QMSCAPA for Workgroups

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ABCI Consultants

"Your Guide through the ISO Maze to Certification"

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QMSCAPA for Workgroups

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1 ISO Management System Software

QMSCAPA for Workgroups, 1.48.1* | What's new in QMSCAPA?

Compliant with FDA (CFR) Title 21, Part 11 & 820

QMSCAPA™ stands for Quality Management System, Corrective Actions and Preventive Actions (CAPA). However, **QMSCAPA™** provides many of the tools necessary to maintain an *excellent quality management system* and other International Management Systems.

QMSCAPA™ is designed by a user group of quality, environmental, occupational health & safety professionals, including assessors, auditors, consultants and compliance managers for management systems. If you have not joined our QMSCAPA user group, we encourage your joining and welcome your input on how we can improve QMSCAPA.

QMSCAPA™ provides tools for conducting Customer Satisfaction Surveys, including survey forms, data collection and analysis.

QMSCAPA™ provides tools for conducting supplier evaluations and supplier surveys.

QMSCAPA™ is a Microsoft Windows compatible software relational database application, which is designed to generate CAPA forms and a log for a International and Quality Management Systems. In addition, QMSCAPA provides a method to flow information into the CAPA log from the Customer Feed-back log, Non-conformance log and findings from *external* and internal audits.

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- ✓ Action Task List for Corrective Action Teams
- ✓ Alert Notices from Quality, Environmental, Health & Safety Systems
- ✓ Audit Planning and Audit Reporting
- ✓ Customer Feed-back (including complaints and satisfaction)
- ✓ Customer Satisfaction Survey Designer
- ✓ Customer Table
- ✓ Document Control Management
- ✓ Electronic signature support for Documents & Records
- ✓ Employee Initiatives & Opportunity for Improvement
- ✓ External Audits
- ✓ FDA Title 21, Sub-Chapter A, Part 11 Compliance
- ✓ Internal Audit Planning & Results
- ✓ Key Performance Tracking
- ✓ Monitoring & Measuring Device Schedules for Calibration and Maintenance
- ✓ Non-conformance Reports
- ✓ Performance Dashboard
- ✓ Records Control Index Module
- ✓ Risk Assessment and Management Tools & Reports for Business Continuity, Environmental, Quality, Safety and Security
- ✓ Relevant Interested Parties Module
- ✓ Risk Management Controls for support of 'Risk-based thinking'
- ✓ Supplier Evaluations and Survey Questionnaires

A Corrective Action Request and Preventative Action Request tracking software system is essential for any quality system. It is a regulatory requirement that FDA / global regulatory inspectors and ISO auditors consider mission critical. When implemented properly, a Corrective Action (CAPA) software system improves product quality and safety, increases customer satisfaction, and more importantly, ensures continual improvement.

Features in Version 1.48.1:

- ✓ Alert Notices for Initiatives and Non-conformance Reports
- ✓ Checklist Generator
- ✓ Corrective Action Module
- ✓ CAPA Graphical Charts
- ✓ CAPA Search & Query tool for CAPA data analysis
- ✓ CAPA Task List
- ✓ Custom CAPA form generator and report builder
- ✓ Manufacturing & Production Quality Metrics Calculator
- ✓ Microsoft Outlook TASK links from the QMSCAPA Task Table
- ✓ Multilevel Multi-level_Security and control.
- ✓ Multilingual support for Editing Window Field Names
- ✓ Multilingual support for User-defined Help

- ✓ Customer Satisfaction Survey & Calculator
- ✓ Document Manager and RTF Editor
- ✓ Dynamic CAPA Query & Search feature for CAPA analysis
- ✓ Database for logging Corrective Actions, Preventive Actions, and Non-conformance.
- ✓ Document Manager and RTF Editor
- ✓ Database for logging Alerts, Initiatives, Messages and Non-conformance for matters related to the Environment, Health, Quality and Safety.
- ✓ Database for logging Customer Feed-back
- ✓ Directory of Management Personnel/Resources
- ✓ Dashboard for Monitoring Quality
- ✓ Database for maintaining a master document index
- ✓ Database for recording calibrations and maintenance of monitoring and measuring devices
- ✓ Database for recording personnel that are associated with the QMS
- ✓ Database for recording personnel training records, includes a method for verifying training effectiveness.
- ✓ Document Revisions and Approval records made be Locked
- ✓ Export to Excel options
- ✓ Graphical Charts for Key Performance Indicators and
- ✓ Graphical and Digital Charts for Quality Objectives.
- ✓ Email Assistant for the Windows default email client.
- ✓ Import from Excel Wizard
- ✓ Internal Audit Checklist
- ✓ Internal Audit Results Log for Management Review
- ✓ Internal Audit Schedule for One or More Standards/System
- ✓ On-Time Delivery Calculator
- ✓ On-time Delivery logs
- ✓ Optional database for managing external documents
- ✓ OSHA Hazard Communication Standard for Safety Data Sheets (SDS)
- ✓ Purchasing Quality Metrics Calculator
- ✓ Preventive Action (CAPA) Module
- ✓ Process & Standard Element Interaction Reports
- ✓ Product Configuration Management
- ✓ Product Life Cycle Planning and Evaluations
- ✓ Quality Key Performance Indicators Database
- ✓ Records Approved may be Locked
- ✓ Records Control Index
- ✓ Risk Assessment and Mitigation Module
- ✓ Risk Assessment Reports
- ✓ Risk Assessment Templates
- ✓ Safety Data Sheets
- ✓ Sales Quality Metrics Calculator
- ✓ Save most reports as an Excel compatible file
- ✓ Support for electronic signatures
- ✓ Support for multiple simultaneous users
- ✓ Supply Chain Management module
- ✓ Supplier/Vendor Evaluation module
- ✓ Training Programs
- ✓ Training Schedules
- ✓ Training Results
- ✓ Vendor database with approval, status and tier levels

Compatible with International Managements Systems:

Many users have reported QMSCAPA to be suitable for International Management Systems based upon the ISO 9001 Standard, AS9003, AS9100, AS9110, AS9120, e-Stewards, ISO 9004, ISO 13485, ISO 14001, IATF 16949, ISO 17025, ISO 18001/45001, ISO 22000, ISO 22716 cGMP, ISO 22301, ISO 27001, R2:2013 and TL9000.

Learn what's new and what's planned for QMSCAPA software

Computer Requirements:

- 32 or 64 bit CPU
- Windows 7, Windows 8, Windows 8.1, Windows 10 or;
- Windows 2003 Server, or;
- Windows 2008 Server (R2), or;
- Windows 2012 Server
- Support for Apple OS devices through Amazon Workspaces

For QMSCAPA installations with multiple users, ABCI recommends Windows 2008 Server, or higher with Remote Desktop Services (Terminal Services) for simultaneous multiple Remote Desktop Users.

*The current application may be later than this publication.

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Nothing gets developed, published or implemented unless someone has a goal to get something done, better and faster.

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- **CRMworx**™ ~ Contact Management for Workgroups
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- **CablePro**™ ~ Network Cable Management and Documentation Database
- **ProjexPro**™ ~ Simplify Complex Project Management
- **CalcTime**™ ~ Calculate Time with Simple Software Tool
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1.1.1 Tech Support

Need help? Here you go!

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We provide several levels of user assistance for our products, from excellent user manuals to direct email support and real-time telephone support, which may include CrossLoop session.

If you have a question about an ABCI Software application, please check out the tutorials and user guides first, which are available for download with each application. You will most probably find your question answered in the appropriate user guide or one of the following online help sites

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1.2 About ABC ISO Consultants

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International Management Systems

QMSCAPA is sponsored by ABC ISO Consultants

Access Business Communications, Inc., founded in 1999 and incorporated in California, has emerged over the past ten years with an excellent reputation for providing consultation, publications, software and training related to advanced communications and international management systems.

Today we offer the following main services:

- Provide advice and assistance on the development and implementation of systems, including preparation of documentation, work instructions, and forms.
- Assist with the development of procedures for management review, internal auditing and training.
- Identify improvement or development within your current management system.
- Prepare an action plan to address those improvement areas, in conjunction with your personnel.
- Help establish a *Process Improvement Team* to assist with the design and implementation of the system requirements.
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2 Download QMSCAPA Software

QMSCAPA may be download from ABCI Software by joining our Quality Users Group.

Once you install QMSCAPA you may need the following login information:

Login = 'mgtrep' (exclude quotes)
Password = 'mgtrep' (exclude quotes)

End-User License Agreement

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2.1 EULA

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FOR QMSCAPA™

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4. No Warranty. The Software is being delivered to you AS IS and ABCI makes no warranty as to its use or performance. ABCI and its suppliers do not and Cannot warrant the performance or results you may obtain by using the software Or documentation. ABCI and its suppliers make no warranties, express or Implied, as to noninfringement of third party rights, merchantability, or Fitness for any particular purpose. In no event will ABCI or its suppliers be Liable to you for any consequential, incidental or special damages, including Any lost profits or lost savings, even if an ABCI representative has been Advised of the possibility of such damages, or for any claim by any third Party. Some states or jurisdictions do not allow the exclusion or limitation of incidental, consequential or special damages, or the exclusion of implied warranties or limitations on how long an implied warranty may last, so the above limitations may not apply to you.

5. Governing Law and General Provisions. This Agreement will be governed by the laws of the State of California, U.S.A., excluding the application of its conflicts of law rules. This Agreement will not be governed by the United Nations Convention on Contracts for the International Sale of Goods, the application of which is expressly excluded. If any part of this Agreement is found void and unenforceable, it will not affect the validity of the balance of the Agreement, which shall remain valid and enforceable according to its terms. You agree that the Software will not be shipped, transferred or exported into any country or used in any manner prohibited by the United States Export Administration Act or any other export laws, restrictions or regulations. This Agreement shall automatically terminate upon failure by you to comply with its terms. This Agreement may only be modified in writing signed by an authorized officer of ABCI.

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3 Quick Start Steps

Follow these simple steps to begin using QMSCAPA.

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The QMSCAPA application may have the security feature activated.

The default Login and Password for QMSCAPA is 'mgtrep.'

Note: New first-time users may see the Path Manager window open to set the **default data path**. Also, be sure to **set a default printer** in the Windows Control Panel before starting QMSCAPA.

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3.1 Icon Quick Access Tool Bar

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(A) Exit, quit QMSCAPA
(B) Document Control Index
(C) Training Schedule and Training Programs
(D) Human Resources
(E) Customer Complaints, filtered by CWG
(F) Measuring and Monitoring Devices
(G) Internal Audit Plan & Results from Internal Audits

(H) Corrective Action & Preventive Action Log (CAPA), filtered by CWG
(I) Corrective Action & Preventive Action Log (CAPA)
(J) Customer Satisfaction Survey Results
(K) Management System Performance Dashboard
(L) QMSCAPA Report Builder Menu for Forms & Reports
(M) Messages for Alert Notices, Employee Initiates and Non-conformance Reports
(N) Information for Risk Assessments and Treatment Plans
(O) Checkist Builder
(P) Task Do List related to CAPA, , filtered by CWG
(Q) Records Control Index
(R) Key Performance Indicators (KPI), filtered by CWG

3.2 Add a First User

First-time users may be required to enter the "first user."

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The "first-user" is also considered the primary system manager.

Suggested first-user:

First Name: Management
Last Name: Representative

Login Code: mgtrep (The login code is also the first password!)

Related Topics:

- Browse Users
- Change User Password

3.3 Browse Users

Security Menu, Browse Users Option

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Browse User Table

User Form

(A) The Work Group field

In the image shown above is a numeric code, which is used to filter or limit the data on specific browse tables. One or more users may be assigned a Work Group code. Therefore, when users login with the a specific Work Group Code specific browse tables are designed to limit access to the records that have a matching Current Work Group (CWG) code.

The Browse Tables that support the CWG filtering are:

Customer Complaint Table

The CAPA Table

The Task Table

The Process KPI Table

For example, members of a Customer Service group may be assigned the Work Group code of '1234'. Therefore, any user in the Work Group '1234' that logs into QMSCAPA shall be limited to records in the Customer Complaints, CAPA, Task and KPI tables that have a Current Work Group (CWG) code of '1234'.

(B) Users Groups

User Groups are related to access and security settings. By setting the access rights of the group then any user that is assigned to the User Group will have the same security settings.

(C) Users Level

Three User Levels are possible. Supervisors by default are allowed all access. Operator access may be customized by the User Group or the individual.

Related Topic: Set User Access Rights

3.4 Change a User Password

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A QMSCAPA Quality Management System user may change their **password** at anytime.

1) From the main menu select the **Security** option.
2) Select the **Change Password** option.
3) In the **Change Password Screen** enter the Old Password (or current password).
4) Enter your new password in the New Password field and again in the Verify Password field.

3.5 Edit Company information

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1. Add or edit your company information and select an appropriate logo "image.jpg" file.

3.5.1 Changing a CAPA Log Number

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CAPA log numbers are automatically generated and protected from inadvertent changes.

To change an existing CAPA number open the Company file.

- Navigate to File > Company Setup > Edit > 2) Optional Controls
- Select the [Change CAPA Number] button
- The Company Setup window will close and the Change CAPA number table will open and display with the CAPA numbers in descending order.
- **USE CAUTION:** Avoid using a number that is less than the highest number in your CAPA log.
- Duplicate numbers are prohibited.

User Tip: Use caution and avoid using a lower CAPA # that is currently in your CAPA log.

3.5.2 Default CAPA form

The default CAPA form may be set in the Company file or directly into the Set the Default CAPA Form window.

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3.5.3 Default File Folder Locations for Documents and Records

Set the default path to electronic file folders for management system documents and records.

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3.5.4 Group Email Address

User Tip: A ***Group Email address*** is a good way to alert multiple persons with essential environmental, quality and safety Alert Notices.

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3.5.5 Set Print To Options

Menu Option for Default Company Settings

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Default Company Settings Browse Table

Default Company Settings Form

Tags: quality management software, corrective action software, iso management software

3.6 Add CAPA Types

Add or edit the CAPA Types table.

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3.7 Add Customers

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The Customer Table may be accessed from the Edit Tables

Customer Table

Customer Form Tab 1)

A. The Customer may be identified with a unique 'Record Name', and Account Number and Company Name.
B. The **Customer Type** is intended to provide a method for classifying customers into groups.
C. The 'Bill To' City, State and Zip Code fields may be automatically formatted on the address line 3 or on line 4 by clicking on the **Format Bill to button**.
D. Click on the **Copy to Ship to button to copy** the *Bill to Address fields* to the *Ship to Address fields*.
E. The 'ShipTo' City, State and Zip Code fields may be automatically formatted on the address line 3 or on line 4 by clicking on the **Format Ship to button**.
F. The 2) Surveys tab contains the results of recorded customer satisfaction surveys.

Customer Form Tab 2)

A. The Comment field is intended for information about Customer Satisfaction Surveys in progress.

B. Click on the **Add Survey button** to add a Survey for the current customer record.

3.8 Add Departments

Use Department Group Emails for Alert Notices.

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3.9 Add Document Control Index

Add or edit the Master Document Index table; a.k.a. Document Control Index (DCI).

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As a minimum, you must add your CAPA form.

1) ***Tab 1 of the The Documents Control Index Form*** (see (A) in the image below) provides a record of the ***document description,*** which includes:
   a. QMSCAPA assigned **Sys Doc Id**
   b. User defined document Id
   c. Current Revision Date
   d. Last Date Approved
   e. Effective Date
   f. User defined Document Title
   g. *File Path* to where the document may be stored electronically
   h. Document approval requirements
2) ***Tab 2 Version Approval and History*** provides access to the document version history log and a log of approvals by persons whom are authorized documents.
3) ***Tab 3 Document Text Editor*** provides access to the QMSCAPA built-in *document generator and text editor.*
4) ***Tab 4 Options*** provides access to additional document control options.

User Tips:

- Press and hold the **Ctrl** key **+** the **F10** key to ***edit Org Chart Position text***. (See Edit the window field names)

In the image above ...

