**Set-Up/Building in Total Quality Control(TQC) 4840 LIS-240**

**Principle**; This is a step by step guide to building in TQC. Please refer to the Screen shots at the end of the procedure.

1. **SoftTotalQC File Build for a New Analyzer**

* Location
  + Is this for a new location/laboratory?
    - Yes – create a new Location Setup record in TQC
    - No – use existing Location Setup record for your facility
* Department
  + Is this for a new department?
    - Yes – create a new Department Setup record. Link to the appropriate Location
    - No – use existing Department Setup record
* Workstation
  + Create a New Workstation Setup record for this analyzer. Link the Workstation to the appropriate Location and Department.
    - Import from Lab if available
    - All instruments have their own workstation defined in TQC. When the old instrument is retired, open the workstation linked to that instrument, place in Edit mode, and change the Active field to “Not Active”, and save the changes to the database. This will prevent the workstation from being used by the system in the future.
* Manufacturer
  + Is this a new manufacturer?
    - Yes – create a new Manufacturer Setup record. It can be defined to a Location only (all departments will be able to use this record for linking to instrumentation and QC items), or to the Department (only the defined department will be able to use this record for linking to instrumentation and QC items).
    - No – use existing Manufacturer Setup record
* Instrument
  + Create new Instrument Setup record. Link the instrument to the newly created workstation. The Implementation date field is required. If you have the Purchase date and Implementation dates please note, the Purchase date must be prior to or the same as the Implementation date.
  + When saving the new instrument record, you will be prompted to copy the setup information to an Equipment Setup record.
    - No – will save the Instrument Setup without creating an Equipment Setup record
    - Yes – will save the Instrument Setup record, and open the Equipment Setup record.
      * Please note: the Name field in Equipment Setup does not copy the name entered in the Instrument record as expected. This is a known issue version 10.3.6.5. You are able to edit the Name field so it matches the Name for your instrument.
      * Save the record.
  + You can come back to the Equipment Setup for defining the manufacturer’s preventative maintenance procedures.
* Test
  + Existing Tests – for example, PT, PTT, GLU, NA, K, WBC, RBC, etc
    - Make a copy of the existing Test Setup records, changing the Workstation field to the newly created workstation for the instrument.
  + New Test – create a Test Setup record for the new test. Link this test the newly created workstation for the instrument
* Return to Instrument Setup record, open in Edit mode
  + Add all tests run on the instrument to the Tests grid.
    - “+” for a single line in the grid
    - “++” to add multiple tests to the grid at one time
  + Complete setup and save the changes
* End here if not using Equipment Maintenance

**2. SoftTotalQC File Build for a New Control**

* Location
  + Is this for a new location/laboratory?
    - Yes – create a new Location Setup record
    - No – use existing Location Setup record for your facility
* Department
  + Is this for a new department?
    - Yes – create a new Department Setup record. Link to the appropriate Location
    - No – use existing Department Setup record
* Workstation
  + Is this for a new workstation or analyzer?
    - Yes – create a new Workstation Setup record. Link to the appropriate Location and Department
    - No – use existing Workstation Setup record
* Manufacturer
  + Is this a new manufacturer?
    - Yes – Create a new Manufacturer Setup record. It can be defined to a Location only (all departments will be able to use this record for linking to instrumentation and QC items), or to the Department (only the defined department will be able to use this record for linking to instrumentation and QC items).
    - No – use existing Manufacturer Setup record
* Test
  + Is this for a new test?
    - Yes – create a new Test Setup record. Link to the appropriate Location, Department, and Workstation (follow SoftTotalQC File Build for New Test Algorithm)
    - No – use existing test
* Frequency
  + Based on your SOP, find or create Frequency Setup record to be used for Daily, Weekly, Monthly, Quarterly, Yearly, and/or Ordered in Lab QC order generation
* QC Method
  + Will the Result Type be defined as Mean?
    - Yes – find or create a QC Method setup record to capture the rules used to validate the result
    - No – no QC Method Setup is needed
* Control
  + Create new Control Setup record. Link to the appropriate Location and Department, it is NOT recommended to define controls to a specific workstation.
  + Add the Manufacturer (this is not required)
  + Add the tests run on this control to the Active/Testing Parameters grids.
  + Define the Result Type (Mean, Range, Keypad, Checkbox, Delta-type, Text, etc)
  + Define Expected Results based on selected result Type (this is not required in setups for QC items; expected results are required for Lot Records when placed in Testing/Active status. The entered values will be copied to newly created lot records, which can be changed in the Lot Record).
  + Define Frequency for each parameter. If orders are generated at posting from the instrument, no Frequency is needed.
  + Complete the setup, save the changes
* Create a Lot Record
  + Using Inventory > Batch Receiving
  + Once loaded, enter the Lot Number and Expiration Date provided by the manufacturer. Enter the number for Purchase Units received. Enter the Purchase Unit (Box, Bottle, Package, Cartridge, Case, etc.).

