

## 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,  $k = (\text{population size} / \text{sample size})$ . 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').

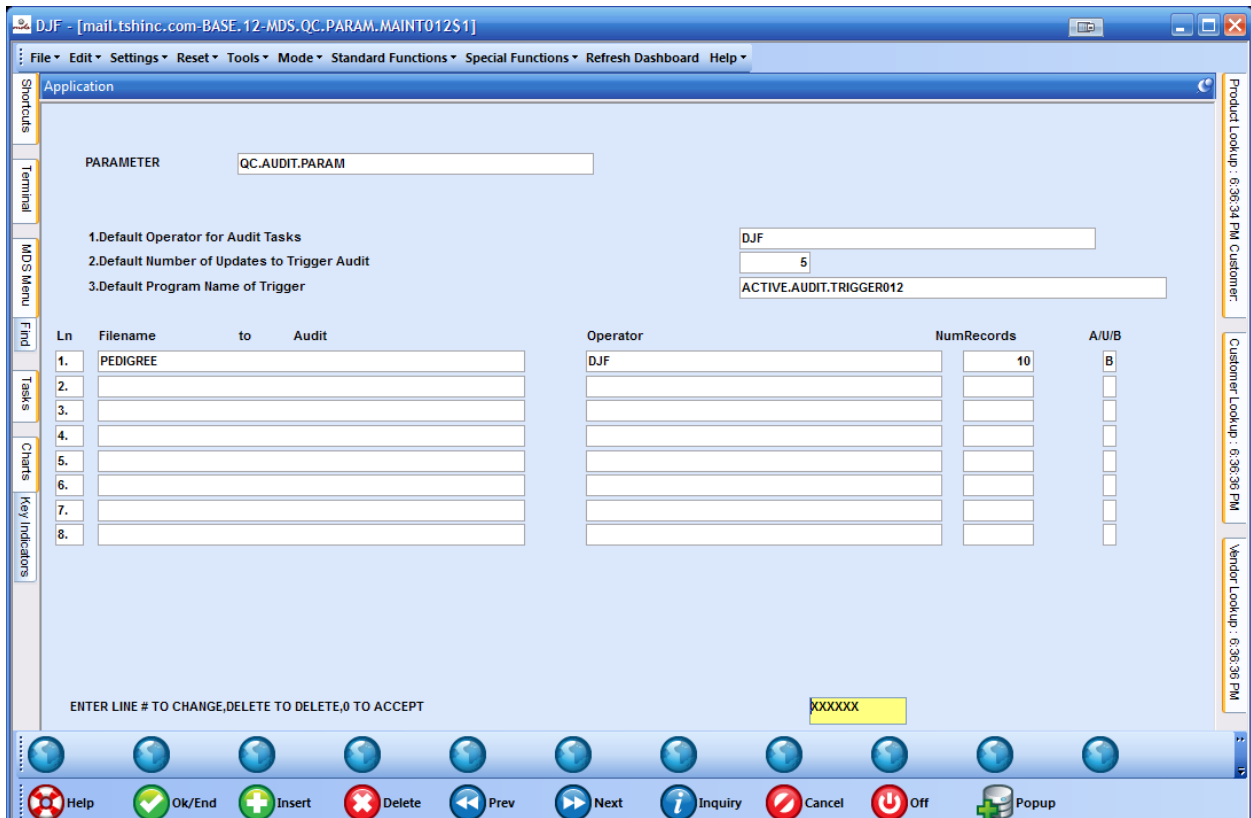
When determining the skip you will enter it into the MDS system as a whole number i.e. 10 and every 10<sup>th</sup> document will be pulled for QC. Each company will have a different sample size or number of records updated on a daily basis. The QC system calculates and stores this number so that as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

As an 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<sup>th</sup> 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.

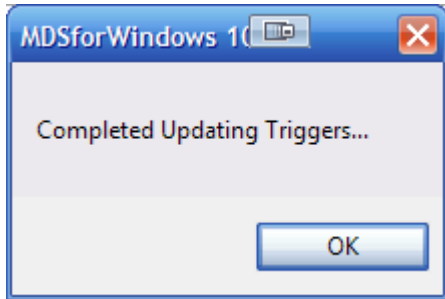
You can then also specify document/file specific audit operators and levels by default each update function will trigger the Audit, if you prefer you may change it to only be triggered on updates to existing records or only for new record creation.