A. The letter (A) positioned at the Tab row provides access to various document control options.
B. The letter (B) positioned at the Required Approval group box of the Job Titles/Organizational Chart Postion required to review and approved documents.
   i. The **Approved by Title field** is typically the person who has been authorized as the person responsible for making the final approval. Enter a specific Job Title for the final required approval.
C. The letter (C) with pointing arrows to
   1. the quantity of ***Approvals Required*** (tally of the ☑ Required Approvals group check-boxes)
   2. quantity of approvals by ***E-Signature*** in the ***Version Approval and History Log***
   3. ***quantity of approvals verified*** by a QMSCAPA user
D. **Approval Requirements are VERIFIED checkbox** is intended to be used as a document approval inspection method to verify that the document approval process has been verified. The ***Date Approved*** (if blank) shall be automatically set to the current date when the ☑ Approval Requirements Verified check-box is checked and the Approvals Required equals the ***Approvals Completed*** and the ***quantity of approvals Verified***.

User Tips:

- Press and hold the **Ctrl** key **+** the **F10** key to ***edit Org Chart Position text***. (See Edit the window field names)
- The ***Document File Path field*** may contain any file type (opening application must be installed on the users computer or server), includes web pages, Word docs, PDF and RTF.
- The ***Document Status field*** is used to report the document status when the QMSCAPA Document Generator is used to create the document and printed.
- The ***Document Comments field*** is intended for unique guidance about the document and may be printed if needed.

Related Topics:

Document Management Table

Document Management Editor

3.9.1 Document Types

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3.9.2 Document Version History

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A. The document version history table is displays the 'entry date' in descending order so the most recent change is displayed first.
B. The 'entry date' and 'last saved' are automatically generated.
C. The 'summary of changes' is a free form field to describe key changes to the controlled document.

3.10 Add Human Resources

As a minimum you will need to add the personnel that QMS responsibilities, including:

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- Anyone allowed to generate a Corrective Action Request or Preventive Action Request;
- Anyone that may be assigned to handle a CAPA;
- Anyone that may be required to verify a finding;
- Internal Auditors;
- Management Representatives;
- Anyone that may be required to conduct a Management Review of CAPAs.

3.11 Add or Edit CAPA Status

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Add or edit the CAPA Status table.

The follow CAPA status records should not be deleted or changed:

1. Completed
2. New CAPA
3. Open
4. Rescheduled

3.12 Add Preventive Action Classifications

Add or edit Classifications for Preventive Action Request table.

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3.13 Add Processes

Add the QMS Process table which may directly be associated with quality.

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3.14 Add Product and Services

Product and Services Menu Option

The Product and Services Table may be accessed form Edit Table main menu.

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Product and Services Table

Product and Services Form

3.15 Getting Started with QMSCAPA

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1) Add human resources (employees and contractors) that have Management System (MS) roles and responsibilities.
   a) Enter Departments.
   b) Enter Security Aspects and Security references.
2) Add the top 20 percent of your customers into the Customer Table.
3) Add the top 20 percent of your products and/or services in the Product and Services Table.
4) Add the top 20 percent of your outsources, suppliers and/or vendors into the Supplier and Vendor Table.
   a) Enter transportation carriers into the Transportation Carrier Table.
5) Add customer complaints into the Customer Complaints Log. If possible go back into your existing customer complaint records and enter complaints from the previous year. Entering the historical data provides a good practice method and will help you ascertain trends.
   a) Add customer complaint reason codes into the Complaint Reason Code Table.

6) Copy customer complaints that should have a 'root' cause analysis into the CAPA log.
7) Enter CAPAs from other sources into the CAPA log.
   a) Enter CAPA types.
   b) Enter MS Processes.
   c) Enter Preventive Action Classifications.
   d) Enter Proof of CAPA effectiveness, as appropriate.
   e) Enter CAPA Status list.
8) Identify the documents under revision control of your management system. Enter the appropriate information into the Document Control Index.
   a) Enter Document Types
9) Enter Training Programs.
   a) Enter Training Schedules.
   b) Schedule Personnel for Training, as appropriate.
   c) Evaluate record training effectiveness.
10) Enter Monitoring and Measuring Devices into the Monitoring and Measurement Device Table:
   a) Record calibration methods and intervals.
   b) Record maintenance methods and intervals.
11) Enter Customer Satisfaction Survey elements (questions and rating methods), as appropriate:
   a) Prepare Customer Satisfaction Surveys, as appropriate.
12) Enter Supplier Evaluations elements (evaluation methods), as appropriate:
   a) Prepare Supplier Evaluation templates, as appropriate.
13) Enter Internal Audit elements and processes:
   a) Enter the Audit Schedule.
   b) Enter observations and findings from your last internal audit, as appropriate.
14) Determine the values for determining Risk Priority Numbers (RPN), which are derived from Risk Impacts:
   a) Enter Risk Assessments.
   b) Enter Risk Assessments Aspects.
15) Enter Checklist, as appropriate for Operational Controls and/or Product Realization.
16) Enter Quality Metrics for Monitoring Quality:
   a) Results from customer satisfaction surveys.
   b) Results from manufacturing and/or production activities.
   c) Results from delivery and shipping activities.

d) Results from purchasing activities.
e) Results from contracts, orders and other sales activities.
f) Results from outsource, supplier and vendor evaluations.
g) Enter QMS Dashboard settings.

17) Enter key referenced documents (not under revision control)
18) Modify QMSCAPA forms and reports, as appropriate.

3.16 Set the default data path

The default setting for ***QMSCAPA data path*** is **C:\Users\Public\Documents\ABCI\QMSCAPA.** The ***QMSCAPA default data path*** is shown in the image below:

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New first-time users may need to navigate to the QMSCAPA data folder.

Of course, if you are installing QMSCAPA on a server or shared drive you will need to set the appropriate shared folder privileges for one or more users.

The default location for the QMSCAPA.EXE file is:

C:\Program Files (x86)\QMS\QMSCAPA

Note about the FIRST RUN option and the Path Manager window
If you move the QMSCAPA data folder you will need to reset the path for the QMSCAPA data folder from the **Windows OS Command Prompt** or a **Windows Shortcut**.

Using /FIRSTRUN with the Command Prompt

Launch the Windows Command Prompt from the Windows Accessories menu.

Navigate to c:\Program Files (x86) \qms\qmscapa and type qmscapa.exe /firstrun

Or type c:\Program Files (x86) \qms\qmscapa\qmscapa.exe /firstrun

The 'FIRSTRUN' option will launch QMSCAPA and open the Path Manager

window shown below.

Using /FIRSTRUN with a Windows Shortcut

Create or open an existing Shortcut for the QMSCAPA.exe

At the end of the Windows Shortcut TARGET field type /FIRSTRUN to the right of the double-quote symbol.

After the appropriate path has been selected the /**FIRSTRUN** should be removed from the **Windows Shortcut TARGET field**.

3.17 Set a Default Printer

QMSCAPA requires a default printer set in the Windows OS to print preview or to print to a printer devices. Be sure to set the default printer in your local computer's Control Panel (see Control Panel > Printers and Devices) before starting QMSCAPA.

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QMSCAPA will automatically link to the computer's default printer. You can select a different print once QMSCAPA starts.

3.18 Set User Access Rights

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Set User Access Menu Option

Security Access to the various tables and window forms may be controlled by the QMSCAPA **Set Access Rights** module, which may be accessed under the Security main menu option.

Browse Access Rights Table

Users may be setup as individuals or members of one or more groups. Security Access may be set or controlled at the individual **User or Group Level**.

Tutorial for Set Access Rights Users and Access Points:

1. Click on an User or Group Name inside the User table and the User/Group's privileges are show in the Access Point table-tree on the right-hand side of the window as shown above.

2. Click on the [check box] to modify the User/Group's setting. The **check** indicates that the privilege is granted and the empty box indicates the privilege is denied.

Alternately, Security Privileges may be set or altered by a Supervisor user by using the **CTRL-F8 key**. When logged in as Supervisor, you must go into every screen and press **CTRL-F8**. This will bring up the **Set User Access screen**. You will see a list of your User & Groups, and a list of protected controls that are initially all set for access. Double-clicking on a **red check** or empty box will cause it to toggle. For each user group, turn off the controls you do not want that user group to have access to in the current screen.

USER TIP: If you give a user **ALL ACCESS** in the [Default Access] field then you must manually reset the controls that you wish to restrict in each module or **QMSCAPA** screen. Conversely, if you set the field to **NO ACCESS** you must manually reset the controls that you wish to enable for the user or group.

(A) User Panel

The left-side panel shows the User Groups and any non-supervisor users that are not part of a group. Supervisors have all access rights.

(B) Access Points

The **Access Points** panel shows all QMSCAPA windows that have Access Controls that may be set per individual user or group that appear in the **User Panel**.

3.19 Transportation Carrier Table

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Menu Option

Browse CARRIER Table

Carrier Form

3.20 User Defined Guidance Table

The **User Defined Guidance table** may be accessed under the Main Help option. The purpose of this document is to provide a centralized repository for QMSCAPA user guides, useful links and other guidance documents, including proposed drafts of controlled documents.

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4 What's new in QMSCAPA?

QMSCAPA for Workgroups, 1.48.1 < What do the version numbers mean?

QMSCAPA™ is quality management software designed by a user group of quality professionals, including assessors, auditors, consultants and quality managers for quality management systems. If you have an idea or new feature that you would like to see in **QMSCAPA** please join our user group by completing our web form.

☑ AS9100 D Implementation & Templates Kit

☑ ISO 9001:2015 Implementation & Templates Kit

Do you have an idea for a new feature in QMSCAPA?

Let is know by sending an email with your feature request to our support group. (sherlock @ abci-software.com). Click here to see what is planned on our list of new features.

10/28/2017 1.48.1

- Updated the Windows 10 manifest.

09/01/2017 1.47.26

- Added the NIST 800-171 Basic Security and Derived Security requirements to the Controls Table.
- Enhanced the Objectives and Controls Table to include a comments field for controls not yet implemented.
- Enhanced the Human Resources Table.
- Enhanced the Risk Management module to allow a direct relationship from the risk element to the control.
- Added an Objectives and Controls report for Controls not implemented.

07/02/2017 1.46.12

- Added a control to copy the Customer Satisfaction Survey records to Excel.
- Added a link from the Risk Assessment module to RIP's Expectations and/or Requirements table.
- Enhanced the Document Control module by adding approval requirements and a method for verifying document approval.
  a. Enhanced the Document Approval and Revision History module.
  b. Added a module to allow access to only unapproved documents that may be approved electronically by authorized signers.

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05/12/2017 v1.43.5

QMSCAPA EasyStart Menu option

- Added a Relevant Interested Parties (RIP) table, which includes:
- RIP Relationship table
- Library lookup table for stored RIP Expectations, Objectives and/or Requirements
- 1 to 999 Expectations, Objectives and/or Requirements may be linked to a RIP record
- Each Expectation, Objective and/or Requirement may be directly linked a Risk Assessment and Impact Statement
- RIP Reports may be printed with or without the related Expectations, Objectives and/or Requirements

03/12/2017 v1.42.2

- The Document Control Module was enhanced to include a 'Login User Code' field to the Document Index, Change History Log and Approval Journal Records.
- Also, Records Control Module was enhanced to include a 'Login User Code' field to the Record Index and Record Approval Journal.
- The Document Control Browse Table now displays the Documents, Change History and the Approvals in the same window.
- The Human Resources Module (Employee Table) has been enhanced with a User Profile Options tab to set folder preferences for saving PDF attachments. Also, options to open the Easy Start Menu and to open the Action Task Reminders module at Login have been created per user.
- The Product Configuration Module has been enhanced with additional Configuration Management reports and the QC Checklist may be selected and linked from the the Product Configuration Edit Form.
- The *Email Assistant* used in the Customer Feed-back, CAPA and AIM NC Reports modules has been enhanced to allow users with web-based email clients to paste the email construct text directly into the client.
- The Objectives and Controls Table has been enhanced when used with a Risk Assessment Module.
- The Print Preview Module was enhanced to improve the Printer Selection options and to Save as PDF.
- The Quality KPI Module was enhanced to improve *ease of use*.

12/23/2016 v1.40.11

- Added an option to copy the ISO Management Standard clauses to create derivatives from similar Standards, e.g. ISO 9001:2015 to AS9100D.
- Enhanced the Report Preview features and options.
- Updated the Supplier Survey report template.

07/05/2016 v1.39.17

- Added an Easy Start Menu option for new users that provides an alphabetical listing of frequently used modules.
- Added an image control to each Checklist Item record, which allows images to be included with each checklist item.

- Added a Product Configuration Management method and reports.
- Added new Product and Services reports.
- Added new Chemical and Material database and reporting module, which provides support for the OSHA Hazard Communication Standard for Safety Data Sheets (SDS) revised in 2012, which includes 16 standardized sections.
- Introduces a new method for Product Life Cycle Planning and Evaluations, which supports product life-cycle based thinking in ISO 14001:2015.
- Added Spell-check for the Windows Edit Form for Safety Data Sheets.
- Added a Label Set Name Sort Tab to the KPI Label Set Table.

05/15/2016 v1.38.8

- Added an advanced CAPA query and search feature to assist with CAPA analysis.
- Added an assignment tool to assist with adding a personnel group to a Training Schedule.
- Added a table to link Training Program requirements to Job Titles.
- Updated the Graphical Charting driver.

04/24/2016 v1.37.6

- Enhanced the Performance Dashboard and Report.
- Added a Microsoft Outlook integration link from the QMSCAPA TASK table to Microsoft's Outlook TASK table.
- Add the ISO 9001:2015 clauses to aid internal audit planning and writing audit findings.

02/01/2016 v1.36.14

- Added new virtual printer drivers for generating reports as
  - Microsoft Excel file (requires Microsoft Excel)
  - Microsoft **Windows Metafile** (**WMF**) (requires Microsoft Word)
  - Portable Document File (PDF)
  - Rich Text File (RTF)
- Added ISO Objectives and Controls table
  - Added ISO 27001 Statement of Applicability report

02/01/2016 v1.35.8

- Enhanced the Supplier /Vendor Evaluation reports
- Enhanced the Customer forms and table
- Added a Quality Targets Table, which may be used to set On-time Delivery and Customer Satisfaction targets per customer record.
- Added a Customer Reports group to report the results achieved from activities used to measure on-time delivery (OTD) and customer satisfaction (CS).
- Added to the CAPA form and database a separate ***Containment Actions field***.

01/15/2016 v1.34.15

- Enhanced the Performance Dashboard.
- Enhanced the Product/Service Database module.
- Enhanced the Process KPI reports.
- Enhanced the User-Defined Help (UDH) module.
- Enhanced the Supplier Survey and Evaluation module

12/23/2015 v1.34.8

- Enhanced the Security Access and Security Aspects Reports.
- Added an optional Record Lock to the Document Control Index to prevent unintended deletion of records.
- Enhanced the Internal Audit Schedule Module and Reports to include Process information.

12/17/2015 v1.34.6

- Added an optional Record Lock to the Document Control Index to prevent unintended deletion of records.
- Enhanced the Internal Audit Schedule Module and Reports to include Process information
- Added Document Approval Journal to Document Revision History
- Added Document Approval Journal Reports
- Enhanced the Document Approval Process to comply with FDA Title 21, Sub-Chapter A, Part 11.
- Corrected E-Signature sort order on HR Table.

12/04/2015 v1.33.9

- Alert Messages and NC Reporting Module
  - Added three new AIM/NC Reports
  - Added to the AIM/NC form a user-defined look-up table forÂ *disposition*
  - Enhanced the AIM NC Module Reports
- Enhanced the CAPA Log Reports
- Enhanced the KPI reports
- Enhanced the Preventive Action Reports

11/05/2015 v1.33.4

- Enhanced the AIM NC Module Reports
- Enhanced the Records Control Index Module
- Records Control Form has new fields to ...
  - allow the record to be locked;
  - record the date the record was locked, and;
  - identify the user that performed the lock, and;
  - identify the position required for a record approval.
- Records Table Structure now includes ..
  - Records Group Name, and;
  - Chronological listing of Records in the Group, and;
- Records Approval Module that includes the Date & Time a Record is approved, and;

  - an option to lock the record to prevent unauthorized changes to approval records,
  - which conforms to FDA Title 21, Sub-Chapter A, Part 11
- Added support for electronic signatures.
- Enhanced the Records Index Reports, including a
- Records Approval Journal.

4.1 What's planned for QMSCAPA?

If you have not joined our QMSCAPA user group, we encourage your joining and welcome your input on how we can improve QMSCAPA.