**3. SoftTotalQC File Build for a New Reagent**

* Location
  + Is this for a new location/laboratory?
    - Yes – create/import a new Location Setup record
    - No – use existing Location Setup record for your facility
* Department
  + Is this for a new department?
    - Yes – create/import new Department Setup record. Link to the appropriate Location
    - No – use existing Department Setup record
* Workstation
  + Is this for a new workstation or analyzer?
    - Yes – create/import new Workstation Setup record. Link to the appropriate Location and Department
    - No – use existing Workstation Setup record
* Manufacturer
  + Is this a new manufacturer?
    - Yes – create a new Manufacturer Setup record. It can be defined to a Location only (all departments will be able to use this record for linking to instrumentation and QC items), or to the Department (only the defined department will be able to use this record for linking to instrumentation and QC items).
    - No – use existing Manufacturer Setup record
* Test
  + Will you be validating the reagent against controls prior to placing the lot into production?
    - Yes – find or create the Test record that will be used to validate the reagent. If defining a new Test, import the record from Lab, or create a new Test record in TQC. Define the Test to the appropriate Location/Department/ Workstation.
    - No – Skip
* QC Parameters
  + Will you be using non-Test items to validate the reagent? (Examples: sterility, acceptable temperature at receipt)
    - Yes – find or create QC Parameter Setup record to document the item checked for your reagent. If defining a new QC Parameter, enter an ID, Name, Type of parameter, and link to the appropriate Location/Department.
    - No – Skip
* Control
  + Will you be validating the reagent using either Tests or QC Parameters?
    - Yes for Tests – find or create Control Setup record to link to the Test. This control is typically the control material you typically use to run QC for patients. The Control and Test will be linked to the Reagent Setup record in the Active/Testing Parameters tab.
    - Yes for non-Tests – find or create a Control Setup record to be used as a “placeholder” in the Active/Testing Parameters tab for the Reagent. If defining a new Control Setup record, enter the ID, Name and Type for the control. Link to the appropriate Location/Department, **uncheck** the option “Include in inventory”. As this control is only a placeholder, a Lot Record is not required.
    - No - skip
* Reagent
  + Create new Reagent Setup record. Link to the appropriate Location and Department, it is NOT recommended to define reagents to a specific workstation.
  + Add the Manufacturer (this is not required)
  + Define the appropriate Control, link to the Test or QC Parameter, define expected results and a Frequency as needed. Define Compnonents.
    - Use the checkboxes UR (Upon Receipt) and OL (Open Lot) as a Frequency to allow TQC to generate an order for the respective parameters when a new shipment is received (new lot record is registered) or when the Lot Record is opened (placed in Active Status)
  + Complete the setup, save the changes
* Create Lot Record
  + Need lot records for both the Control linked to the Test in the Parameters tab (if defined), and the Reagent
  + Using Inventory > Batch Receiving
  + Once loaded, enter the Lot Number and Expiration Date provided by the manufacturer. Enter the number for Purchase Units received. Enter the Purchase Unit (Box, Bottle, Package, Cartridge, Case, etc.).

**4. SoftTotalQC File Build for a New Test**

* Location
  + Is this for a new location/laboratory?
    - Yes – create a new Location Setup record in TQC
    - No – use existing Location Setup record for your facility
* Department
  + Is this for a new department?
    - Yes – create a new Department Setup record. Link to the appropriate Location
    - No – use existing Department Setup record
* Workstation
  + Is this for a new workstation or analyzer?
    - Yes – create a new Workstation Setup record. Link the appropriate Location and Department
    - No – use existing Workstation Setup record
* Test
  + Create new Test Setup record. Link to the appropriate Location, Department, and Workstation(s).
  + Import from Lab if built in Lab/Mic
  + Complete setup, save changes
* Add Test to Instrument Setup Record
  + Existing Instrument – open in Edit mode
  + Add Test to the Tests grid, save changes
  + Skip to Controls if no instrument is associated with this Test
* Controls
  + Existing Control – open the control setup record in Edit mode, add the Test to the Active/Testing Parameters grid(s), save changes. This will be reflected in all newly registered lots.
  + Existing Lot Record(s) – both Open/Active and New/Not Active or New/Testing – add the Test to the Active/Testing Parameters grids as done in Control Setup.
  + New Control – follow the algorithm for New Control File Build
* Create a Lot Record
  + Using Inventory > Batch Receiving
  + Once loaded, enter the Lot Number, Received Date, Expiration Date and appropriated Status Date provided by the manufacturer. Enter the number for Purchase Units received. Enter the Purchase Unit (Box, Bottle, Package, Cartridge, Case, etc.).