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

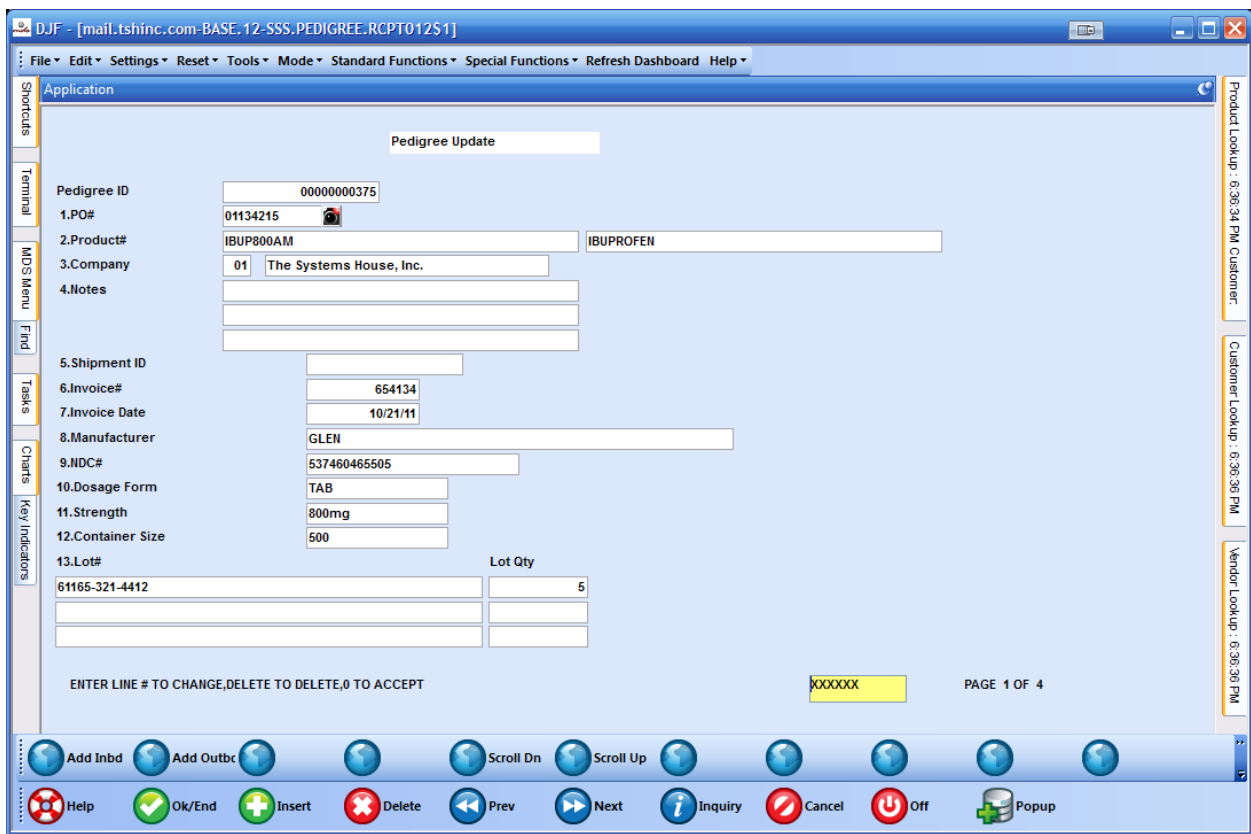
1. Default Operator for Audit Tasks      DJF
2. Default Number of Updates to Trigger Audit      5
3. Default Program Name of Trigger      ACTIVE.AUDIT.TRIGGER012

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

The screenshot shows the MDS Menu application interface. The main window displays a list of tasks with columns for Date, Time, Description, Status, D..., O..., and Task Nu... The tasks listed are:

Date	Time	Description	Status	D...	O...	Task Nu...
4/25/2011	08:00am	Call for Pricing Check	Past			0000256
4/29/2011	08:00am	update product sell sheet...	Past			0000257
10/23/20...	8:00 am	DAVID CREATED	Past			0000304
10/23/20...	07:38pm	PEDIGREE - 00000000375 Re...	Past			0000307

Below the task list is a 'Charts' section with a line chart titled 'Bank Cash Balance - Annual Trend'. The chart shows the monthly trend of the bank cash balance from January to December. The Y-axis ranges from -200,000,000 to 0. The X-axis lists the months from JAN to DEC. The legend indicates the data series is 'Bank Cash Balance'.

By clicking on the task I can view the description

The screenshot shows the 'Edit Task' dialog box. The fields are:

- Description:** PEDIGREE - 00000000375 Requires Auditing
- Date:** 10/23/2013
- Time:** 07:38pm

Buttons for 'OK' and 'Cancel' are visible at the bottom.

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

DJF - [mail.tshinc.com-BASE.12-TASK.LISTS.ENTRY012S1]

mail.tshinc.com-BASE.12-TASK.LISTS.ENTRY012S1

File Edit Settings Reset Tools Mode Standard Functions Special Functions Refresh Dashboard Help

Application

Task Lists Entry (Detail)

Task ID: 0000307

1.Operator: David Fertig

2.Responsibility: Audit\_Function

3.Customer/Prospect: [Empty]

4.Priority Code: [Empty]

5.Status Code: [Empty]

6.Description: PEDIGREE - 0000000375 Requires Auditing

7.Notes: [List of 5 empty text boxes]

8.Due Date / Start Date: 10/23/13

9.Start Time: 07:38pm

10.Recurring Task: N Not Recurring

11.Ending Date of Task: [Empty]

12.Day of Week / Month: [Empty]

13.Day of Month-2: [Empty]

14.Complete (Y/N): N Original Task ID: [Empty] Last Record of Original Task?: [Empty]

ENTER LINE # TO CHANGE,DELETE TO DELETE,0 TO ACCEPT

XXXXXX

Prev Rec Next Rec [Empty] [Empty] [Empty] [Empty] [Empty] [Empty] [Empty] [Empty]

Help Ok/End Insert Delete Prev Next Inquiry Cancel Off Popup

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.