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The planning information and feature descriptions that appear under the topic "What's Planned for QMSCAPA" are subject to change without notice. Some features may be incorporated into a custom version and released as a minor product upgrade (number to the right of the decimal in a version designation and formed as #.#.

Do you have a suggestion or improvement for **QMSCAPA**? Contact sherlock@abci-software.com. The following is our current "To Do List" to improve **QMSCAPA**.

Currently in Development and Early Release

Future Development

- Management Review input form and database.
- Product and customer requirements review form and actions arising from the review.
- Design input records database relating to product requirements, design review and necessary actions.
- Results of the design verification database.
- Validation of processes form and database.
- Customer property records of lost or damaged customer property and communication to the customer.
- Records to record the person authorizing the release of product.
- QR Codes for printing labels that when scanned with a hand-held smart phone the instructions for quality, environmental and safety messages from a web site are displayed.
- Predictive Maintenance Journal

5 Alert Messages and NC Reports

ALERT NOTICES
for Quality, Environment & Safety

INITIATIVES
from Employees and Stake Holders

NCR
Non-conformance Reporting

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QMSCAPA provides a method for alert notices, initiatives from employees, messages and Non-conformance Reports.

Alert Message Menu Option

Browse Table

A. The 'AIM/NCR' Message Browse Table provides a method to sort and view messages by many fields.
B. Alerts, Initiatives, Messages and Non-Conformance Reports may be 'moved' into the CAPA log by clicking on the ***Copy to CAPA*** Log button.
C. Print one AIM/NCR form.
D. Print the AIM/NCR forms according to a date range.
E. Print the AIM/NCR log table according to a range on the date reported.
F. Print the highlighted AIM/NCR with the Task Log.
G. Print the AIM/NCR(s) with the *Task Log* according to a range on the date reported.

AIM/NCR Form, Tab 1) Description

A. The AIM/NCR form includes Id fields for the Author, the Person Reporting and the Department. Also, the Process Name can be linked to the AIM/NCR.
B. The AIM/NCR Type may be linked to a *user-defined look-up table*. Also, the end-user can define the *AIM/NCR Report* Title for printed forms and reports.
C. The Statement of Concern field may be used for *Alert Messages, Personnel Initiatives and Non-conformance* reports.

AIM/NCR Form, Tab 2) Parts and Management Review

A. The *AIM/NCR Vendor* Id field may be linked to a Vendor by entering or selecting a Vendor Id.
B. And the *AIM/NCR Part/Service #* field may be linked to a Part or Service Id number.
C. The *AIM/NCR Reference Id* field may be user-defined, e.g. Job Number, Work Order, etc.
D. The *AIM/NCR Disposition* field is linked to a user-defined *table for dispositions*.
E. Use the *AIM/NCR Management Review Comments* field to record final review or disposition comments.
F. The *AIM/NCR Requires CA/PA* check box is automatically set when copied to the CAPA log.

AIM/NCR Form, Tab 3) Task

A. The *AIM/NCR form* includes a Task list, which may be used assign an investigation to multiple persons and, or to record a journal of events (or task) associate with the AIM/NCR.
B. The Activity Reported field displays a snippet of the *AIM/NCR Task record*.

Related topic: Printing an Alert, Initiative, Message or Non-Conformance Report

5.1 Printing an AIM or NCR Message

Reporting a Non-conformance

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AIM and NC Report

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A Non-Conforming Product

AIMNCR Id# 3	Reported	Issued	Due	Reviewed
	12/05/15	12/05/15	12/15/15	12/06/15

Person Reporting, (Id#): Samuel C. Allen, (18)
Process: Order Entry
Type of Report: Software Normality
Person Assigned, (Id#) : Stephen D. Brown, (22)
Status: Reported
Disposition: Not Determined

B Description of Concern of Non-conformance:
This data is recorded in the AIM/NCR concern field. This AIMNCR does not have a related TASK record entered.
Part#/Service Id: MyNewPart
Reference Id: User-defined Reference #
Supplier/Vendor Id#: (9) My Special Vendor C

Management Review/Disposition Notes:

D Reviewed and Dispostioned By & Date: Jack T. Bogle, (9), 12/06/15
Requires CAPA?: No
Reviewers Comments: Material or part disposition is recorded in the Management Review comments field.

In the image above ...

A. The *AIM/NCR Report Form Title* is user-defined
B. The *AIM/NCR Part #/Service* Id information is a print option
C. The *AIM/NCR Supplier/Vendor* Id# information is a print option
D. The *AIM/NCR Management Review* information is a print option

6 Configuration and Installation Tips

Single User

Essentially, the QMSCAPA executable, binary libraries and data files may be installed on any drive provided that you allow the OS security system to execute programs; plus read and write data to the selected folder.

The default and recommended installation path for executable and binary libraries are shown below:

C:\Program Files (x86)\QMS\QMSCAPA

The default and recommended installation path for data files and report templates are shown below:

C:\Users\Public\Public Documents\ABCI\QMSCAPA

Recommended Configuration for Multiple Users

The QMSCAPA ***reporting templates*** are stored into a file folder named **REPORTS**, which is a requirement of the QMSCAPA software.

The default path to the QMSCAPA reporting templates is:

C:\Users\Public\Documents\ABCI\QMSCAPA\REPORTS

When ABCI publishes an update for QMSCAPA the reporting templates are included and the installation wizard places the updated reports into the default path.

However, some end-users have elected to locate the QMSCAPA data files in other drives and folders.

For example, Q:\ManagementSystems\QMSCAPA

Therefore, the person executing the installation of the updated **REPORTING TEMPLATES** must navigate and select the appropriate path for the **REPORTS**.

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6.1 Recommended Configuration for Multiple Users

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QMSCAPA is designed for multiple simultaneous users when used in a Microsoft Server that provides **Remote Desktop Services**. Remote Desktop Services (**RDS**), known as Terminal Services in Windows Server 2008 and earlier is one of the components of Microsoft Windows that allows a user to take control of a remote computer or virtual machine over a network connection.

Remote Desktop Services is Microsoft's implementation of thin client, where Windows software and the entire desktop of the computer running Remote Desktop Services, are made accessible to a remote client machine that supports Remote Desktop Protocol. With Remote Desktop Services, only software user interfaces are transferred to the client system. All input from the client system is transmitted to the server, where software execution takes place.

Remote Desktop Services provides the multiple-user community many benefits, which includes:

- ✓ Easy and single point installation for initial installation and upgrades;
- ✓ Domain security for internal and external users;
- ✓ Ubiquitous cloud connection from any windows computer with available **Remote Desktop Services**.

The QMSCAPA single user version is license free. However, if you wish to have more than one simultaneous user of QMSCAPA you will need a license/copy for each user.

Installing QMSCAPA on a LAN.
Microsoft Remote Desktop Connection RDC (Windows client)
QMSCAPA single-users

6.2 Multiple Users On a LAN (Small Business)

User Note: For installations that require more than three users we recommend running QMSCAPA on a Windows Server through Terminal Services or Remote Desktop Connection.

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See Recommended Configuration for Multiple-Users

Also Multiple Users on a LAN (Larger Business)

If you wish to have more than one simultaneous user of QMSCAPA you will need a license/copy for each user and a shared drive/folder in Local Area Network. Although not recommended by ABCI Software, the following configuration may be suitable for up to three users, that are running the same *Windows Professional operating system*. Mixed computers on a LAN using Vista or Windows 7/8/10 could be problematic for the QMSCAPA data files. *Windows XP computers* are not supported.

Simple Installation for Client to a Network Shared Drive or Server

In this scenario the QMSCAPA executable binary libraries are installed on each client computer and the data files coexist in the same share drive/folder in a central computer or server.

1) First decide which computer will serve as your main computer or file server where QMSCAPA's databases will

be kept. We refer to this main computer as your Server. We refer each additional computer as the Client.

2) Install QMSCAPA on your main computer or file server. First-time or new users must use the DEMO INSTALLATION PROGRAM, which includes SAMPLE DATA. The default location for QMSCAPA data is c:\Users\Public\Documents\ABCI\QMSCAPA.
3) On each Client computer that you wish to run QMSCAPA, map a drive letter (e.g. Q) to the literal path name on your main computer or file server for QMSCAPA.
4) Next, using your Windows File Explorer on your Client computer you can map this folder as drive Q:\ABCI\ on your Client computer. We recommend that you set the root for the Q:Drive to ABCI, which will allow you to have multiple sub-folders in the ABCI folder (see the image example below).
5)

6) On each Client computer that you wish to install QMSCAPA, run the 'Demo' installation program using the default settings.
7) Once the QMSCAPA is installed on the Client launch the program to verify QMSCAPA can run with the local demo data.
8) To share the data on your LAN/SERVER shared 'Q Drive' you must execute the FIRSTRUN option on each client computer.
9) Using /FIRSTRUN with a Windows Shortcut on each Client
10) Create or open an existing Shortcut for the QMSCAPA.exe
11) At the end of the **Windows Shortcut TARGET field** type /FIRSTRUN to the right of the double-quote symbol.

12) FIRSTRUN option

13) Apply the changes to the Properties of the short-cut. Restart QMSCAPA with the modified short-cut and the QMSCAPA Path Manager will open.

11) Select the Folder button to navigate and select your mapped drive. QMSCAPA should launch and connect with your shared data on your Server.

12) Once you have verified that the QMSCAPA Client is sharing data on your Server the you should remove the **/FIRSTRUN** from the **Windows Shortcut TARGET field**.

6.3 Mulitple Users on a LAN (Larger Business)

User Note: For installations that require more than three users we recommend running QMSCAPA on a Windows Server through Terminal Services or Remote Desktop Connection.

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If you do not have a Windows Server or if you do not have a Windows Server configured as or with a Domain Controller then you may want to consider the ABCI IP Data Server, which can be configured for a Windows Server or other Windows operating systems. The IP Data Server allows larger business to operate across a LAN with a Windows File Server.

- Requires a single single computer with Windows Server or a Windows 8/10 Professional Computer to be designated as a file SERVER. This computer should have a robust configuration.
- A static IP address must be assigned to the SERVER.
- The QMSCAPA IP Client must be installed on each client-user computer.

Please call 800-675-2415 or write to sherlock@abci-software.com to learn more about this configuration and special license fees.

7 Corrective Actions & Preventive Actions

The CAPA Log (Corrective Actions & Preventive Actions) may be accessed from the Main Menu > Browse Logs > CAPA Log

Alternately you may open the CAPA Log by using the Icon Bar

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Shown in the image below ...

A. The CAPA Log may be displayed (sorted) in a specific order described by the **Tab #)**.
B. Use the button controls to Add, Edit or Delete a CAPA record.
C. The *Make Chart button* provides several options to print the CAPA Log as a graphical representation.
D. The *Print Form button* will print the highlighted record to a user-selected form template (CAPAform02.rpt is shown).
E. The *Copy to Excel button* sends the CAPA Log to an Excel workbook (requires Microsoft Excel to be installed).
F. The *CAPA Log by Status button* prints the CAPA Log by a user-selected CAPA status.
G. The *CAPA Log by Range button* prints the CAPA Log by a user-selected CAPA Due Date Range.

The Browse CAPA Log menu provides two options:

1. By Auditor / MR View Level, shows all CAPAs for all users/groups and requires a "supervisor" login or the appropriate access rights applied to a specific login.
2. By Work Group, shows all CAPAs for the Current Work Group (CWG code) as set by the users login rights.

The CAPA table may be viewed according to the following sort orders:

1. By CAPA Id
2. By CWG (Current Work Group)
3. By Due Date
4. By CAPA Process or Department
5. By CAPA Type
6. By Status & Due Date
7. By Preventive Action Classification
8. By Author (originator) & Created Date
9. By Assigned & Due Date
10. By Verifier & Due Date
11. By CWG
12. By PA Classification (Preventive Action)

7.1 Add or Edit a CAPA

The CAPA window form is divided into tabs:

1) Incident / Non-Conformity and Containment;
2) Cause and Corrective Action
3) Preventive Action and Review (includes verification)
4) View Attachments (related to the CAPA)
5) Task List (related to the CAPA)

1) Incident / Non-Conformity and Containment tab;

1. Use the default CAPA form name/number, the Version and Effective Date are populated by the Form Id.
2. Enter the appropriate CAPA Due Date.
3. The Created and Saved dates are automatically generated.
4. The Author Name is the person who originates the CAPA request.
5. The Process or Department that is most directly involved with the Statement of Concern or problem.
6. The Type of CAPA is related to the Action Request or Preventive Action and, or non-conformances.
7. The Client information is optional.
8. **Assigned to** is the person who will be taking or leading the Corrective Action or Preventive Action.
9. The CWG (Current Work Group) is a code that is related to the person or a group the person belongs as a member. The CWG is used to filter CAPAs that are for a specific person or group.
10. The Statement of Concerns is required.
11. The Containment Action or Initial Action field was added in v1.35
12. The Statement of Cause, also known as "root cause."

2) Cause and Corrective Action tab

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A. Use the ***Statement of Cause field*** to record the cause of the problem, also commonly referred to as the ***root cause***.

B. Use the ***Corrective Action field*** to record the appropriate corrective action used.

C. Use the ***Form for Printing field*** to select the appropriate form for printing.

- The "CA completed by" is the person that completes the Corrective or Preventive Action request, which may be the same as the "Assigned to" person.
- The CA attachment is optional.
- The "CA completed date" is related to the Correction Action completion.
- The "CAPA Status" is related to whether or not the CA or PA has been acted upon and, or completed.
- If the CAPA Status is set to "New CAPA" then the "new CAPA Id number" should be entered into the "CAPA Reference" field.

3) Preventive Action Request and Review Tab:

1. The "PA Classification" is used to group Preventive Actions into specific classes or types and groups.
2. The "Solution for Preventive Action" is optional, if not appropriate.

3. The 'PA Completed by" is the person that completed the PA.
4. The "PA Attachment" is optional.
5. The "PA Completed date" is the date the PA solution is adopted or implemented.
6. The "ISO Clause" and Non-conformance type (Major, Minor, OFI [Opportunity for Improvement] are optional.
7. The "Verified by" is the person that inspects the CAPA and determines if the solution was effective.
8. The "Verified date" is required.
9. The "Proof Effectiveness" is a comment that reports the proof used to verify the effectiveness of the CAPA.
10. The "Reviewed by Mgr" is the Management Representative or the appropriate Top Management person who reviews the CAPA.

7.1.1 CAPA Status

CAPA Status refers to the current and, or last known status of the Corrective or Preventive Action, or Customer Complaint.

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User Tips:

With regard to Management Review and making the Management System more effective record the following information:

1. Who completed the corrective or preventive action?
2. Date corrective or preventive action was completed?
3. Who verified the effectiveness of the corrective or preventive action?
4. Date verified?
5. Who completed the Management Review of the corrective or preventive action and proof of effectiveness?
6. Date Management Review was completed?

Guidance for Corrective & Preventive Action Status

- If corrective actions have been COMPLETED but not VERIFIED change the STATUS to PENDING VERIFICATION.
- If corrective actions have been VERIFIED but not REVIEWED by top management then change the STATUS to PENDING MGT REVIEW.
- Once MGT REVIEW has been completed then change the STATUS to COMPLETED.

7.1.1.1 Corrective Action & Preventive Action Form

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The QMSCAPA Corrective Action & Preventive Action (CAPA) Form is organized into five Tabs or sections. The collection of fields and related Tables are designed to provide tools for the user to record information about an incident or nonconformity, plus information about the cause and corrective actions.

The numeric references in the CAPA form image above are described below:

1) Incident or Nonconformity and Cause

   The **CAPA Incident or Nonconformity and Cause tab** is designed to be used for recording information about the incident or nonconformity, including:

   a) Process / Department
   b) Client identifier
   c) Part # or Product/Service identifier
   d) Group # (reference #, batch #, lot # etc.)
   e) CAPA Dates (created, saved, issued, due, etc.)
   f) Type of CAPA
   g) Assignments
   h) Customer Feed-back (complaint)

2) Corrective Action

   The **CAPA Corrective Action tab** is designed to be used for recording Corrective Actions, including:

   a) Person (primary) assigned, date completed and primary record attachment.

