MDS Audit and QC Setup Training Guide

DJF 10/23/13

Overview:

This document outlines the MDS Audit and QC (Quality Control) subsystem. The MDS Audit and QC system allows you to audit any document or transaction on the MDS system. It is designed to allow your company to comply with TITLE 21--FOOD AND DRUGS, CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES , SUBCHAPTER C--DRUGS: GENERAL – also known as 21 CFR 211 - (1) Sample size and test intervals based on statistical criteria for each attribute examined. While there are many methodologies used in sampling, this guide covers Systematic sampling as a method of choosing which documents to check.

Systematic sampling relies on arranging the study population according to some ordering scheme and then selecting elements at regular intervals through that ordered list. Systematic sampling involves a random start and then proceeds with the selection of every kth element from then onwards. In this case, k=(population size/sample size). It is important that the starting point is not automatically the first in the list, but is instead randomly chosen from within the first to the kth element in the list. A simple example would be to select every 10th name from the telephone directory (an 'every 10th' sample, also referred to as 'sampling with a skip of 10').

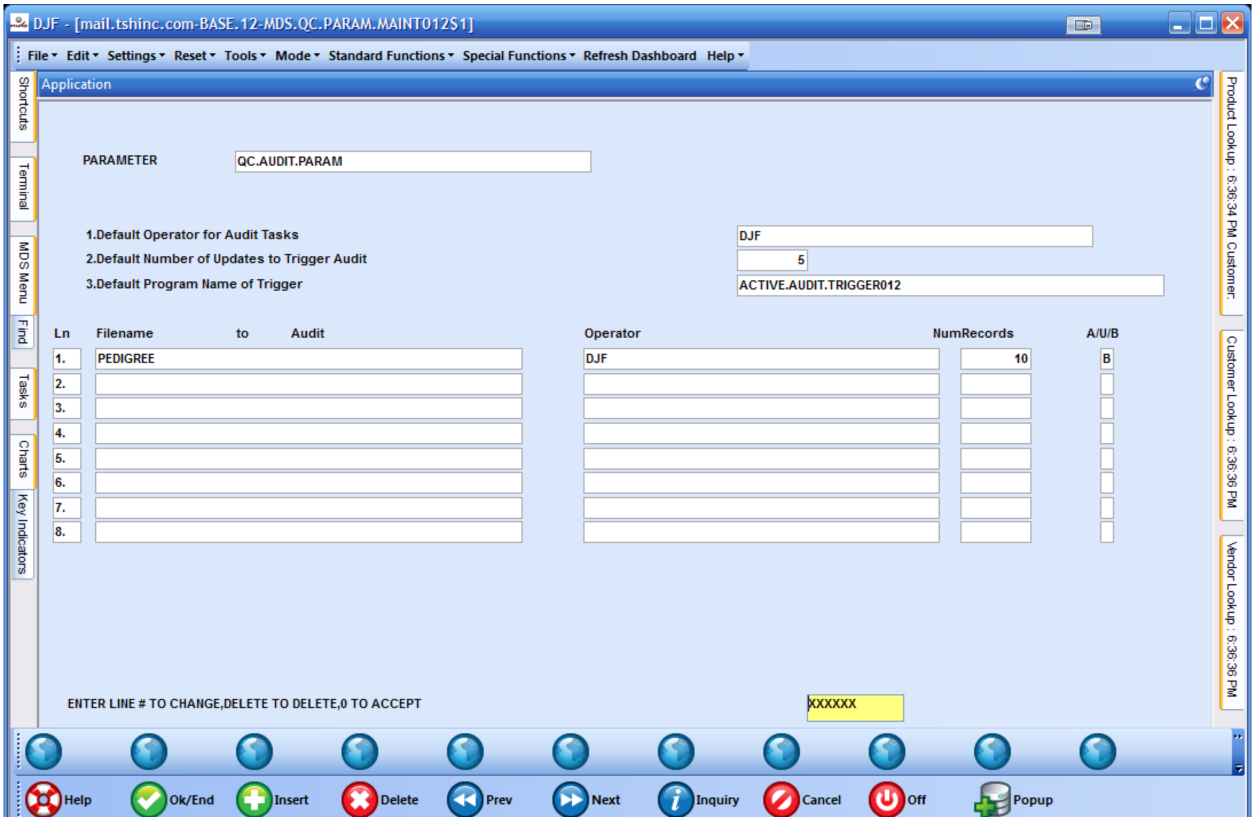
When determining the skip you will enter it into the MDS system as a whole number i.e. 10 and every 10^{th} document will be pulled for QC. Each company will have a different sample size or number of records updated on a daily basis. The QC system calculates and stores this number so that as you use the system you can adjust your skip based upon the number of documents updated.