**4. SoftTotalQC for a Kit with Integrated Control Documentation**

\*\*The example used for this workflow is a Pregnancy Test

**In SoftLab**

* Create a “Control Test” (Internal QC Test) in Test Maintenance. This is used to document the internal control result.

NOTE: Most of the Departments in the lab have created a test called “Internal QC”

The result for that test is a default of “Internal QC OK.”

* Create a Group test which includes the Test ID used to report the pregnancy result on the patient sample, and the Control Test ID.
* Ensure Flag 50 is checked for the Test ID used for patient results
* Add Test to a Worklist

**In SoftTotalQC**

* Location
  + Find or create a Location Setup record for your facility
* Department
  + Find or create a Department Setup record for the department responsible for running the assay. Link to the appropriate Location
* Workstation
  + Find or create a Workstation Setup record where the testing is to be performed. Link to the appropriate Location and Department.
* Keypad
  + For qualitative resulting, select an appropriate Keypad or create a new keypad.
  + List each possible result as a separate Key
* Test
  + Is this a new Test?
    - Yes – create new Test Setup record. Link to the appropriate Location/Department/Workstation
    - No – use existing Test Setup record
  + Please note: use only the Test ID for resulting Patient orders, do not include the “Control Test”
* Frequency
  + Based on your SOP, find or create Frequency Setup record to be used for Daily, Weekly, Monthly, Quarterly, Yearly, and/or Ordered in Lab QC order generation
* Controls
  + Internal Control
    - Define similarly to external controls. Link to the appropriate Location and Department.
    - UNCHECK the “Include in Inventory” option
    - Do NOT define any Active and/or Testing Parameters for this control.
      * This control will be used in the Reagent Setup.
  + External Control
    - Link to the appropriate Location and Department
    - “Include in Inventroy” should be checked.
    - Do NOT define any Active/Testing Parameters for this control.
      * This control will be used in the Reagent Setup
* Reagent
  + Enter the ID and Name for the Reagent and, in the Type field, select “Kit” from the lookup.
  + Link the Reagent Setup record to the appropriate Location and Department.
  + In the Active/Testing Parameters tabs, add both the internal and external controls, along with the Test
  + Enter the expected results for each parameter, add a Frequency for order generation
  + Complete the setup, save your changes

**5. Adding Tasks to the SoftTotalQC Scheduler**

The SoftTotalQC Scheduler provides the ability to automatically perform routine tasks within the TotalQC application.

* Orders can be generated for QC Items based on the Frequencies defined for the parameters in the QC item.
* Reports and Worklists templates can be defined, then added to the Scheduler to print to a Network printer at a predetermined date and time.
* Utility can be setup to check the expiration for Lot Records, set the Expired flag if the expiration date has passed, close the expired lot, and open the next available lot record for the same QC item.

**Assumptions:**

* For Reports: Setup Templates for the desired reports are available
  + Network printers are defined, and available for use.
* For Order Generation: Active/Testing Lot Records, and Equipment Maintenance Records have at least one parameter defined with a Frequency (other than Ordered in Lab)
* For Check Lot Open/Close/Expiration: QC Item Lot Records are available in the database

**Adding a Report or Worklist to be printed:**

* Place the Scheduler in Edit mode
* Right click on the calendar displayed to open a Context menu
* Select New Task or New Recurring Task
  + \*Note: you can set recurrences from either option
* A new context menu displays:

**Report:**

* L-J Graph, Result Report, Action Log Report, Linearity Report, Statistics Report, Inventory Report, Inventory Workload Report, Vendor Report options display in a nested context menu.
  + Select the desired Report type
* In the Report window
  + Enter the template ID in the Report ID field. The Name, Location, Department, Workstation fields will be automatically populated with the details from the Report template.
  + In the Start Time fields, verify the date and time at which the report is to be run.
  + Add a Task Color if desired
  + Define a network printer if it differs from the printer defined in the template
  + If the printer is located in a different time zone than the server, select the “Use custom printing time zone” and select the appropriate time zone.
* Is this is a Recurring Task?
  + If “Yes”, click the Recurrence button
    - In the Appointment Recurrence window, verify the time, define the Recurrence pattern, and Range of recurrence.
    - Click OK
    - Click OK in the Reports window
  + If “No”, click OK
* The appointment, or recurring appointments, is added to the Scheduler.
* Save your changes