3) Preventive Action and Review

The **CAPA Preventive Action and Review tab** is designed to be used for recording Preventive Actions and Management Review information, including:

a) Verification, proof of effectiveness and the date verified
b) Management review comments and review date

4) View Attachments

The **CAPA Form View Attachments tab** is designed to assist with the organization and retrieval of attached (or stored) electronic documents that are related to a CAPA.

5) Task List

CAPA Form Task List are designed to organize the investigation and assign others to task that are relevant to the investigation or corrective actions necessary to prevent the incident or nonconformity from being repeated.

6) Tab 1: Statement of Concern or Problem and the Immediate Action Taken

The **Statement of Concern field** is designed to be used for recording the initial facts of an incident or nonconformity and the immediate actions taken.

7) Tab 1: Statement of Cause

The **Statement of Cause field**, often referred to as the 'root cause', is a large text field for recording the results or determination of an investigation into the cause of an incident or nonconformity.

8) Tab 1: New CAPA Reference #

The field labeled **Enter New CAPA Reference #** provides a mean to link an existing CAPA # to a new CAPA# if the CAPA is re-opened for any reason in the future.

7.1.2 CAPA Task List

QMSCAPA provide a **Task List** that is specific to a single CAPA.

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1) The Task List may be accessed and maintained by opening the related CAPA #.
2) Alternately, the Task List may be accessed and maintained directory from the QMSCAPA main icon menu shortcut.

CAPA Task List Form

A. Enter information about the activity or actions needed to complete the CAPA.
B. Actions can be verified by inspection, internal auditing, management review or other approach methods for verification.
C. Optionally a TASK can be linked to a SWORD Work Order

7.1.3 CAPA Types

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See Auto-calculating Customer Complaint Due Dates.

7.1.3.1 CAPA Due Date Auto-Calculation

CAPA Type Form

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To **auto-calculate the CAPA Due Date** check the **Use Default for Due check-box** and enter the quantity of days that should be added to the **Date Issued** in the CAPA form.

7.1.4 Copy the CAPA log to Excel

The **Copy to Excel button** on the CAPA Log Table will copy every CAPA record that appears in the CAPA log to Excel.

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Related Topics:

Customer Complaints Log
CAPA Log

7.1.5 MS (Management System) Processes

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7.1.6 Preventive Action Classifications

Add or edit Classifications for Preventive Action Request table.

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7.1.7 Printing a CAPA Task List

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A. Select a TASK (highlight) and then click on the Task List by CAPA button.
B. The Entry Data window opens to verify or change to an appropriate CAPA #.

7.1.8 Proof of Effectiveness

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7.2 Set the Default CAPA Form

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7.3 Printing a CAPA Form

1. Highlight the CAPA that you intend to print.
2. Click on the [Print Form] button.

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7.4 Printing a CAPA Report

Additional CAPA forms and reports may be selected and printed from the Report Builder Table.

Open the Report Builder Table.

1. Select the "Report" that you intend to print.
2. Click on the [Print Selected] button.

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8 CAPA Query & Search

Menu Option

Click the ***CAPA Search button*** to open a CAPA Table with advanced Query & Search features.

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Browse Table

The ***CAPA Search button*** opens the ***Fast text search options***.

Query by Example Form

A. The JOIN drop-down offers AND & OR options to extend the query of the text fields.
B. The FIELD drop-down offers all fields in the CAPA log.
C. The OPERATOR drop-down offers Boolean logical experssion, e.g. CONTAINS, EQUAL, BEGINS WITH, GREATER THAN, LESS THAN and NOT.
D. The VALUE field is user-defined variable.

Tags: quality management software, corrective action software, iso management software

9 Browse Table Options

Some of the QMSCAPA browse tables contain options to allow the user to control which columns appear and in what order they may appear in the table. To access the **Browse Table Options** simply click on the column heading.

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11 CAPA Graphical Charts

QMSCAPA provides several options to graphically chart Corrective and Preventive Actions.

Menu Option

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CAPA Chart by Process

CAPA Chart by Type

CAPA Charts by Status

12 Checklist Generator

Use the QMSCAPA Checklist Generator for:

- Contract Review
- Job Travelers
- Meeting Customer Requirements
- Service Orders
- Project Management
- Quality Inspections
- Root Cause Analysis
- Work Orders

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Checklist are very good for business and help business people get better on a continual basis. They can help determine if employees doing what they want to do, or doing what management would like them to do?

- Checklist are good for planning, doing, checking and acting (PDCA).
- Checklist are good for creating evidence of execution and records;
- Checklist are good for quality control inspections;
- Checklist are good for controlling design and development input and output;
- Checklist are good for producing data, which can be easily analyzed, and
- Checklist are good for getting things done right the first time.

Related topics: Checklist Table

12.1 Checklist Table

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1) QMSCAPA provides a database table for many *checklist and document control*.

2) The *Checklist Editor* window form provides many options for naming and controlling the checklist.
3) User-defined text may be added for the top and bottom of the checklist.
4) User-defined *Pass* or *Fail* text fields are available on the checklist and for each checklist item added.
5) User-defined *Used by and Reviewed by fields* are available.
6) From the Checklist browse table window the checklist items may be managed by clicking on the ***Items in the Checklist button***.

Related topic: Items in the Checklist Table, Checklist Items Tab

12.1.1 Checklist Items Tab in the Checklist Form

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The Checklist Items may be accessed directly from the Checklist Form by selecting the 2) Checklist Items tab.

12.2 Items in the Checklist Table

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1) The QCC list id is associated with *Checklist header record* used for document control.
2) The Section column is user-definable.
3) The Row # allows for precise positioning of a checklist item.
4) The Checklist may contain the inspection criteria and instruction for an item fail.

Related Topic: Checklist Item Edit

12.3 Checklist Item Edit

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1) The ***Checklist Row Number*** may used to position the checklist item within the (2) ***Section Name***.
2) The ***Section Names*** are user-definable.
3) Each ***Checklist Item*** may have a unique PASS or FAIL.
4) Use the ***Instructions for Fail field*** to describe what should be done if the inspection point fails.

Related Topic: Printing Checklist

Checklist may be further customized using the QMSCAPA Report Builder.

12.4 Copying and Printing Checklist

1) Use the ***Copy Checklist button*** to create a new or modified version of an Checklist. The highlighted Check list will be copied.
2) To ***print a checklist*** first highlight a Checklist record and then click on the ***Checklist Form print button***.

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Checklist may be further customized using the QMSCAPA Report Builder.

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12.5 Images Used in the Checklist

Checklist Item Image

Each Checklist record may contain an image, which may be used to guide an inspector or production through a process.

Checklist Image

Checklist Printed Report with an image file.

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Job Traveler Example

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Page 3 of 6

d) good for getting things done right the first time.

Row 7 instructions if the inspection point fails.

Note:			

2-Doing / Performance

Type of Inspection	Measurement	PASS	FAIL

Checklists are good for inspecting what you expect.

Row 8 instructions if the inspection point fails.

Note:			

Checklists are good for creating a systematic and documented approach for process improvement, like ISO 9001.

Row 9 instructions if the inspection point fails.

Note:			

Good for Management

Row 10 instructions if the inspection point fails.

Note:			

Form Name & Version # ABCI Checklist Example v# 1 | Printed 7/01/2016
Approved by: Quality Manager | Effective: 2/01/2014

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12.6 Sample Checklist Report

1) Use the ***Copy Checklist button*** to create a new or modified version of an Checklist. The highlighted Check list will be copied.
2) To ***print a checklist*** first highlight a ***Checklist record*** and then click on the ***Checklist Form print button***.

- Show Sample Check List Page 1
- Show Sample Check List Page 2

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12.6.1 Sample Checklist Page 1

Sample Checklist Page 1 of 2 from QMSCAPA Software.
QMSCAPA checklists may have one or more pages.

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ABCI Checklist Example

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Checklist are good for planning, doing, checking and acting (PDCA). Checklist are good for creating evidence of execution and records. Checklist are good for producing data that can be easily analyzed.

1-Planning

Type of Inspection	PASS	FAIL
Checklists are very good for business and help business people get better on a continual basis.		
Describe what should be done if the inspection point fails. Are employees doing what they want to do, or doing what management would like them to do?		
Checklists are good for planning, doing, checking and acting (PDCA).		
a) Good for planning;		
b) Good for creating evidence of execution and records;		
c) Producing data, which can be easily analyzed, and		
d) good for getting things done right the first time.		

2-Doing / Performance

Type of Inspection	PASS	FAIL
Checklists are good for inspecting what you expect.		
Checklists are good for creating a systematic and documented approach for process improvement, like ISO 9001.		
Good for Management		
Checklists are good for Resource Management.		
Checklists are good for Product realization		

Form Name & Version #: ABCI Checklist Example v# 1 | Printed 1/30/2014
Approved by: Quality Manager | Effective: 2/01/2014

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12.6.2 Sample Checklist Page 2

Sample Checklist Page 2 of 2 from QMSCAPA Software.
QMSCAPA checklists may have one or more pages.

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ABCI Checklist Example

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Checklists are good for Measurement, analysis and improvement.

3-Inspection or Checking

Type of Inspection	PASS	FAIL
Checklists are good for verifying purchased products.		
Checklist are good for controlling outsourced services.		
Checklist are good for work orders or work instructions.		
Checklist are good for verifying Sales Contracts prior to acceptance.		
Checklist are good Design and Development.		
Checklist are good for Management Review		
Checklist are good for Process Auditing		

4-Act if Corrections are Needed

Type of Inspection	PASS	FAIL
Checklist are good for controling non-conformance products.		
Checklist are good for corrective actions.		

Select Section

Type of Inspection	PASS	FAIL
Checklist are good for preventive actions.		

Checklist are good for getting things done right the first time.

The below signed person(s) have inspected the material/products received as indicated above.

Checked by: Job Title of Checklist User (Signature & Date)

Reviewed by: Job Title of Checklist Reviewer (Signature &

Form Name & Version #: ABCI Checklist Example v# 1 | Printed 1/30/2014
Approved by: Quality Manager | Effective: 2/01/2014

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13 Chemical and Material Table

QMSCAPA provides a **Chemicals and Materials module** to maintain a database of chemical and materials that make up a product item. The module is designed about the OSHA Hazard Communication Standard Safety Data Sheets.

The Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)), revised in 2012, requires that the chemical manufacturer, distributor, or importer provide Safety Data Sheets (SDSs) (formerly MSDSs or Material Safety Data Sheets) for each hazardous chemical to downstream users to communicate information on these hazards. The information contained in the SDS is largely the same as the MSDS, except now the SDSs are required to be presented in a consistent user-friendly, 16-section format. This brief provides guidance to help workers who handle hazardous chemicals to become familiar with the format and understand the contents of the SDSs.

The SDS includes information such as the properties of each chemical; the physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. The information contained in the SDS must be in English (although it may be in other languages as well). In addition, OSHA requires that SDS preparers provide specific minimum information as detailed in Appendix D of 29 CFR 1910.1200. The SDS preparers may also include additional information in various section(s).

Sections 1 through 8 contain general information about the chemical, identification, hazards, composition, safe handling practices, and emergency control measures (e.g., fire fighting). This information should be helpful to those that need to get the information quickly. Sections 9 through 11 and 16 contain other technical and scientific information, such as physical and chemical properties, stability and reactivity information, toxicological information, exposure control

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information, and other information including the date of preparation or last revision. The SDS must also state that no applicable information was found when the preparer does not find relevant information for any required element.

The SDS must also contain Sections 12 through 15, to be consistent with the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS), but OSHA will not enforce the content of these sections because they concern matters handled by other agencies.

Chemical Menu Option

Main Menu > Edit Tables > Product and Services

Chemical Browse Table

Form for Chemicals and Materials management

Tags: quality management software, corrective action software, iso management software

☑ AS9100 D Implementation & Templates Kit

☑ ISO 9001:2015 Implementation & Templates Kit

14 Chemical and Material Form

The QMSCA Chemical and Material module provides support for the **OSHA Hazard Communication Standard for Safety Data Sheets**. The information contained in the new (2012) SDS is largely the same as the previous MSDS, except now the SDSs are required to be presented in a consistent user-friendly, 16-section format.

The QMSCAPA form design contains fields for all of the required 16 sections found in the new SDS format.

Sections 1 through 8 contain general information about the chemical, identification, hazards, composition, safe handling practices, and emergency control measures (e.g., fire fighting). This information should be helpful to those that need to get the information quickly.

Sections 9 through 11 and 16 contain other technical and scientific information, such as physical and chemical properties, stability and reactivity information, toxicological information, exposure control information, and other information including the date of preparation or last revision.

The SDS must also state that *no applicable information was found when the preparer does not find relevant information* for any required element.

The SDS must also contain Sections 12 through 15, to be consistent with the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS), but OSHA will not enforce the content of these sections because they concern matters handled by other agencies.

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Tags: quality management software, corrective action software, iso management software

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15 Chemical and Material Reports

The QMSCAPA Chemical and Material module includes an option to print **OSHA Hazard Communication Standard for Safety Data Sheets.** Optionally, Sections 12 through 15, the non-mandatory sections may be excluded from the report at the time of printing.

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SDS

Page 1 of 4

Printed: 7/04/2016

A Chemical Identifier for Sample Record #1 on Tab 1), shown END

Section 1: Identification

EDIT DATE: 7/04/2016 AUTHOR ID: 13 | VERSION ID: Version of SDS Tab 9) >>> >> >> >>> >>>> >>>> >>>>> >>> >>>> END

PRIMARY SUPPLIER: 4 | ADDURS
Add your vendor or personnel
Add an address Include Suites and/or units
City Name Here CA 92649

Office 800-644-2056
Mobile 800-644-2066
Fax 800-644-2076

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RECOMMENDED USE:
Recommended use of the chemical (e.g., a brief description of what it actually does, such as flame retardant) and any restrictions on use (including recommendations given by the supplier).

Section 2: Hazard(s) Identification

Health Rating	Flammability Rating	Instability Rating	Special Rating	Signal Word
2	1	3	1	Signal Word!

HAZARD STATEMENT:
Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes

Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab

PRECAUTIONARY STATEMENT:
Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statemen

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16 Current Work Group Filtering

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Security Menu, Browse Users Option

Browse User Table

Browse Users
Users
Name
Login
Level
Initial Access
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abci
Supervisor
Supervisor
Carrie Haarberg
CBH
Operator
All Access
Customer Service Repres
CSR
Operator
All Access
Jeff Spira
JJS
Supervisor
Supervisor
Management Representat
mgtrep
Supervisor
Supervisor
My Assistant
MYA
Operator
All Access
Sam Wallis
SWB
Operator
All Access
User Groups
Support
Team 1
Team 2
Tearm 3
Insert
Change
Delete
A checkbox indicates the user is part of the user group
Close

User Form

(A) The Work Group field

In the image shown above is a numeric code, which is used to filter or limit the data on specific browse tables. One or more users may be assigned a Work Group code. Therefore, when users login with the a specific Work Group Code specific browse tables are designed to limit access to the records that have a matching Current Work Group (CWG) code.

The Browse Tables that support the CWG filtering are:

Customer Complaint Table

The CAPA Table

The Task Table

The Process KPI Table

For example, members of a Customer Service group may be assigned the Work Group code of '1234'. Therefore, any user in the Work Group '1234' that logs into QMSCAPA shall be limited to records in the Customer Complaints, CAPA, Task and KPI tables that have a Current Work Group (CWG) code of '1234'.

(B) Users Groups

User Groups are related to access and security settings. By setting the access rights of the group then any user that is assigned to the User Group will have the same security settings.

(C) Users Level

Three User Levels are possible. Supervisors by default are allowed all access. Operator access may be customized by the User Group or the individual.

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17 Customer Feed-back Log

QMSCAPA provides an option to *log customer complaints* separate from the CAPA log.

The Customer Feed-back Table includes the following sort options:

1. Complaint or Case Id number.
2. By Client Number
3. By Customer Name
4. By Complaint Type Code
5. By Part/Service Number
6. By Assigned To
7. By Due Date

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8. By Customer Status

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17.1 Copy Customer Feed-back to the CAPA Log

1) To *copy a customer complaint to the CAPA* log highlight the record to be copied.
2) Select the *Copy Complaint to CAPA button*.
3) When the copy has completed the confirmation window will appear. Click the *OK button* to close the window.
4) Use the *Print form button* to print the default complaint form.
5) Use the *Print log button* to print the default complaint log report.