As and Example you can audit All Updates to Pedigree documents and have the system automatically create a task for a specific operator to check and verify the Pedigree in question.

It can also be used for Inventory checks, Product Updates, Customer Updates etc.

In our example today we will show you how to setup an audit on the pedigree table such that every 10^{th} update will trigger an Audit Task for operator DJF.

Step 1. Setting up your Audit Configuration



Initially you would need to fill in the default operator for the Audit Tasks as well as the default number of updates to trigger the event.

You can then also specify document/file specific audit operators and levels by default each update function will trigger the Audit, if you prefer you may change it to only be triggered on updates to existing records or only for new record creation.

As an example you can have an audit on new product creation but not product updates.

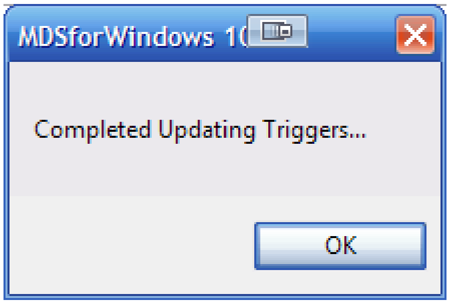
1. Default Operator for Audit Tasks DJF

2. Default Number of Updates to Trigger Audit 5

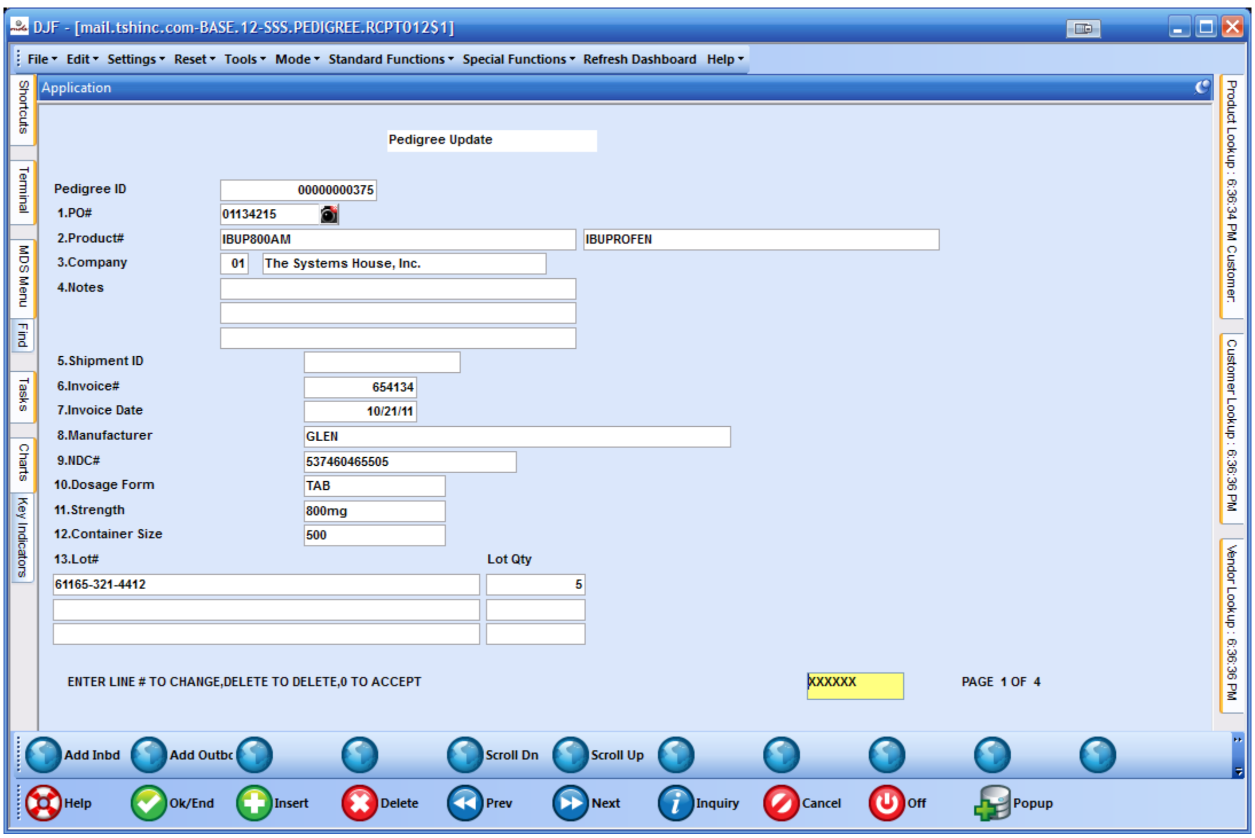
3. Default Program Name of Trigger ACTIVE.AUDIT.TRIGGER012