**Worklist:**

* Resulting Worklist Reports, Review Worklist Reports, Autodownloading options display in a nested context menu.
  + Select the desired Worklist type
* In the Worklist window
  + Enter the template ID in the Worklist ID field. The Name, Location, Department, Workstation fields will be automatically populated with the details from the Worklist template.
  + In the Start Time fields, verify the date and time at which the worklist is to be run.
  + Add a Task Color if desired
  + Select the available Report options as needed
  + Define a network printer if it differs from the printer defined in the template
  + If the printer is located in a different time zone than the server, select the “Use custom printing time zone” and select the appropriate time zone.
* Is this is a Recurring Task?
  + If “Yes”, click the Recurrence button
    - In the Appointment Recurrence window, verify the time, define the Recurrence pattern, and Range of recurrence.
    - Click OK
    - Click OK in the Worklist window
  + If “No”, click OK
* The appointment, or recurring appointments, is added to the Scheduler.
* Save your changes

**Order Generation**

* Place the Scheduler in Edit mode
* Right click on the calendar displayed to open a Context menu
  + Select New Task or New Recurring Task
    - \*\*Note: you can set recurrences from either option
  + Select Tools > Generate Order Tool
* In the Tools window
  + Define a name for the order generation in the Subject field.
  + QC Item Type field defaults to All.
    - You can click the lookup to open a static list of available QC Item types. You can choose to generate orders for any or all of the available types.
  + Verify the date and time for the task to run in the Start Time field
  + Define a Task Color as needed
  + In the Location and Department fields, enter the appropriate Location and/or Department so that it matches the Location and/or Department defined for the QC Items to be included in the order generation.
    - \*Note: If a Location only is defined, QC items defined to the corresponding Location ONLY will qualify for order generation.
    - \*Note: If a Location and Department is defined, QC items defined to the corresponding Location AND Department will qualify for order generation.
  + Under the Generate Order Tool Options section, the field “Number of hours to generate pending QC orders:” is defaulted to 1. This means QC orders will be generated for QC items with a scheduled time (See Frequency setup) matching the scheduled time for the task, plus one hour. For example, if the task is to run at 04:00, orders will be generated for 04:00 to 05:00. To capture all QC orders to be run throughout the shift, starting at 06:00 to 13:59, with the tool scheduled for 04:00, enter a value of 9 in the field. Orders with a scheduled time between 04:00 and 13:59 will be generated.
  + Trace level is set to “0”, it is recommended to increase the value in this field only when requested by SCC for troubleshooting purposes.
* Is this is a Recurring Task?
  + If “Yes”, click the Recurrence button
    - In the Appointment Recurrence window, verify the time, define the Recurrence pattern, and Range of recurrence.
    - Click OK
    - Click OK in the Inventory window
  + If “No”, click OK
* The appointment, or recurring appointments, is added to the Scheduler.
* Save your changes

**Check Lot Open/Close/Expiration:**

* Place the Scheduler in Edit mode
* Right click on the calendar displayed to open a Context menu
  + Select New Task or New Recurring Task
    - \*\*Note: you can set recurrences from either option
  + Select Inventory > Check Lot Open/Close/Expiration
* In the Inventory window, enter a name for the task in the Subject field
  + Define the date and time at which the task is to be run in the Start Time field.
    - \*Note: it is recommended to run this Tool after midnight on a daily basis as the system checks the lot records for the expiration. If the lot record’s expiration date/time has past, the “E” or Expiration flag is set, the Status is change to Not Active for the expired lots, the Lot Records are Closed, and the next available Lot Record for the same QC Item is Opened.
  + Click the Recurrence button
    - In the Appointment Recurrence window, verify the time, define the Recurrence pattern, and Range of recurrence.
    - Click OK
    - Click OK in the Inventory window.
  + The appointment, or recurring appointments, is added to the Scheduler.
  + Save your changes

**Editing a recurring task on the Scheduler.**

1. In the Launch Bar select “Scheduler”.
2. Select the “Edit” icon.
3. Right click on the task in the scheduler that needs to be changed.
4. Select “Modify Recurring Task”.
5. Select the “Recurrence” tab on the bottom of the box. For modifying existing recurring tasks, you ALWAYS need to click the “Recurrence” tab first, even is your changes are in the first “Tool” box that opens. By clicking on the “Recurrence” tab you will open up the “Appointment Recurrence” box.
6. Make any changes in the “Appointment Recurrence” that are needed and click “OK”.
7. The original “Tools” box will again appear as the scheduler screen will toggle back to the original start of the task.
8. Make any needed changes and click “OK”.
9. Click on the “SAVE” icon.

**Reference :**

SOFT Total QC Module.

**Screen shots from the Total QC Module:**

Most of the Build items will be in the Setup drop down in the Launch Bar



Click on the arrow and open Setup.



Click on the section in Setup that you want to open. For example Locations.

The Locations tab will open and you can add a new location.

**NOTE: When building in TQC, you must follow the Setup steps in order.**

Each section of Setup has required fields which must be filled in. You do not have to fill in everything in the section.

Click on the File folder to view existing records.

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Click on the Blank sheet to create a new file.

Follow the same steps in each section of the Setup.