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17.2 Copy the Customer Feed-back log to Excel

The **Copy to Excel button** on the Customer Complaint Table will copy every Complaint record that appears in the Complaint log to Excel.

Related Topics:

Customer Complaints Log
CAPA Log

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17.3 Customer Feed-back Form

1) The *Complaint Id Number* or *Case Number* is automatically generated.
2) The *Client Number and Client name fields* may be populated by the Customer look-up table .
3) The Complaint Type Code and Description may be populated by the Compliant Type look-up table.
4) Use the *Remarks field* to record important Customer comments.
5) Optionally you may record *part numbers/names.*
6) The complaint may be assigned to others with a target due date.
7) *Corrective Actions* may be recorded in the *Customer Complaint form*.
8) Use the *Complaint Status* and *Status Updated* fields to record the appropriate complaint stats.
9) The [ ] *Recorded in CAPA log checkbox* indicates the Customer Complaint was copied to the CAPA log or entered manually in the CAPA log. Customer complaints may be excluded from the Customer Complaint log report by un-checking [ ] *Include for Report Tally checkbox*.

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The image below shows additional fields added in a later version.

A. User defined Reference field.
B. Estimated and Actual Cost related to the Customer Complaint.

17.3.1 Complaint Reason Codes

Customer Complaint *reason codes* and the descriptions should be appropriate for the products and services of the organization.

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17.3.2 Auto-calculation of Due Dates

Complaint Type Form

To **auto-calculate the Customer Complaint Due Date** check the **Use Default for Due check-box** and enter the quantity of days that should be added to the **Date Reported for Customer Compliant**.

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17.4 Customer Feed-back Reports

1) The Customer Complaint reports and forms may be found in the Report Builder and Reports Menu.
2) To *print Customer Complaint reports* and forms select the appropriate report in the table and then click on the Print button.

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17.4.1 ComplaintLog01.rpt

Customer Complaint Log

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Customer Complaint Log
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Created From: 1/01/2012 Through 12/31/2012
Date Printed: 10/27/2012

Created	Case Id #	Customer Name	Type Code	Complaint Type	Due Date	Assigned	Status
10/25/2012	1	My New Customer	A	Product Not Working	10/31/2012	PA Completedby	Completed
Customer Remarks:		Record the customer remmarks.					
Corrective Actions:		Corrective action taken, all is well.					
10/27/2012	2	Customer Four	B	Shipment late	/ /		
Customer Remarks:		The customer complained about getting the product late.					
Corrective Actions:							
10/27/2012	3	Customer Number 5	A	Product Not Working	/ /	Trainer Two	Open
Customer Remarks:		Add some remarks made by your customer.					
Corrective Actions:							
10/27/2012	4	CUSTOMER 6	B	Shipment late	/ /		Open
Customer Remarks:		Customer was very unhappy.					
Corrective Actions:							
10/27/2012	5	9 CUSTOMER	C	Shipment short materials	/ /	*Not Assigned	Open
Customer Remarks:		Record your customer comments here.					
Corrective Actions:		You can copy and paste information from EMAIL MESSAGES too.					
		Use the F7 Key to check your spelling.					

Total Complaints Logged: 5

17.4.2 ComplaintLog02.rpt

Customer Complaint Log

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Customer Complaint Log By Type
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Created From: 1/01/2012 Through 12/31/2012
Date Printed: 10/27/2012

Created	Case Id #	Customer Name	Type Code	Complaint Type	Due Date	Assigned	Status
Complaint Type A, Product Not Working							
10/25/2012	1	My New Customer	A	Product Not Working	10/31/2012	PA Completedby	Completed
Customer Remarks:	Record the customer remmarks.						
Corrective Actions:	Corrective action taken, all is well.						
10/27/2012	3	Customer Number 5	A	Product Not Working	/ /	Trainer Two	Open
Customer Remarks:	Add some remarks made by your customer.						
Corrective Actions:							
						Subtotal Complaints By Type A: 2	
Complaint Type B, Shipment late							
10/27/2012	2	Customer Four	B	Shipment late	/ /		
Customer Remarks:	The customer complained about getting the product late.						
Corrective Actions:							
10/27/2012	4	CUSTOMER 6	B	Shipment late	/ /		Open
Customer Remarks:	Customer was very unhappy.						
Corrective Actions:							
						Subtotal Complaints By Type B: 2	
Complaint Type C, Shipment short materials							

17.4.3 ComplaintForm01.rpt

Customer Complaint Form

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Customer Complaint Forr
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Date Printed: 10/27/2012

Customer Name	Report Date	Create Date	Due Date	Case Number
9 CUSTOMER	10/27/201	10/27/201	/	5

COMPLAINT TYPE: C, Shipment short materials
PART NUMBER: *

CUSTOMER REMARKS: Record your customer comments here.

You can copy and paste information from EMAIL MESSAGES too.

Use the F7 Key to check your spelling.

CORRECTIVE ACTION:

17.5 Customer Feed-back Chart

QMSCAPA™ Quality Management Software provides an option to make a graphical chart for customer feed-back.

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18 Customer Survey Table

Customer Satisfaction Surveys may be directly accessed from the Customer Form.

Customer Table Menu Option

Customer Survey Browse Table

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18.1 Customer Survey Sets

Menu Option for Customer Satisfaction Survey Sets

QMSCAPA includes a tool for designing and executing Customer Satisfaction Survey. The survey results may be linked directly to the Customer record.

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Browse Table Customer Satisfaction Survey Sets

Form Customer Satisfaction Survey Sets

18.2 Copy Customer Satisfaction Survey Records to Excel

Menu Option

The Customer Survey Browse Table file may be copied to an Excel file.

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19 Customer Table

The QMSCAPA **Customer Table** may be accessed from the Edit Tables > Customer Table option.

A. The *top row of tabs* provide an instant sort on each field when selected.
B. The some *tabs* include a search tool to assist with the location of specific records.

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Related Topic: Customer Edit Form

19.1 Customer Edit Form

1) Customer Location and Contract Information tab

A. The Customer may be identified with a unique 'Record Name', and Account Number and Company Name.
B. The **Customer Type** is intended to provide a method for classifying customers into groups.
C. The 'Bill To' City, State and Zip Code fields may be automatically formatted on the address line 3 or on line 4 by clicking on the **Format Bill to button**.
D. Click on the **Copy to Ship to button to copy** the *Bill to Address fields* to the *Ship to Address fields*.
E. The 'ShipTo' City, State and Zip Code fields may be automatically formatted on the address line 3 or on line 4 by clicking on the **Format Ship to button**.
F. The 2) Surveys tab contains the results of recorded customer satisfaction surveys.

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2) Survey tab

A. The Comment field is intended for information about Customer Satisfaction Surveys in progress.
B. Select ***Quality Targets*** from the Quality Targets Table
C. Click on the **Add Survey button** to add a Survey for the current customer record.

19.2 Customer Reports

A) The ***CS/OTD (1) button*** prints the Customer Satisfaction (CS) and On-time Delivery report for one customer according to the Customer Id# entered or selected by the highlight bar.
B) The ***CS/OTD (all) button*** prints the CS/OTD report for all customers that have CS/OTD records entered. In this report each new customer record begins on a new page, which allows all CS/OTD records to be printed at once.
C) The CS/OTD List button prints the CS/OTD report for all customers that have CS/OTD records entered. In this report one or more customer records may appear on the same page.

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20 Dashboard for Monitoring Quality

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The Performance Dashboard for Monitoring Quality accumulates all of the management system measurements that are recorded in QMSCAPA.

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The **QMS Dashboard** consists of:

- ✓ The QMS Dashboard table, which is designed to capture quality measurements over a period of time. You can accumulate quality measurements on user-defined intervals. For example, you can record quality measurements monthly, quarterly, semi-annually or annually, among others.
- ✓ The QMS Dashboard form is a quality measurement calculator that provides a roll-up of data according to a user-defined date range.
- ✓ Any QMS Dashboard data can be easily printed simply by selecting the appropriate dashboard record in the QMS Dashboard Table.
- ✓ The QMS Dashboard may be configured according to user-defined settings in the Dashboard Label Sets.

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20.1 Performance Dashboard Table

The ***Performance Dashboard*** Table displays the Dashboard data in descending order by the 'Date Created'.

A. Section (A) in the Dashboard Table may contain records to represent a user defined period of time.
   1. One Year
   2. One Month

3. One Quarter

B. Section (B) shows the summary data for the selected or highlighted record.
C. The ***Copy Dashboard Record*** button (C) provides an easy means to copy an existing record. For example, you may need to create a Quality Monitoring record for the first quarter and later copy the first quarter for the second quarter and then only change the date range for the quality measurements.
D. Section (D) provides controls to add, edit or delete a record.
E. Section (E) contains shortcuts to add ***Performance Data*** to the Dashboard.

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20.2 Performance Dashboard Form & Calculator

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1) Choose a Label Set, which automatically populates the dashboard labels, the 'include QPV' settings, and the criteria for calculating on-time delivery settings.
2) The end-user can change the Labels on the Dashboard but not the formula of what must be calculated. The Q%V1, which means Quality Percentage Value # 1, always calculates Customer Satisfaction. Q%V2 always calculates on-time delivery. Q%V3 always calculates Mfg/Production quality. Q%V4 always calculates Purchasing quality. Q%V5 always calculates Sales quality.
3) Using the settings on the **Dashboard Label Sets** form window an end-user can select which quality metrics should be included on the dashboard.
4) Also, the criteria or formula for calculating on-time delivery is controlled by the **Dashboard Label Set** selected.

20.3 Performance Dashboard Label Sets

The QMS Dashboard Label Sets may be accessed from the File menu > Company Setup option menu.

(A) Criteria for On-Time Delivery controls the formula of how on-time delivery is calculated on the Dashboard.

- The check box SBD vs ASD means to calculate on-time delivery according to the Ship by Date (SBD) compared to the Actual Ship Date (ASD).
- The check box CDD vs ARD means to calculate on-time delivery according to the Customer Due Date (CDD) compared to the Actual Received Date (ARD).
- The check box Calc OTD means to only calculate the deliveries that were on-time and not early.
- The check box Calc OTD plus Early means to calculate the deliveries that were on-time, plus add the deliveries that were early.

(B) An end-user may edit the Dashboard calculator labels. However, the function of each calculator metric is fixed and may not be changed from its intended purpose.

(C) The check boxes with 'Include QPV # ...' determine whether or not the metric should be calculated on the Dashboard.

(D) Target Percentages for each metric may be set and activated for each '***Dashboard Label Set***'.

(E) The Over-all Performance Target Percent can be automatically averaged or entered.

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20.4 Performance Dashboard Report

1) To access the **Dashboard Print button** select View or Edit to open the Dashboard.
2) **Dashboard print button** may be used to print the highlighted or selected record in the QMS Dashboard report (sample shown below).

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Management System Dashboard Report v2

User-defined labels

2016 Quality Performance

				Goal/ Target %	Actual % of Achievement	Attainment %
Report Id Number:	1	Label Set:	1			
Start Date:	1/01/2016	End Date:	12/31/2016			
Author:	PYH	Date Printed:	4/24/2016			
Customer Satisfaction				96.50	97.50	101.04
On-Time Shipping				98.00	93.25	95.15
Product Conformity				99.00	100.00	101.01
Purchasing				100.00	100.00	100.00
Sales Order Processing				97.00	100.00	103.09

Continual Improvement

AVERAGE TARGET %	AVERAGE % OF ACHIEVEMENT	AVERAGE % OF ATTAINMENT
98.10	98.15	100.0

20.5 Performance Dashboard Chart

QMSCAPA provides an option to make a chart of the dashboard results.

Right-mouse-click in the image for additional options for copying, printing or saving the image.

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21 Documents Control Index

QMSCAPA provides a centralized database for recording controlled documents. The *Documents Control Index* is central depository for recording:

- Alpha & Numeric version codes
- Approval Journal
- Date Approved
- Date Created
- Date Effective
- Date Last Saved
- Date Revised
- Document Path and File Name
- Document Identification
- Document Type
- Document Title
- Revision History Journal

In the image below …

A. Section (A) of the browse table provides instant sort tabs by:
   (1) Document Id (user defined)
   (2) Document Title (user defined)
   (3) File Path Name where stored (user defined)
   (4) Department (user defined)
   (5) Status (user defined)

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(6) System Document Id (*Sys Doc Id*)
(7) Document Type (user defined)

B. Section (B) displays the *Revision History Journal* for the highlighted record in Section (A).
C. Section (C) displays the approval journal of the highlighted record in Section (B) of the *Revision History Journal record.*
D. The (D) **Copy to Excel button** creates a Microsoft Excel compatible file of the browse table.
E. The **Document Index button** prints the entire index.
F. The **Approval Journal button** prints the *Revision History Journal* that have an associated approval record.
G. The Add, Edit and Delete buttons are used to control records in the **Documents Control Index** table.

Related Topics:

[Electronic Document Deployment]

[Document Control Index Form]

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21.1 Adding a QMSCAPA Form to the DCI

Menu Option

Browse Logs > 4) Document Control Index

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Browse Table

Click on the **Add button** to enter a new document to the **DCI**.

Form

Enter the Report Builder File Name into the DCI form, which will allow the user to select the Report Form in the CAPA window.

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21.2 Approval of Documents

Each **Document Control Index Record** has a related table for the revision history and each revision history record has a related table of authorized approvals.

In the image shown below:

A. In section (A) the Document Control Index Table may be accessed from the Main Menu > Browse Logs > 4) Document Control Index.
B. In section (B) on the tab titled 3) Version History Log a table showing the Revision History displayed in descending date order.
C. In section (C) the Revision History Form and the Approval Journal is shown.
D. In section (D) the **Authorized Approval Form** is shown, which includes the use of **electronic signatures**.

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Related Topics:

- Electronic Document Deployment

- Document Approval Process

21.3 Document Version History

The document **Version Document History** may be accessed and edited by opening the Document Index Record.

In the image above ...

A. Move the scroll bar to the document record to be changed. The Document Index record will open with double mouse click or by clicking on the edit button.
B. The tab 1) User Defined Data contains fields for identifying documents. Use the fields appropriate for your use.
   I. The Version History contains revision history information.
C. The Document File Path may be used to catalog the location of the current or previous the documents.
D. If you elect to use PDFs for your released and approved documents, then you will be able to view those documents inside QMSCAPA.

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21.4 Copy Document Index to Excel

QMSCAPA provides a **Copy the Document Index** to Excel feature, which copies the browse table to an Excel file in the same sequence of data that appears in the browse table.

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21.5 Document Approval Process

Guidance for Document Approval

1) Open the Control of Document Index
   a) Main Menu > Browse Logs > **Document Control Index**
   b) Select a Record in the Document Control Index Table and click on the Edit button.

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2) When the Document Record is open for editing ...
   a) In the image below, the letter (A) positioned at ***Tab 2) Version Approval and History*** provides access to the document version history log and a log of approvals by persons whom are authorized documents.
   b) The letter (B) positioned at the Required Approval group box of the Job Titles/Organizational Chart Postion required to review and approved documents.
      i. The **Approved by Title field** is typically the person who has been authorized as the person responsible for making the final approval. Enter a specific Job Title for the final required approval.
   c) The letter (C) positioned the **Approval Requirements are VERIFIED checkbox** is intended to be used as a document approval inspection method to verify that the document approval process has been verified.

QMSCAPA v1.46.10

3) Select the **Version History Log** tab
   a) The upper table in section (A) displays the revision history.
   b) The lower table in section (B) displays the Authorized Approval Log.
   c) The **Document Revision Record** and the **Document Revision Approval Record** may be locked to prevent unintended changes to the records.

4) Document Revision Information and Authorized Approvals Form (shown below)
   a) A **document revision history record** may be locked to prevent any untended changes.
   b) The **Authorized Approvals** count is related to the Authorized Approval Log in section (E) shown in the image below.
   c) A **document revision history record** may be synchronized with the Document Control Index record.
   d) The field labeled as **'Required for Approval'** is the Job Title of the person for the minimal required approval.
   e) The **Authorized Approval log** is shown in section E.

5) Document Revision Approval Record Form
   a) The *authorized person for approval* should record a brief statement of their intent.
   b) The **Approved By field** indicates the authorized approval or authorized signer.
   c) The **Lock Record checkbox** provides the option to lock the approval record from unintended changes.

