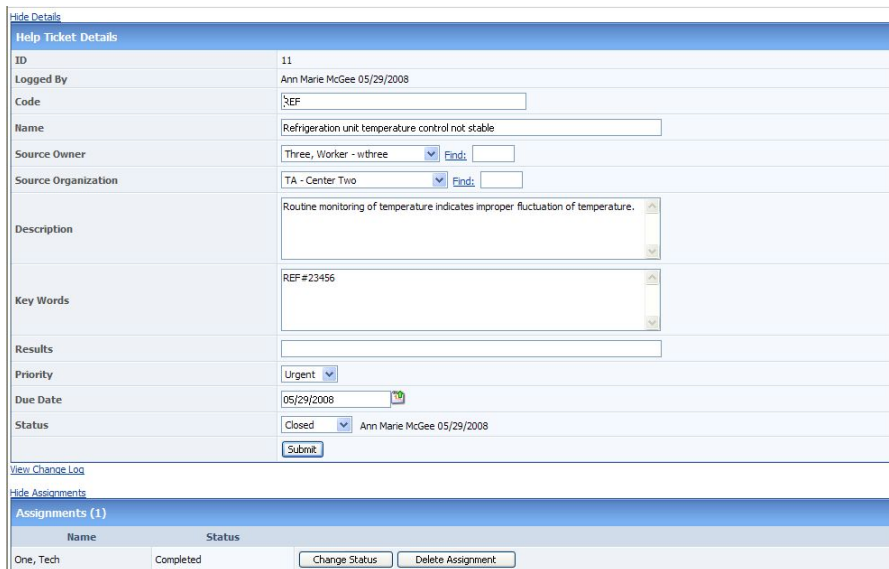
Next, the process owner needs to grant process permissions the staff who will handle complaints as well as other persons needing to monitor the process components.



Process Details	
ID	48
Type	Routine
From Template	Weekly Help Desk Processing
Revision	5
Code	TA.MLP.1130
Name	Weekly Help Desk Processing 2008-05-26-Monday
Description	For each Help Desk item requiring additional response and/or follow up, a Punchlist item will be issued and assigned to the appropriate person. Any additional documentation shall be completed and attached to the respective Punchlist item.
Owner	Ann Marie McGee
Organization	Client - Help Desk
Parent Process	-
Audited Process	-
Priority	High
Status	At Risk
Planned Start Date	05/26/2008
Planned End Date	06/02/2008
Actual Start Date	05/26/2008
Actual End Date	Label
Activate and Notify	5 days before start date
In Categories	Help Desk Choose...

Finally, the process owner makes any assignments necessary, outside of assigning specific Complaint tickets.

## Step 3: Receive and Assign Complaints



Help Ticket Details	
ID	11
Logged By	Ann Marie McGee 05/29/2008
Code	SEF
Name	Refrigeration unit temperature control not stable
Source Owner	Three, Worker - wthree
Source Organization	TA - Center Two
Description	Routine monitoring of temperature indicates improper fluctuation of temperature.
Key Words	REF#23456
Results	
Priority	Urgent
Due Date	05/29/2008
Status	Closed Ann Marie McGee 05/29/2008

Assignments (1)	
Name	Status
One, Tech	Completed

As a complaint is received (via calls, emails or other communications), the staff member receiving the complaint creates the complaint *Ticket* in the process. The user records all pertinent data. While there are options to select the internal organization and person requesting assistance, the user can also record an external source, describe the complaint, enter standard key words (for search and filter) and set a priority and due date. Once the complaint ticket is logged, it will appear in the Ticket library, regardless of the source

process or date, until completed or cancelled and then archived.

## Step 4: Track and Monitor Complaints

The process owner and other authorized persons have several ways to monitor open and completed complaint tickets. From the dashboard the process owner has access to all assigned tickets. The tickets remain on the assignee's dashboard until completed and on the process owner's dashboard until the ticket process is completed.

Each ticket is listed in the owning process as well as in the ticket library, both accessible by authorized (role assigned) personnel.

Sentinel's Reporting wizards can be used to create real-time tracking reports. The user creating a report can restrict its access to an organization or make it available to all persons having reporting access. The creating

Help Ticket Summary							
Processes Accessible by Sentinel Administrator Sorted by Id							
Process Filter: Name Contains(Weekly Help)	Name	Logged	By	Status	Priority	Due Date	
Process 48 - TA.HLP.1110 - Weekly Help Desk Processing 2008-05-26-Monday							
4	DMS	Incorrect donor response	05/27/2008	Helper One	Open	Medium	-
5	DMS	NCDR entered incorrectly	05/27/2008	Helper Two	Closed	Medium	-
6	DMS	Cannot print bleed labels	05/27/2008	Helper Two	Open	High	-
7	REF	Refrigeration Unit temperature control appears unstable	05/27/2008	Helper Three	Open	Urgent	-
8	DMS	DMS is down	05/27/2008	Helper Two	Open	Urgent	-
9	DMS	Network down	05/27/2008	Helper One	Open	Urgent	-
10	DMS	Can't print bleeder labels	05/29/2008	Helper One	Open	High	-
11	REF	Refrigeration unit temperature control not stable	05/29/2008	Ann Marie McGee	Closed	Urgent	05/29/2008

user can also make the report a private report by posting it on their dashboard. Every time the report is opened it will display the most current ticket data, including assignment status.