The Program name of the trigger is currently ACTIVE.AUDIT.TRIGGER012 , this can be modified and updated by your analyst to allow for customization of the logic while still using the core subsystem.

Step 2. Once the updates are setup enter 0 to access and the triggers on the database will be setup and activated

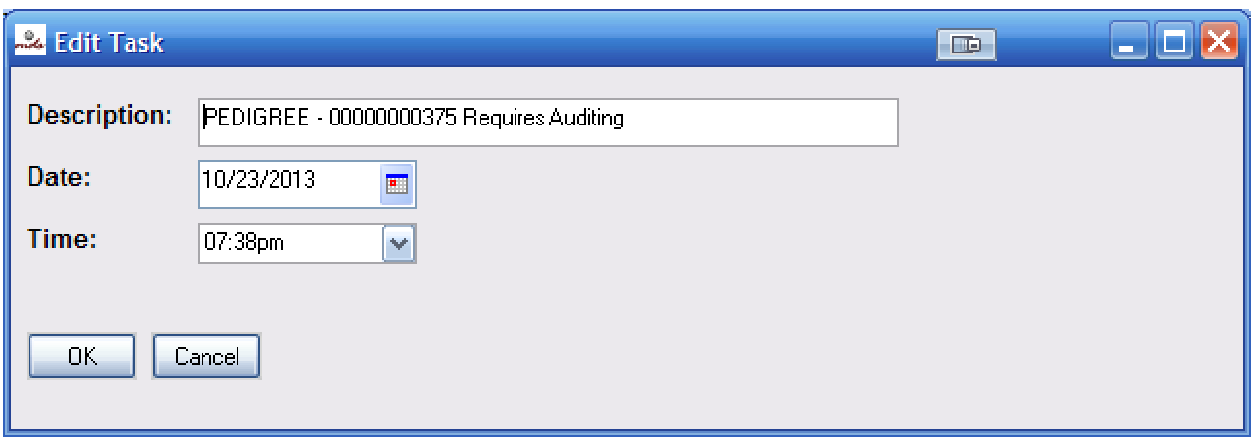


IN OUR EXAMPLE I am updating information into our existing pedigree record

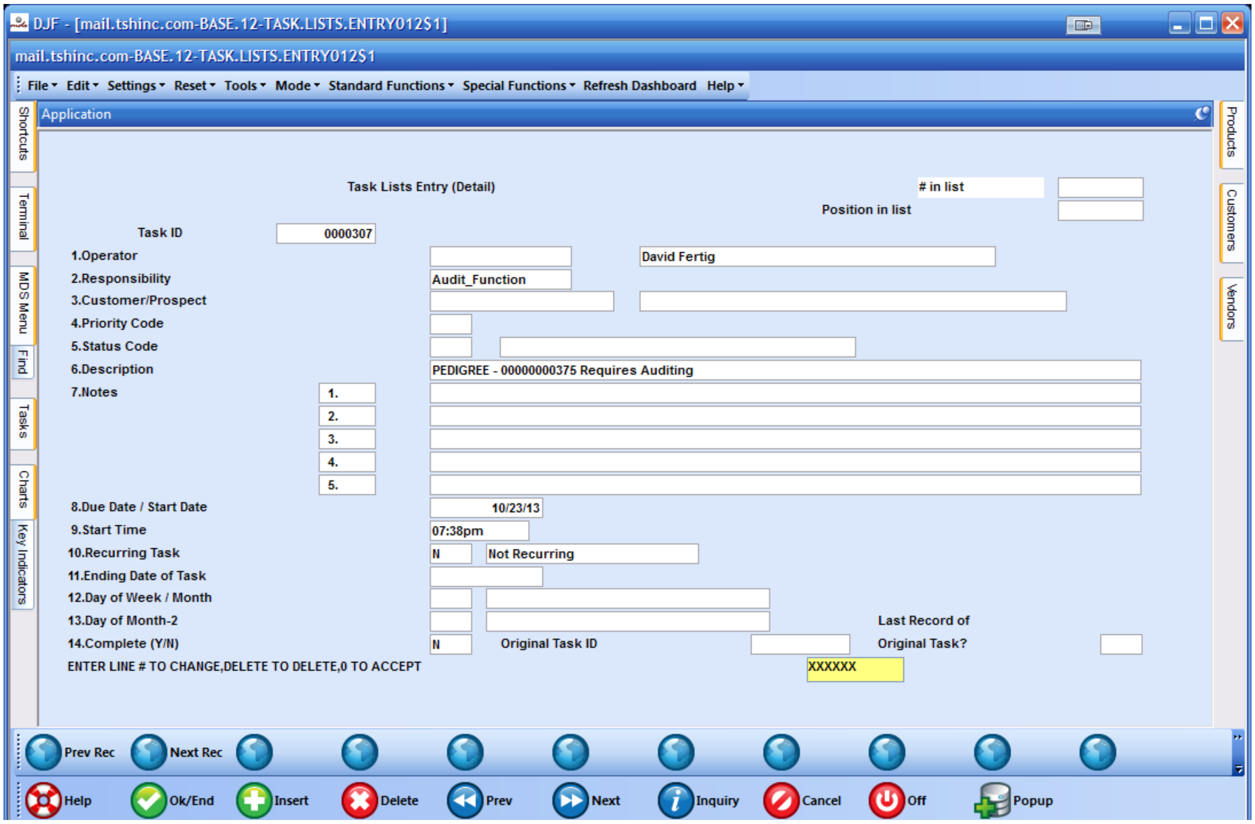


After updating our pedigree, we can now see a new task has appeared on our dashboard

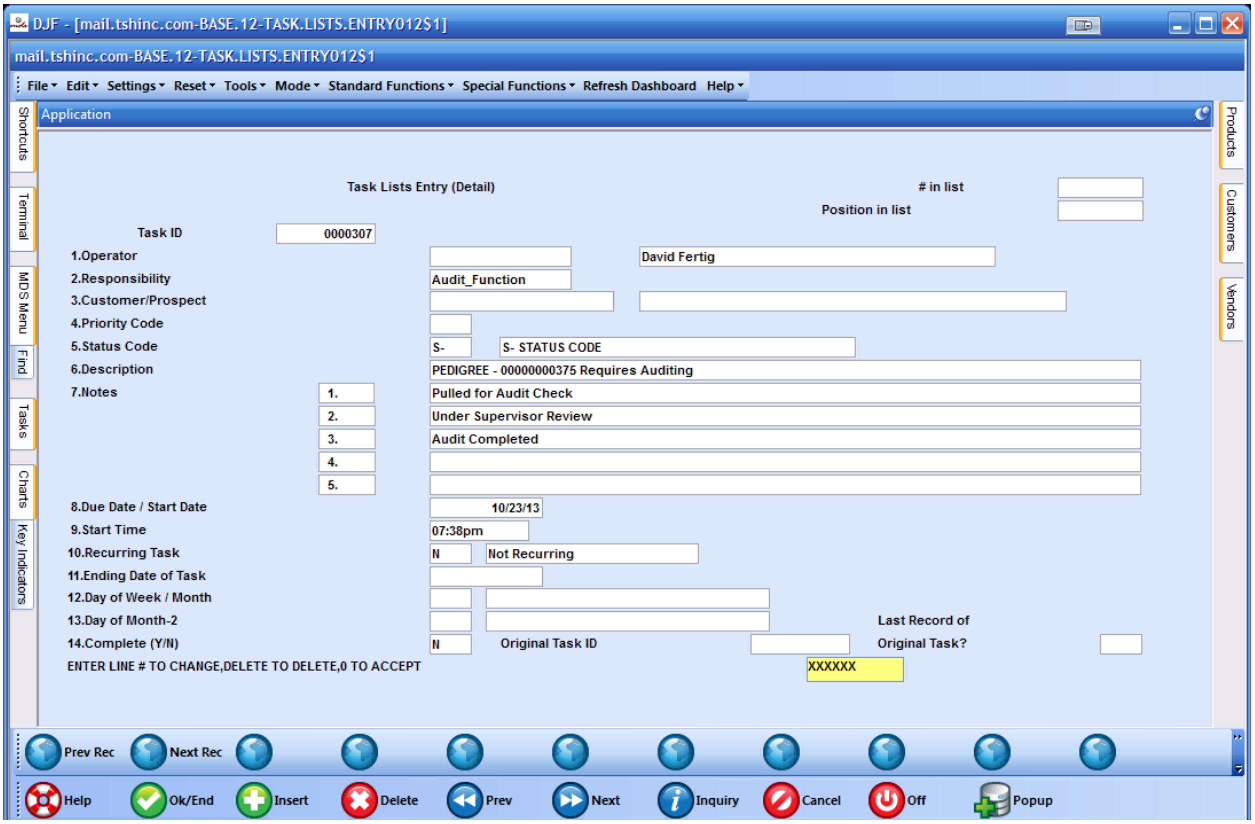
By clicking on the task I can view the description