21.5.1 Electronic Document Approvals

Menu Option

- From the Easy Start menu ...

- From the Main Menu select > Browse Logs > Approve Documents in the Index

Browse Table

1) As shown in the image below select (highlight) the document for approval and click on the **Approve of Edit button.**
   a. Select the first or newest version history record and click on the **Add Approval button.**

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- The **Authorized Approval Record** (shown below) will open.

- Note: The table of Authorized Approvals may include other records by other authorizations for the same document version.
- Click on the **+Approval button** to enter your **electronic signature.**
- The **Document Approval Record window** shall open as shown below.

A. The **electronic signature** may be entered or selected by clicking on the **Select E-signature button**.
B. The **Approved Date & Time** are automatically entered.
C. The **approving person** may **Lock the Approval Record**.

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21.6 Electronic Document Deployment

Concept for Control of Documents

The QMS documentation is made up of the following main components:

- QMS Document Control Index
- EMS Document Control Index
- QMS & EMS Documents

- QMS & EMS Forms
- QMS & EMS Journals & Logs
- QMS & EMS Manuals
- QMS & EMS Procedures
- QMS & EMS Work Instructions

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Document Naming Convention

The QMS & EMS documents are constructed as 'electronic or paper sections' with each having an electronic file name that matches the paper document title name. Example the QMS manual has an electronic file name of *422 Quality Manual v01* and a document title of Quality Management System Manual.

A working draft may be annotated with (draft #), e.g. *422 Quality Manual v01 (draft 1)*

- ### indicates a clause or element in the Standard that the document is directly related with;
- Descriptive name, indicates the intended purpose;
- V## indicates the revision (version number);
- (draft#) indicates a proposed draft under development or review;

An Optional trailing Date formatted as YRMONTHDAY, e.g. 130115 (January 15, 2013) may be used for the effective date, e.g. *422 Quality Manual v01 130115.*

QMS Document Control Index is a comphrehensive report made possible by printing the QMSCAPA Document Report.

Other Document Conventions

QMS/EMS Manual (QM/EM):
The QM top-level document section defines the company's Quality policies and Quality objectives; defines the scope of the Quality system, including details and justification for any exclusion. The QM describes the overall QMS, its processes, and their sequence and interaction; and references applicable operational procedures.

QMS/EMS Procedures (QP/EP):
QP's are second-level document section defining specific ISO 9001 & 14001 Quality system procedures. Quality procedures are code numbered QP-SSS. QP stands for Quality Procedure; SSS is the related section in the ISO 9001 & 14001 to which the procedure pertains.

QMS/EMS Documents (QD/ED)

QD's are third-level reference documents intended to provide a more in-depth explanation of QMS related subjects and topics. Quality documents are code number as QD-SSS. QP standards for Quality Document; SSS (if used) is the related section in the ISO 9001 & 14001 Standard.

QMS/EMS Forms (QF/EF):
QF's are fourth-level documents. These are usually one-page forms or matrices defining a "template" for establishing a record. Forms are code numbered USC-QF-SSS Long Name -v#, e.g. QF stands for Quality Form, SSS is the related ISO clause of the procedure to which the form pertains, and the long name is the common name of a form (document) pertaining to the same procedure. Forms are established as separate documents, but are associated with specific procedures, and work instructions through the numbering system.

QMS/EMS Journals or Logs (QJ,QL/EJ,EL)
Journals and Log are document names used interchangeably and considered to be fourth level forms and records. Journals and logs are intended to be perpetual or periodical records, which are usually in the form of a Microsoft Word or Excel document or another form of electronic data.

QMS/EMS Work Instructions (WI):
WI's are third-level documents. The purpose of work instructions is to guide personnel in performing specific tasks, such as carrying out and controlling a production processes (process operator instructions), handling products, calibrating measuring equipment, conducting tests or inspections, etc.

The following diagram is for QMS electronic file folder storage:

22 Documents Control Index Form

Document Control Management System

1) ***Tab 1 of the The Documents Control Index Form*** (see (A) in the image below) provides a record of the ***document description,*** which includes:
   a. QMSCAPA assigned **Sys Doc Id**
   b. User defined document Id
   c. Current Revision Date
   d. Last Date Approved
   e. Effective Date

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f. User defined Document Title
g. *File Path* to where the document may be stored electronically
h. Document approval requirements

2) ***Tab 2 Version Approval and History*** provides access to the document version history log and a log of approvals by persons whom are authorized documents.
3) ***Tab 3 Document Text Editor*** provides access to the QMSCAPA built-in *document generator and text editor.*
4) ***Tab 4 Options*** provides access to additional document control options.

QMSCAPA v1.46.10

In the image above ...

A. The letter (A) positioned at the Tab row provides access to various document control options.
B. The letter (B) positioned at the Required Approval group box of the Job Titles/Organizational Chart Postion required to review and approved documents.
   i. The **Approved by Title field** is typically the person who has been authorized as the person responsible for making the final approval. Enter a specific Job Title for the final required approval.
C. The letter (C) with pointing arrows to
   1. the quantity of ***Approvals Required*** (tally of the ☑ Required Approvals group check-boxes)
   2. quantity of approvals by ***E-Signature*** in the ***Version Approval and History Log***
   3. ***quantity of approvals verified*** by a QMSCAPA user

D. **Approval Requirements are VERIFIED checkbox** is intended to be used as a document approval inspection method to verify that the document approval process has been verified. The ***Date Approved*** (if blank) shall be automatically set to the current date when the ☑ Approval Requirements Verified check-box is checked and the Approvals Required equals the ***Approvals Completed*** and the ***quantity of approvals Verified***.

User Tips:

- Press and hold the **Ctrl** key **+** the **F10** key to ***edit Org Chart Position text***. (See Edit the window field names)
- The ***Document File Path field*** may contain any file type (opening application must be installed on the users computer or server), includes web pages, Word docs, PDF and RTF.
- The ***Document Status field*** is used to report the document status when the QMSCAPA Document Generator is used to create the document and printed.
- The ***Document Comments field*** is intended for unique guidance about the document and may be printed if needed.

Related Topics:

Document Management Table

Document Management Editor

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☑ ISO 9001:2015 Implementation & Templates Kit

22.1 Document Approval and Revision History

Document Control Index Menu Option

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Document Control Index Browse Table

Document Control Index Form

22.2 Locking a Document Control Index Record

The Document Control Index Form 4) Options tab contains a check box to **Lock an Index Record to Prevent Deletion**.

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22.3 Synchronized Current Revision Dates

Document Control Index Form: Tab 3) Version History Log

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(A) The Current Revision Date in the Document Index may be synchronized (Sync) with the Revision Date in the Revision History Log. First enter the Current Revision Date and click on the checkbox ☑ Sync Current Revision Date with History Log.

(B) Only the last entry or most recent entry in the Version History Log is synchronized with the Current Revision Date on the Index Record.

(C) The section shows the full snippet of information that describes the document changes.

23 Document Management Table

The ***Document Management Table*** is designed for use as ***document segments*** or ***document paragraphs*** or a collection of paragraphs.

1) The Document segment ***Sequence in Document*** field is a user-definable field to allow precise placement within the Document.
2) The Document ***Heading for Text field*** is intended as a quick reference of the document content.

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3) Each Document segment may contain an optional Trailing Image.
4) The ***Document RTF controls*** may be used for font selection, color, attributes and size variations.
5) The ***Print RTF Document button*** prints all segments of the currently displayed document.

Related Topics:

Document Management Editor

☑ AS9100 D Implementation & Templates Kit

☑ ISO 9001:2015 Implementation & Templates Kit

23.1 Document Management Editor

1) The Head for Text field is used for easy reference.
2) The Rich Text File (RTF) controls mimic the Microsoft Windows Wordpad application.
3) The Document Management Editor supports direct typing, pasting text form other applications or importing text from an existing RTF compatible document.
4) Each document segment may have an optional ***Trailing Image*** as shown in the Tab 2) Trailing Image.
5) Print the Heading Text [Check box]

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23.2 Print the Heading Text

☑ Print the Heading Text Field

The ***Print the Heading check box*** option provides a method to print the Heading Text. Otherwise s*egment, section and paragraph headings* may be put in the TEXT field with RICH TEXT attributes for font, size and color.

Alternately, the *segment, section and paragraph headings* may be added to the **HEADING FOR TEXT** field.

24 Easy Start Menu

QMSCAPA Menu Option(s)

Ctrl+Shift+m opens the Easy Start Menu

Auto open the Easy Start Menu upon start-up may be set by a Enable Easy Start Menu [√] checkbox in the Company Setup module or the Easy Start Menu option [√] checkbox in the Employee/User Profile.

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24.1 Default Setting for Easy Start Menu

QMSCAPA Menu Option(s)

Ctrl+Shift+m opens the Easy Start Menu

The **Easy Start Menu** may be set to open at start-up inside the Company Default settings.

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25 Edit Menu Names

QMSCAPA has a built-in feature to allow a user to edit the **Menu Names** for support of alternate languages and vocabulary.

This feature allows a user to change the text in **QMSCAPA** Menu Name during use, including:

- All visible text
- Window Captions, Prompts
- Buttons and so on can be translated.

Translating a Window Text

1) Open Main Menu that QMSCAPA displays at start-up; all other windows should be closed.
2) Press the **Ctrl+F10 Key** to open the Translation Window.
3) The Translation Window opens as shown below:

The QMSCAPA **Menu Names** may be edit by using the

(A) The original Menu Names appear in alphabetical order (sans &);

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(B) Changes that appear in the Global Translation column will appear through the whole application;
(C) Changes that appear in the Local Translation column remain local to the current window.
(D) The Type column confirms the location in a Menu, Window or Other control.

26 Edit the Window Field Names

QMSCAPA has a built-in feature to allow a user to edit the field prompts for support of alternate languages and vocabulary.

This feature allows a user to change the text in **QMSCAPA** during use, including:

- All visible text
- Buttons and so on can be translated.
- Menu Name options.
- Window Captions, Prompts

Translating a Window Text

1) Open a window to be translated

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2) Press the **Ctrl+F10 Key** to open the Translation Window.
3) The Translation Window opens as shown below:

1) Column 1 shows the QMSCAPA standard text.
2) Column 2 is an edit in place field for the Global Translation. Translations entered into the Global Translation column will appear in every window with that uses the same standard text.
3) Column 3 is an edit in place field for the Local Translation. Translations entered into the Local Translation column will appear only in the current active window.
4) To add a translation click into the appropriate column field and type directly into the space. Saving is automatic once another field is selected or the **Close button** is clicked.
5) The Type column confirms the text phrase is related to a Menu, Window or Other control.

27 Email Assistant

QMSCAPA provides a feature to copy a summary of an ALERT MESSAGE from Customer Complaints, CAPA Request and Non-conformance to the default Email client program.

Look for the **Email button** to launch the **Email Assistant**.

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Available in the following modules:

- ✓ Alert Messages for Initiatives, and Non-conformance
- ✓ Corrective or Preventive Action Request
- ✓ Customer Complaints

The **Email button** launches the **Email Assistant window**:

A. The Assigned to Name is derived from the person assigned to the CAPA, Customer Complaint or Alert Message.
B. The Subject is derived from the contents found in the respective record (Customer Feed-back, AIM-Non-Conformance or CAPA).
C. The Email Assistant will search for an available email address by going through the following progression:
    1. The email address recorded with the employee record of the person that is assigned to handle Alert.
    2. The email address recorded with the Department.
    3. The email address recorded as the QMSCAPA user Company group email address.

D. The *Email construct* is placed into the Windows Clipboard when ***Click here to Copy to the Clipboard... button*** or the ***Launch Email Client button*** or clicked.

E. The button, Launch Email Client calls the Windows User's default Email Client. If you are using a web-based client then the specific window may not open. Once you have navigated to the appropriate window for you web-based Email then you may paste (Ctrl+V) the Email construct into the Email body area.

F.

Related Topics:

- Excel Output
- HTML Output

28 Excel Files from Reports

Output Option

Many QMSCAPA reports provide an option to save the reported data as an Excel compatible file.

During the standard print execution the Excel option appears as an ' ***XLS Icon*** '

To save the file as an Excel Workbook click on the XLS Icon and the **OK button**.

✓ Before saving the report may be previewed
✓ After saving the report may opened

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Use the Standard print controls to initiate the save as an Excel file.

(A) Navigate to location to store Excel Output.
(B) Click on the appropriate folder to open the location.
(C) Enter an Excel compatible file name, e.g. ' myexceloutput.xlsx '

When the Print Control is used a dialog window for the Save XLS file opens

29 HTML Output from Reports

Many QMSCAPA reports have an option to output *HTML files.*

User Tip:

1. Select the HTML icon to redirect the output away from the printer and ***save as*** an HTML file.
2. Use the standard Print menu options and icons to open the naviagtion window to ***save as*** an HTML file.

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3. If appropriate, select a shared Public location that can be accessed by others.

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Related Topics:

- Excel Output
- Email Assistant

30 Human Resources

The Human Resources table may be accessed from the Edit Tables *main menu option* or the icon menu bar.

The Employee or Human Resource form:

A. The 1) Profile tab describes the person, and the relationship to the organization. Use the 'attachment' field for professional (CV) data.
B. The 2) Additional Attachments are for documents related to the person.
C. The 3) Security Access tab is for areas and information that the person is authorized to access.

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D. The 4) Training Required +Completed tab is a listing of training programs that the person was scheduled and, or completed.
E. The 5) E-signature tab contains an option to generate a unique *electronic signature* and/or attach a *graphical image of a signature*.
F. The 6) User Profile tab contains a folder preference for saving temporary PDFs generated by the QMSCPA user, login code and module start-up options upon login by the user.

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Related Topics:

- Electronic Signatures
- Security Access Table
- Training Required +Completed
- User Profile options

30.1 Electronic Signatures

QMSCAPA provides support for electronic signatures, which may include ...

- Unique identifier
- Public Key (encryption key)
- Graphical Image (signature, stamp, 2D or 3D bar codes)

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In the image above ...

(A) The check-box **Auto assign electronic signature**, when checked, combines the name initials with the **employee identification number** to form a ***unique electronic signature***.

(B) The Electronic Signature may also hold an Public Key (the Private Key is only known to the signer).

(C) Check the **Authorized Signer check-box** if the person is authorized to sign records or other documents. Only Authorized personnel shall appear in the authorized approval look-up table when approving records.

(D) The Signature Image Path field provides a link to *graphical image* (signature, stamp, 2D or 3D bar codes).

Tags: quality management software, corrective action software, iso management software

30.2 Security Access Table

Menu Option

A) The Company Security Aspects and the Security Access for each affiliated person may be accessed through the ...

1)Main Menu > File option
2)Company Setup >
3)Company Security Access Table
4)Company Security Aspects Table

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Security Access Browse Table

The **Security Access Table** displays the Security Aspects associated with each affiliated person.

In the image shown below ....

A)The Security Access for each affiliate person must be address through the Human Resources Table.
B)The Security Access controls allow for Editing and Deletions.
C)The Security Access for each affiliated person may be printed by clicking on the **Access List print button**.

Tags: quality management software, corrective action software, iso management software

30.3 Training Required +Completed

Human Resource Training records for specific employees may be accessed directly in the employee form.

Also, the *Show Required Training for Job Title button* provides access to a table of the *Training Programs that are required by Job Title*.

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Tags: quality management software, corrective action software, iso management software, training records software

30.4 User Profile Options

Employee Edit Form

A. The User Profile options are only applicable to QMSCAPA System Users.
B. The *profile folder* is a Windows File System folder that is set to users preference for storing permanent or temporary PDF documents.
C. The ***User Login field*** is protected and can only be entered by selecting the Login Code from the User Security Table.
D. There are currently two options to start modules, 1) Show Task List at Login and 2) Show Easy Start Menu at Login. When these checkbox options are checked the respective module is launched for the user once the login has been completed.

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31 Information Flow

Key information from external and internal communications flows through the **QMSCAPA** relational databases and into the CAPA log, including ...

- Action Task List
- Alert, Initiatives, Messages and Non-Conformance Reports
- Customer Complaints
- Findings from Internal Audits

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32 Internal Auditing for Quality

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QMSCAPA can support the **Internal Audit Plan** of one or more Systems (ISO Standards).