DJF - [mail.tshinc.com-BASE.12-TASK.LISTS.ENTRY012S1]

mail.tshinc.com-BASE.12-TASK.LISTS.ENTRY012S1

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Application

Task Lists Entry (Detail)

Task ID: 0000307

1.Operator: David Fertig

2.Responsibility: Audit\_Function

3.Customer/Prospect: [Empty]

4.Priority Code: [Empty]

5.Status Code: S- S- STATUS CODE

6.Description: PEDIGREE - 0000000375 Requires Auditing

7.Notes:
 

- 1. Pulled for Audit Check
- 2. Under Supervisor Review
- 3. Audit Completed
- 4. [Empty]
- 5. [Empty]

8.Due Date / Start Date: 10/23/13

9.Start Time: 07:38pm

10.Recurring Task: N Not Recurring

11.Ending Date of Task: [Empty]

12.Day of Week / Month: [Empty]

13.Day of Month-2: [Empty]

14.Complete (Y/N): N Original Task ID: [Empty] Last Record of Original Task?: [Empty]

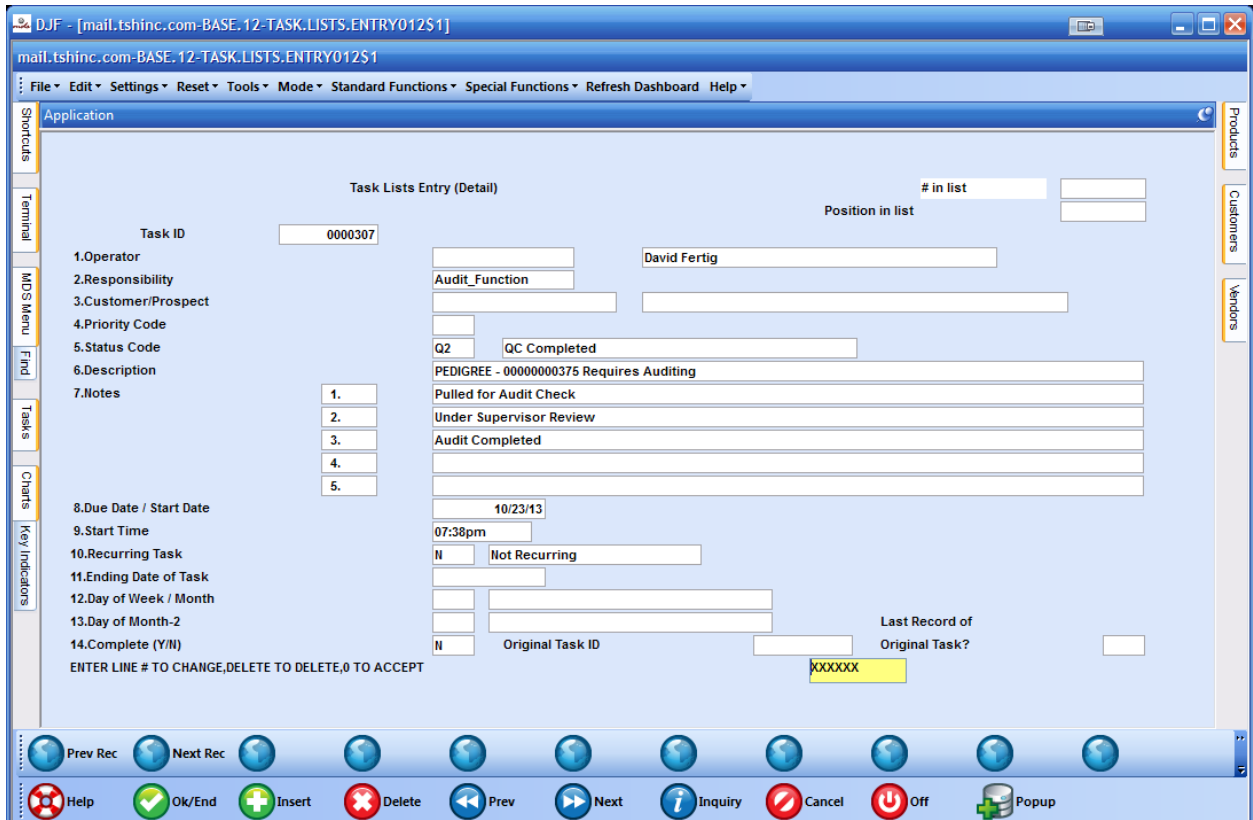
ENTER LINE # TO CHANGE,DELETE TO DELETE,0 TO ACCEPT

XXXXXX

Prev Rec Next Rec [Empty] [Empty] [Empty] [Empty] [Empty] [Empty] [Empty] [Empty]

Help Ok/End Insert Delete Prev Next Inquiry Cancel Off Popup

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.