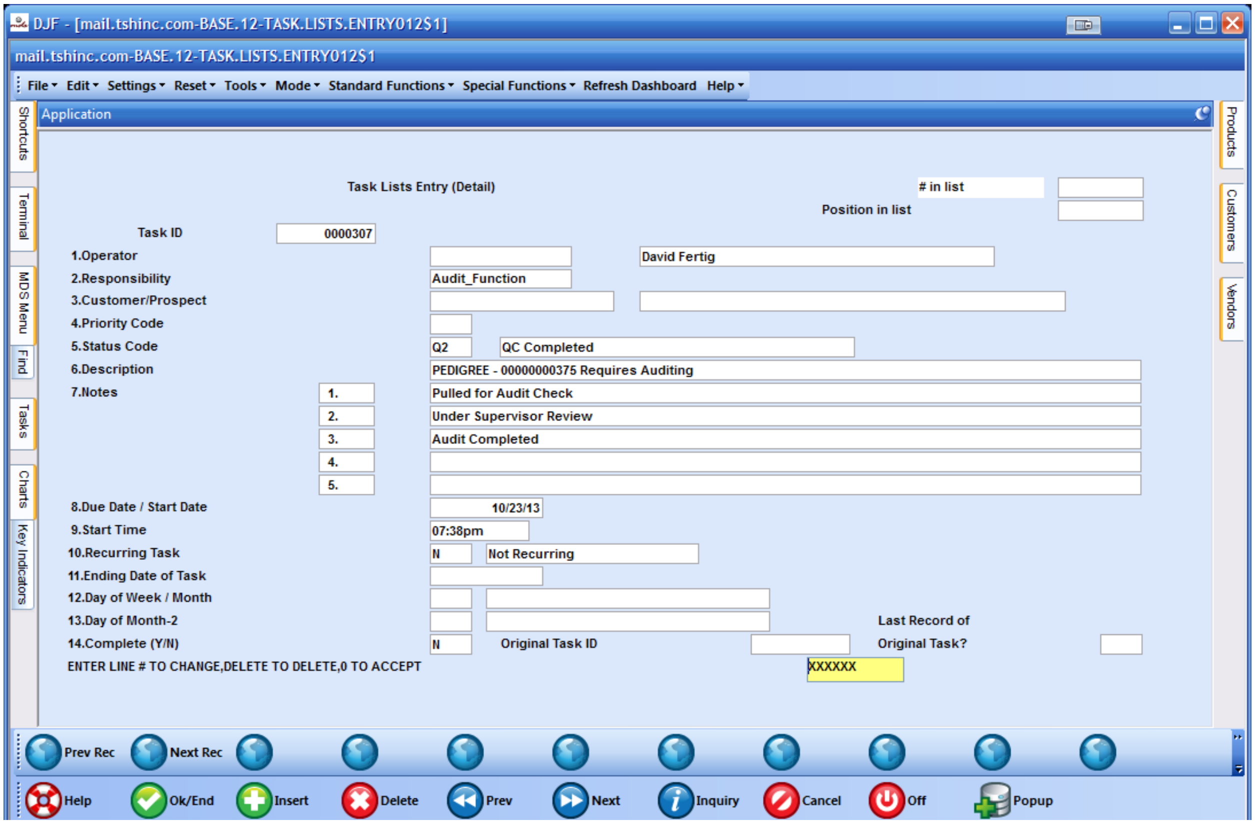
And by clicking on the task number I can add a note saying I forwarded the document to my supervisor after my initial review.



Once I have updated the status code and added a quick note I can forward to each department to perform their portion of the task, or I can simply update the task to mark the completion of the Audit.



AFTER EACH STEP updating the status code creates an internal audit to track any changes to the task



ONCE THE task is completed – you can simply go into the maintenance and mark the task as complete.

Once it's marked as complete it no longer shows on your dashboard until the next QC/Audit function pops up.