Each **element** may have one or more **auditor records**, or entries into the **audit log or Audit Results table.**

Related Topics

- Audit Plans
- Audit Plan Relationships to Audit Elements (or Processes) and Audit Results
- Audit Plan File Relationships
- Audit Schedule

32.1 Audit Plans

Audit Plans are the top level of Audit Schedules, which provides a process of grouping Audit Schedule elements into a single Standard and, or Year. Therefore, if an Audit Plan is copied then all of the Audit Schedule records are copied into a new Audit Plan.

1) In the image below, Section (1) shows a browse table of Audit Plans.
2) Section (2) refers to the button [Edit/View ISO Audit Schedule], which opens to the detailed Audit Schedule.
3) Section (3) displays the step that are needed to *make a copy of an Audit Plan* and Audit Schedule.

To *copy an Audit Schedule*:

1. In Section (1) of the image below highlight the Audit Plan that you intend to copy.
2. Enter the appropriate System name that you wish to appear in the new Audit Plan and Schedule.
3. Enter the year for the new Audit Plan and Schedule
4. Click on the button [3rd Perform Copy].

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Audit Plan Window Form

1) The Plan Id field is automatically numbered.
2) The Plan Year may be edited when an *Audit Plan is Copied* for a following year.
3) Use the Name & Description field to describe the Audit Plan.

32.1.1 Audit Plan Relationships to Elements & Audit Results

Preparing for an Audit of an ISO Management System

The image below shows the relations ship of the Audit Plan to the Audit Elements (or Processes) and the Audit Results that are directly linked to the Audit Element.

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32.1.2 Audit Plan File Relationships

Planning an Audit of an ISO Management System

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The Database File Structure provides support for:

- Unlimited Audit Plans
  - Unlimited Audit Elements or Processes per Audit Plan
    - Unlimited Audit Results per Audit Element or Process

Main Menu > Browse Logs > 5) Internal Audit Plan

In the image below ...

1) Click on the **Edit/View Audit Schedule button**.

Tags: quality management software, corrective action software, iso management software

32.2 Audit Schedule

1) Multiple Systems or Standards are supported.
2) An unlimited number of elements to be audited may be added.
3) A schedule over multiple years is supported.

The window image above shows the **Audit Schedule** in the upper table and the **Audit Log** in the lower table.

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32.2.1 Audit Schedule Printing Options

Additional Audit Schedule Printing Options may be found in the Report Builder Table.

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32.2.2 On Screen Audit Schedule

The **on screen audit schedule** shows the System, Element, Audit Year and Audit Month.

You may enter Processes to be audited and the Clauses to various Standards.

System	Element For Audit	Audit Year	January	February	March	April	May	June	July	August	September	October	November	December	Schedule
ISO 9001	4.1 General RequirementsHas your organizatior	2012	X				X		X				X		
ISO 9001	4.2 Document Requirements	2012	X			X			X			X			
ISO 9001	4.2.3 Control of Documents	2012		X			X			X			X		
ISO 9001	4.2.4 Control of Quality Records	2012		X	.		X	.		X			X		
ISO 9001	5.0 Management Responsibility	2012													
ISO 9001	5.2 Customer Focus	2012			X			X			X			X	
ISO 9001	5.3 Quality Policy	2012	X			X			X			X			
ISO 9001	5.4.1 Quality Objectives	2012			X			X			X			X	
ISO 9001	5.4.2 QMS Planning	2012		X			X			X			X		
ISO 9001	5.5.1Responsibility and Authority	2012							X	.	.	.			
ISO 9001	5.5.2 Management Representative	2012	X						X						
ISO 9001	5.5.3 Internal communication	2012			X							X			
ISO 9001	5.6 Management Review	2012													
ISO 9001	5.6.2 Review Input	2012													
ISO 9001	5.6.3 Review Output	2012												X	
ISO 9001	5.6.3 Review Output	2012													
ISO 9001	6.0 Resource Management	2012													
ISO 9001	6.2.1 Human Resources-General	2012													
ISO 9001	6.2.2 Competence Awareness and Training	2012					X								
ISO 9001	6.3 Infrastructure	2012						X							
ISO 9001	6.4 Work Environment	2012								X					
ISO 9001	7.0 Product Realization	2012													
ISO 9001	7.2 Customer-Related Processes	2012													
ISO 9001	7.2.2 Review of Requirements Related to the F	2012								X					

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32.2.3 On Screen Audit Results

The **Audit Table displays** on-screen the **Audit Results Log**.

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32.2.4 Printing an Audit Schedule

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32.2.5 Sample Audit Schedule

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Audit Schedule by Selected System

ISO 9001 Quality Management System

ELEMENT	JAN	FEB	MAR	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
4.1 General RequirementsHas your organization established a management system (QMS) giving consideration to:a)Identifying the proces												
	X				X		X				X	
4.2 Document Requirements												
	X			X			X			X		
4.2.3 Control of Documents												
		X			X			X			X	
4.2.4 Control of Quality Records												
		X	-		X	-		X			X	
5.0 Management Responsibility												
5.2 Customer Focus												
			X			X			X			X
5.3 Quality Policy												
	X			X			X			X		
5.4.1 Quality Objectives												
			X			X			X			X
5.4.2 QMS Planning												
		X			X			X			X	
5.5.1Responsibility and Authority												
							X	-	-	-		
5.5.2 Management Representative												
	X						X					
5.5.3 Internal communication												
			X							X		
5.6 Management Review												
5.6.2 Review Input												
5.6.3 Review Output												
												X
6.0 Resource Management												
6.2 1 Human Resources-General												
6.2.2 Competence Awareness and Training												
					X							
6.3 Infrastructure												
						X						
6.4 Work Environment												
								X				

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33 Job Titles & Training Requirements

Menu Option

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Browse Table

A. The Job Titles table is sorted in alphabetical order.
B. The Job Titles table Add, Edit and Delete controls.
C. Job Titles +Training Requirements report

Form

A. The Job Titles table is sorted in alphabetical order.
B. The Job Titles form contains a Tab to access the Job Training Requirements.
C. Training Requirements form links to the Training Programs.

Related Topics

- Training Required +Completed

Tags: quality management software, corrective action software, iso management software

34 Login and Security Settings

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About Security

Security will always be a balancing act. The opposite of security is convenience, foolproof security is almost impossibly inconvenient, while simplifying it almost always leads to lower levels of security.

When a user is created in QMSCAPA they can be classified into one of 3 possible Levels. The level with all the power is called a Supervisor. The Level with no power (in fact they will be denied access) is called No Access. In between, where a user has potentially limited power, they are allocated a Level called Operator. The difference between a Supervisor, and an Operator is obviously a significant one. Simply put, a Supervisor is allowed to change the security access rights of other Users. An Operator can not change either their own, or anyone else's, Access rights.
QMSCAPA may be distributed without its Security option enabled. When the Security option is enabled and the program is run the User is asked to enter a Login and a Password. A User's information is made up of a First Name, Last Name and Login code. When you first add a user the Password is automatically set to be the same as the Login code. After you have finished entering the first user, then you can use the Login, and Password (which will be the same at this point) to log in.

Three things must be done to implement security in QMSCAPA.

1. First, set up your user groups. Take some time to organize groups of users by department or job function.
2. Second, add your users. Assign every user a Login and Password.

3. Third, define screen access levels.

Related topics:

Browse User Security
First User

34.1 User Security Options

CAUTION: This feature should only be used by a System Manager.

Open the User Security Browse Table.

The User Security edit window allows specific security settings for Supervisors and Operators.

Open the Security Setting Access Control window to adjust specific access of Window Controls.

Select the [User Security] button control. The User Security window will open. At the bottom of this screen, press the button labeled User Group Details. You will see a list box, probably empty, so press the Insert button. You will see a form that asks for a User group name, and default access. Type in the name of the new user group and select "All Access" for the default access. Leave the Level set to Operator. The next User Group you enter will allow you to select a previously defined user group for a default access. User groups can inherit other user groups access privileges.

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User Group Details
The Operator Browse screen is on the QMSCAPA Update User screen in the Company/Vendor section. Any Supervisor can add new Users using these built-in Operator Browse and Form Screens. On the Form are the following fields;

First name & Last name: These apply to the Operator.

Login: This is the Login Code the user will use to identify himself to the system. Note that the Supervisor cannot set the Password QMSCAPA for the user. The Password for QMSCAPA will default to be the same as the Login Code, after that only the user can change it.

Level: Set the User to be either another Supervisor, and Operator, or a User with No Access to this Area.

Default Access: If the User is an Operator, then you can set their Default Access. this is typically either All Access, or No Access, but it can also be set to the Login code of another Operator. In that case the new Operator will assume all the current Screen Security settings of the selected Default Access Operator.

User Group: If the User is an Operator, then he can belong to a pre-defined User Group. For complete information on what User Groups are, read the section in this guide entitled Setting-up User Groups>Main.

35 Management Systems Table

Management System Standard Menu Option

The ***Management Systems and Clauses*** may be accessed through the Edit Tables menu option.

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Management System Standard Browse Table

The browse table contains three sort tabs for the 1) Standard by System Name, an 2) ISO System Id number (internal to QMSCAPA) and 3) ***Create Audit Plan and Checklist***. Therefore, once the Management System Standard has been entered into the Table it can be copied into an Audit Plan for a particular year.

Management System Standard Form

(A) The upper portion of the form is used to identify the Management System Standard.

(B) The browse table in the form contains Clauses and Elements found in the Standard.

(C) This section shows additional information about each Clause and element.

Enter topic text here.

35.1 Copying Management Standard Clauses

Menu Option to ISO Management Systems

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QMSCAPA
File
Edit Tables
Browse Logs
Quality Measurements
Reports
Windc
Cut
Copy
Paste
1) CAPA Task List
2) Feed-back Codes
3) Customer Table
4) Customer Survey Question Sets
5) Department Names
6) Human Resources
7) Inspection Checklist
8) Monitoring + Measuring Devices
9) Process Names and Descriptions
Label Sets
Job Titles and Training Requirements
Management System Controls
Management System Names of (ISO) Standard Table
Products and Services
Risk Assessment Tools
Transportation Carriers
User Defined Fields and Labels for QC Fields
Vendor /Supplier Survey Questionnaires
Vendor /Supplier Table
w) Vendor Criteria Evaluation Sets
x) Vendor /Supplier Evaluations

Browse Table for ISO Management Systems

To copy an existing ISO Standard Management System clauses first click on the **Copy Standard button**.

The Window with refresh and display the **Copy Highlighted Standard button**.

Next, Select an existing Standard to be copied and click on the button [**Copy Highlighted Standard System**].

Tags: quality management software, corrective action software, iso management software

36 Monitoring and Measurement Device Table

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The Monitoring and Measurement Device Table provides extensive support for device inventory and calibration and/or maintenance dates.

36.1 Calibration and Maintenance Journal

The **Calibration and Maintenance Journal** may be accessed from the Monitoring & Measuring Device Form.

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The Reschedule Selected button, as shown in the image below, will copy the selected record as a new schedule record for Calibration or Maintenance.

The Reschedule button becomes active when the highlighted record has a Completion Date and a Next Date is entered.

36.2 Form for the Calibration and Maintenance Journal

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(A) The Calibration or Maintenance Record includes information for scheduling dates, completion dates, who performed the actions, results of the activities and the final status, along with a rescheduling or next event date.

2) Calibration Description and 3) Maintenance Description tabs may be used to record additional calibration and maintenance requirements or notes from the activities.

(B) Calibration and Maintenance records my coexist in the journal.

(C) Optionally the Refresh Result Text check-box can assist with auto-populating the Calibration/Maintenance Results field.

(D) The Status field contains common phrases for calibration and maintenance activities.

(E) The Next Schedule Date is computed based upon the Completion Date field + the Interval Days field recorded in the Calibration Frequency field and Maintenance Frequency field of the M&M Device form.

36.3 Lookup Tables for M & M Devices

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Add the Monitoring and Measurement Device Look-up Tables to normalize your database information:

a) Brand table
b) Calibration & maintenance frequency table
c) Calibration standards table
d) Device types
e) Device location names
f) Device owners
g) Device status

36.4 M&M Device Scheduling Aids

The Monitoring and Measuring Device form includes fields for **Calibration Frequency** and **Maintenance Frequency**. Both fields have look-up validation tables. Each entry in the look-up table contains an option for intervals in day. Therefore, when a calibration or maintenance record is entered into the Calibration and Maintenance Journal the 'next date to schedule' may be automatically calculated.

The above form was update in QMSCAPA v1.29.x

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36.5 M&M Device Reports

The Monitoring and Measurement Devices module includes important several important reports for planning, scheduling and recording calibrations and maintenance.

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The above form was update in QMSCAPA v1.29.x

The Monitoring and Measuring Device form includes fields for **Calibration Frequency** and **Maintenance Frequency**. Both fields have look-up validation tables. Each entry in the look-up table contains an option for intervals in day. Therefore, when a calibration or maintenance record is entered into the Calibration and Maintenance Journal the 'next date to schedule' may be automatically calculated.

37 Objectives and Controls

Menu Option for ISO Objectives and Controls

Edit Tables > Management System Controls

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Browse Table for ISO Objectives and Controls

A. Add, Edit or Delete associated documents of the control.
B. Print a Statement of Applicabilitiy
C. Add, Edit or Delete a Section Id, Objective or a Control record.

Form for ISO Objectives and Controls

A. The 1) General Tab tab contains the Objective Description.
B. The 2) Control Descriptions tab contains the Control Description.
C. The 3) Justification for Exclusions tab contains the Justification for excluding the control.

Tags: quality management software, corrective action software, iso management software, ISO 27001 Statement of Applicability

37.1 Statement of Applicability Reports

The Statement of Applicability (SoA) is a central, mandatory part of the ISO 27001 standard for implementing an Information Security Management Systems.

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Statement of Applicability

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ISO 27001

A.05 Information security policies

A.05.1 Management direction for information security

Objective: To provide management direction and support for information security in accordance with business requirements and relevant laws and regulations.

A.05.1.1 Policies for information security

☐ Applicable ☐ Client ☐ Regulatory ☐ Stakeholders

Responsible: Job Title
Control: A set of policies for information security shall be defined, approved by management, published and communicated to employees and relevant external parties.

Risk Assessment Completed? No 0
Justification: Justification for EXCLUSION has not been written.

A.05.1.2 Review of the policies for information security

☐ Applicable ☐ Client ☐ Regulatory ☐ Stakeholders

Responsible:
Control: The policies for information security shall be reviewed at planned intervals or if significant changes occur to ensure their continuing suitability, adequacy and effectiveness.

Risk Assessment Completed? No 0
Justification: Justification for EXCLUSION has not been written.

A.06 Organization of information security

A.06.1 Internal organization

Objective: To establish a management framework to initiate and control the implementation and operation of information security within the organization.

A.06.1.1 Information security roles & responsibilities

☐ Applicable ☐ Client ☐ Regulatory ☐ Stakeholders

Responsible:
Control: All information security responsibilities shall be defined and allocated.

Risk Assessment Completed? No 0
Justification: Justification for EXCLUSION has not been written.

A.06.1.2 Segregation of duties

☐ Applicable ☐ Client ☐ Regulatory ☐ Stakeholders

Responsible:
Control: Conflicting duties and areas of responsibility shall be segregated to reduce opportunities for unauthorized or unintentional modification or misuse of the organization's assets.

Risk Assessment Completed? No 0

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Tags: quality management software, corrective action software, iso management software

38 Other Locations

The other locations table is intended to identify multiple locations of the organization. This table is related to the QMSCAPA Company file.

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Menu Option

The Other Locations Table may be accessed from the Company Setup menu. The Other Locations may also be referred to as the Ship To address.

Browse Other Locations Table

Form for Other Locations

39 Preventive Actions

(CAPA) Corrective Action & Preventive Action Browse Table

Access the *Preventive Action log* from the Main Menu > Browse Logs > 1) CAPA Log

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In the *CAPA browse table* image above ...

A. Preventive Actions are combined into the Corrective Actions log or *CAPA log*.
B. Use the Add button to open the CAPA form and *add a Preventive Action* or Corrective Action.

(CAPA) Corrective Action & Preventive Action Form, Tab 1) Incident or Non-Conformity and Cause

In the *CAPA form Tab 1*) image above ...