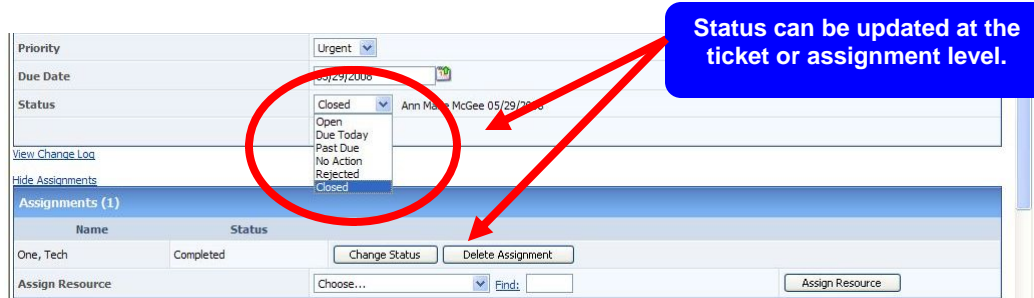
Sentinel records changes in each ticket in the ticket's Change Log. The log records the person making the change, the date and time of the change, the fields changed *from* and *to*.

### Step 5: Update the Complaint Ticket

Depending on the nature of the complaint a variety of actions may occur during the processing of the complaint. Sentinel supports the following:

- ◆ Update the ticket and its status by entering data directly into the ticket.
- ◆ Attach supplemental documents directly to the ticket.
- ◆ Re-assign the ticket to another person based upon need or assign it to multiple persons.
- ◆ Create a

Punchlist item and assign to an appropriate user. This is an important function in the complaint

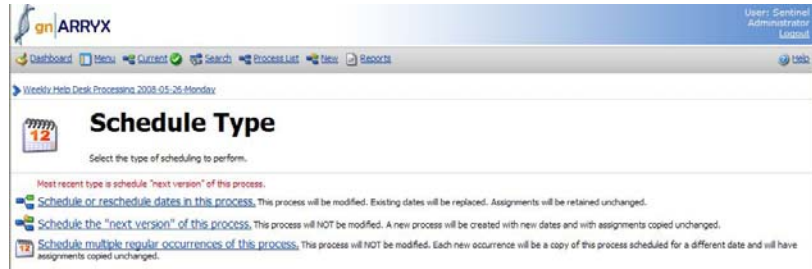


process. The complaint may be resolved; however, it may point to further action that is required to ensure that such an issue does not recur. The Punchlist item can be created and assigned to an appropriate person to take more definitive corrective action.

- ◆ Activate a risk and execute a contingency or contingency process. This is the most extreme response to a complaint (or Help request). This can involve any degree of defined steps and assignments.

## Step 6: Schedule Next Occurrence of the Process

Sentinel's powerful Scheduler can be used to schedule a single, next occurrence of the complaint management process or schedule a series of the process to occur on any regular frequency, e.g. daily, weekly, monthly, etc. When using the scheduler, the user selects and sets a series of options. Sentinel remembers these options and displays them the next time the scheduler is used to schedule a future occurrence of the same process.



The scheduler enables the user to retain or discard documents and folders. The scheduler automatically forwards all assignments, unless changed by the scheduling user. Even library document links are retained unless changed.

## Summary

Sentinel's innovative, user-definable functionality supports the simplest to the most rigorous and demanding processes. Whether managing internal help requests or external complaints, Sentinel simplifies and provides full management control, monitoring and documentation of complaints, including a detailed audit trail in the Ticket Change Log. By using the process templates to standardize complaint management, the enterprise can be assured that all processing is done to corporate standards and in compliance with internal and external controls. In addition, the processes can be managed and accessed anywhere the internet is available and only by those persons with proper permission and authorization.

Finally, by using Sentinel to manage complaint processing, along with the management of other important processes, all control and documentation is in a single, central repository. This simplifies control and reporting and the association and delegation of required follow up. It is a fact that a single complaint can initiate an intense set of processes within an enterprise. Sentinel's innovative, user-definable process methodology supports the most complex process integration, from initiation to consolidation and analysis to corrective action and reporting.

## About Alinion

Alinion empowers regulated organizations to dramatically improve and simplify how you manage and monitor the documents and processes controlling your business. Our innovative Alinion Sentinel software-as-service helps you quickly **take command and control** by improving efficiency, reducing operating costs, enhancing visibility and consolidating information. It is easy to use and cost-effective to run. Sentinel integrates powerful document control with process management, providing you with a closed-loop system for continuously improving how you run your life science business.