A. For a Preventive Action, record the Statement of Concern into the field for *Statement of Concerns*.
B. Typically Preventive Actions do not require a Statement of Cause.
C. If you wish to *print a Preventive Action record* using a *specific form for Preventive Actions* then you can select or designate a form listed in the Control of Documents module and index.

(CAPA) Corrective Action & Preventive Action Form, Tab 3) *Preventive Action* and Review

In the *CAPA form Tab 3)* image above ...

A. For a Preventive Action, record the Statement of Concern into the field for *Statement of Concerns* on the CAPA form, Tab 1).
B. On CAPA form, Tab 3) record the Solution for Preventive Action into the *Solution for Preventive Action field.* In addition, record the (PA) *Preventive Action Classification field*, which is linked to a user-defined look-up table.
C. For a Preventive Action, check the *Intended as a Preventive Action Record check-box field*.
D. Identify the person that completed the Preventive Action, date completed and essential attachments.
E. For a Preventive Action, record the appropriate proof of effectiveness, including the *Action Verified check-box* and *Action Effective check-box*.
F. Record the Management Review comments for the Preventive Action.
G. If you wish to *print a Preventive Action record* using a *specific form for Preventive Actions* then you can select or designate a form listed in the Control of Documents module and index.

Tags: quality management software, corrective action software, iso management software

40 Products and Services Module

Menu Option

The QMSCAPA ***Product and Services Module*** may accessed through the Edit Tables main menu option, which includes the following options in the module.

A. Chemical and Material Table - provides a database tool for environmental and safety documented information for management of Safety Data Sheets (OSHA SDS 16 Clauses).
B. Product Group Configurations - provides a database tool for product configuration management.
C. Product Group Names - Top level identification for Product Configurations and Products & Service items.
D. **Product and Services Table** - main database for products and services.

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Product & Services Browse Table

Product & Services Edit Form

Tags: quality management software, corrective action software, iso management software

40.1 Product & Services Browse Table

Menu Option

Main Menu > Edit Tables > Product and Services > Products and Services Table

Product Items & Services Browse Table

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Tags: quality management software, corrective action software, iso management software

40.2 Product & Services Edit Form

- Tab 1) Product and/or Services Name Form - Update form for Product Items and Services.
- Tab 2) Input Materials - Contains a browse table of chemicals and, or materials used in the product or to make or package the product.

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Tab 2) Input Materials

(A) The Chemical Browse Table may contain one or more records for chemicals and, or materials that are related to a Product Item.

(B) The Tally section shows:

1. Chemical related records.
2. Total percent of the chemical/material that make-up the product item.
3. Percent of the chemical/material used in or contained in the product item.
4. Percent of the chemical/material that may be re-used again to make other product items.
5. Percent of the chemical/material that may be recycled.

6. Percent of the chemical/material that is waste.

Product Items and Services Reports

Tags: quality management software, corrective action software, iso management software

40.3 Product & Services Reports

Reports for Product Items and Services may be initiated from the Product Items and Services Table or directly from the Report Builder Table of Forms and Reports.

Print Options in the Product Items and Services Table

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Tags: quality management software, corrective action software, iso management software

41 Product Configuration Groups

QMSCAPA ISO Management System software provides a simple method to aid configuration management and product life-cycle planning.

1) Product Groups - a product group may have many different Product Configurations
   a) Product Configurations - a product configuration may contain many different items. An item may exist in many different configurations.
      i) Product Items in a Configuration - Items may contain many *chemicals and materials*. A chemical or material may exist in many different items.
      ii) Chemical or material - Chemical or material are identified by Chemical Abstracts Service Source Index Identifier and Product Identifier.

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In the image above:

1) Product Group Configurations - use this menu option to access the Product Group Configuration table.
2) Product Group Names - use this menu option to add, edit or delete Product Group Names.

Tags: quality management software, corrective action software, iso management software

41.1 Product Configuration Management Method

QMSCAPA ISO Management System software provides a simple method to aid configuration management and product life-cycle planning.

1) Product Groups - a product group may have many different Product Configurations
   a) Product Configurations - a product configuration may contain many different items. An item may exist in many different configurations.
      i) Product Items in a Configuration - Items may contain many *chemicals and materials*. A chemical or material may exist in many different items.
      ii) Chemical or material - Chemical or material are identified by Chemical Abstracts Service Source Index Identifier and Product Identifier.

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QMSCAPA Product Configuration Management Method
Product Groups
Groups are 1 to Many
Product Configurations
Examples of Groups:
1) Consumable Products
2) Durable Products
Product Configurations
Configurations are 1 to Many
Items:
Examples of Configurations:
1) Assembled electric motor
2) Automobile Transmission
3) Bottle of hand-lotion
Items are Many to Many Chemicals / Materials
Examples of Items:
1) Rotor used in electric motors
2) Gear used in a Transmission
3) Bottle cap used in a bottle of hand-location
Items in the Configuration
Chemicals & Materials in Items
Examples of Chemicals & Materials in Items:
1) Copper in the rotor wrap
2) Vanadium in the gear
3) Polypropylene in the bottle cap

41.2 Product Group Names

Menu Option

Main Menu > Edit Tables > Product and Services > Product Group Names

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Browse Table and Form

Tags: quality management software, corrective action software, iso management software

41.3 Product Safety Data Sheets

Menu Option

Main Menu > Edit Tables > Product and Services > Chemical and Materials

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Browse Table for Safety Data Sheets

Edit Form Window for Safety Data Sheets

Record Will Be Changed (A Chemical Identifier for Sample Record #1 on Tab 1), shown END)

9) Regulatory, Other Information | Pictogram Image
5) Physical, Chemical Properties | 6) Stability and Reactivity | 7) Toxicological, Ecological | 8) Disposal and Transport
1) Identification and Hazards | 2) Composition/Ingredients | 3) Safety Measures | 4) Handling, Storage, Exposure Controls

Record Id: 1 Author Id: ... 13 Created: 6/26/2016 Edited: 8/04/2016

Product Identifier: A Chemical Identifier for Sample Record #1 on Tab 1), shown END CAS Id: 0012345-67-8

Signal Word: Signal Word!

Primary Supplier Id: ... 4 Add your vendor or personnel

Recommended Use: Recommended use of the chemical (e.g., a brief description of what it actually does, such as flame retardant) and any restrictions on use (including recommendations given by the supplier).

NFPA Health and Safety Ratings

Flammability: 1 Health: 2 Instability: 3 Special: 1

Hazard Statement: Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes

Precautionary Statement: Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement

Other Hazards: Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Ta

Activate Spell Check (F7) | Update | Save +Close | Cancel | v1.39.17

Record Will Be Changed (A Chemical Identifier for Sample Record #1 on Tab 1), shown END)

5) Physical, Chemical Properties | 6) Stability and Reactivity | 7) Toxicological, Ecological | 8) Disposal and Transport
1) Identification and Hazards | 2) Composition/Ingredients | 3) Safety Measures | 4) Handling, Storage, Exposure Controls
9) Regulatory, Other Information | Pictogram Image

Record Id: 1 Author Id: ... 13 Created: 6/26/2016 Edited: 7/04/2016

Product Identifier: A Chemical Identifier for Sample Record #1 on Tab 1), shown END CAS Id: 0012345-67-8

Pictogram Path: ... C:\Users\Public\Documents\ABCI\QMSCAPA\Images\Health-pictogram.png

v1.39.15

Update | Save +Close | Cancel

Sample Safety Data Sheet

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SDS

Page 1 of 4

Printed: 7/04/2016

A Chemical Identifier for Sample Record #1 on Tab 1), shown END

Section 1: Identification

EDIT DATE: 7/04/2016 AUTHOR ID: 13 | VERSION ID: Version of SDS Tab 9) >>> >> >> >>> >>>> >>>> >>>>> >>> >>>> END

PRIMARY SUPPLIER: 4 | ADDURS
Add your vendor or personnel
Add an address Include Suites and/or units
City Name Here CA 92649

Office 800-644-2056
Mobile 800-644-2066
Fax 800-644-2076

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RECOMMENDED USE:
Recommended use of the chemical (e.g., a brief description of what it actually does, such as flame retardant) and any restrictions on use (including recommendations given by the supplier).

Section 2: Hazard(s) Identification

Health Rating	Flammability Rating	Instability Rating	Special Rating	Signal Word
2	1	3	1	Signal Word!

HAZARD STATEMENT:
Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes into this field. Harard statement goes

Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab 1) Other hazards from Tab

PRECAUTIONARY STATEMENT:
Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statement goes here. Precautionary statemen

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Tags: quality management software, corrective action software, iso management software, product environmental life-cycle management, safety data sheets

42 Product Life Cycle Planning and Evaluations

Menu Option

Product Life Cycle Planning and Evaluations Module

Currently in a beta release

The QMSCAPA *Product Life Cycle Planning and Evaluations module* is designed to provide support for the ISO 14001:2015 Life-Cycle based thinking for product planning and production.

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Product Life Cycle Planning Browse Table and Form

In the image shown below:

(A) Product Life Cycle Planning may be recorded along with the evaluations of specific Product Configurations, product items and any related chemicals and/or materials.
(B) Product Life Cycle evaluations may begin at the Product Group level or the Product Configuration level.
(C) All Plans may be printed as a group or a single selected Product Life Cycle Plan.

Tags: quality management software, corrective action software, iso management software, ISO 14001:2015

43 Quality Key Performance Indicators

KPI Menu Option

Use the KPI Database to record performance across all processes.

KPI Browse Table

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KPI Form

(A) Select a Label Set to customize the data entry form for KPIs.
(B) The labels for each data field is controlled and populated from the Label Set selected.

43.1 KPI Charts

QMSCAPA Quality Management System software includes an option to chart Process Key Performance Indicators.

Sample (see below) KPI Chart for the Manufacturing Process showing Percent Attained.

Sample (see below) KPI Chart for the Manufacturing and Sales Processes showing Target Percent, Actual Percent and Percent Attained.

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43.2 Quality KPI Label Sets

KPI Label Set Menu Option

Label Sets provide a method for an end-user to customize the KPI data entry form and set unique variables for each process.

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KPI Label Set Browse Table

KPI Label Set Form

A. Use the **Label Set Name** to identify a Label Set and its association with a Process (e.g. Location, Product, Year, etc.). Describe the intent of the metrics.

B. **Record Type** is used to identify the requirements for collecting the KPI data. (e.g. Per shift, day, week, month, quarter, year)

C. All of the KPI metric labels may be customized by the end-user. The **Quantity Goal field** is used to set a goal or quota for production.

D. The **AQL** (Acceptance Quality Limit) is used to identify the minimum quantity that should be inspected.

E. The **QMS Target Percent** is intended to be used with *measuring quality objectives*.

43.3 Reference Id

QMSCAPA provides a **Reference Id**, which may be used to record batch numbers, lot numbers, configuration numbers and other reference identifications.

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44 Quality Measurements

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QMSCAPA includes eight Quality Measurement tools:

- Customer Survey & Satisfaction Calculator
- Dashboard for Quality Monitoring
- Key Performance Indicators for Processes
- Manufacturing and/or Production Calculator
- On-time Delivery Log & Calculator
- Purchasing Quality Calculator
- Sales Quality Calculator
- Vendor / Supplier Evaluations

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☑ ISO 9001:2015 Implementation & Templates Kit

44.1 Customer Survey & Satisfaction Calculator

The Customer Survey and Satisfaction Calculator contains:

- A survey log or running table of survey questionnaires that are recorded.
- A Survey Form, which is designed to generate a Survey Questionnaire that can be sent to a customer and capture the results returned by the customer.
- The Survey Questionnaire is designed for 10 rating type questions that are answered on a scale of 1 to 10. Therefore the highest possible score is 100.
- The 10 X 10 Survey can be easily modified or customized for a variety of surveys, including a 5 question and scale of 1 to 5 rating.
- Survey Sets are a collection of Survey questions and our elements of customer satisfaction. The select a Survey Set through the lookup table will populate the question fields in the Survey Form window.
- The [Customer Id field] is a reference to your customer and is linked to Customer lookup table.
- Survey Groups may be used to designate regions, products and other user defined purposes.
- The ☑ Completed checkbox may be used to signify that the response from the customer has been recorded and completed.
- The numerical spin field limits the rating response to be between 1 and 10.
- The Comments Tab may be used to record customer comments.

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Quality Management Systems

44.1.1 Survey Reports

- Survey Form: The report form is designed to be a blank or unscored form for the selected record.
- Selected Survey Results: The report shows the actual customer response and the survey questions.
- Select Survey Results summary score: The report shows the summary results of the selected survey.
- Survey Summary Results for ALL surveys. The report shows summary of ALL surveys in the table that have been checked as complete.

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Quality Management Systems

44.2 Manufacturing and Production Quality Calculator

The Manufacturing and Production Quality Calculator contains:

- A Manufactured and/or Production log, and;
- A Mfg. & Production quality calculator form
- Mfg. & Production quality analysis report

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44.2.1 Manufacturing / Production Quality Chart

QMSCAPA™ Quality Management System software includes an option to chart Manufacturing or Production quality performance.

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44.2.2 Mfg. & Production Calculator Form

1) The Label Set field is linked to a Look-up Table for User Defined Metric Label Sets.
2) The Product or Service Id field is linked to a Look-up Table of User Defined Product and Services.
3) The User Defined Label field and User Defined Data field are linked to Look-up Tables for labels are information.
4) The Metric Label fields (1 -5) are auto-populated by selecting the Label Set.
5) The Add QM Value check boxes are auto-populated by selecting the Label Set.

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44.3 On-time Delivery Log & Calculator

The On-time Delivery Calculator contains:

- A delivery log table
- An on-time delivery calculator form
- An on-time delivery analysis report
- Copy OTD Batch Records
- OTD Batch Entry option to enter OTD data from external programs.

The table below shows a quick view of the delivery status for the highlighted record, which can be early, on-time or late.

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44.3.1 Batch Entry Option for the OTD Table

On-time Delivery Table for Management Systems

QMSCAPA includes an '**OTD batch entry**' option to enter on-time delivery data or calculations from an external program.

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Batch Entry Table & Form

A. To use the Batch Entry Table and Form enter an appropriate ending date for the batch of data that should be represented in the On-time Delivery Table. E.g. 3/31/2015 may be appropriate for the 1st Quarter of 2015 or the Month of March.

B. Enter the percent 'on-time' or 'late'; the sum of the two percentages may not exceed 100.

Tags: quality management software, corrective action software, iso management software

44.3.2 Copy On-time Delivery Records

Browse Table

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User Tip: Use the **Copy for Batch button** to create batch record representatives for bulk entry of delivery records. For example, it is determine through an external method that 100 shipments are on-time and 20 are late, which creates a 10 to 2 ration of on-time records to late records. Therefore, create 1 on-time record and then copy the representation 9 more times as opposed to entering 100 records. Also, enter two records that are late to represent the batch of twenty records that are late.

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44.3.3 On-time Delivery Analysis Report

The On-time Delivery Analysis Report shows the results of both on-time delivery formulas.

- SBD vs. ASD = Ship by Date is subtracted from the Actual Shipped Date
- CDD vs. ARD = Customer Due Date is subtracted from the Actual Received Date

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Optionally you can print a summary analysis or a full shipping log with the analysis.

1) In section 1 below the actual shipping log is displayed.
2) Number 2 shows the Total Shipments in the analysis.
3) Number 3 shows the SBC vs. ASD comparison as percentages for early shipments, on-time shipments and late shipments.
4) Number 4 shows the CDD vs. ARD comparison as percentages for early shipments, on-time shipments and late shipments.

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On-time Delivery Analysis (All Records)

Date Printed: 6/24/2012

RECORD ID	ORDER #	CUSTOMER NAME	CARRIER NAME	SHIP BY DATE	ACTUAL SHIP DATE	SBD vs. ASD	CUST. DUE DATE	RECEIVED DATE	CDD vs. ARD	ARD VERIFIED?
1	456456456	Another New Customer	UPS	6/15/2012	6/14/2012	-1	6/27/2012	6/28/2012	1	Yes
2	222222222	Customer Four	UPS	6/24/2012	6/23/2012	-1	6/29/2012	6/29/2012	0	Yes
3	33333333	Random Customer	UPS	6/05/2012	6/05/2012	0	6/10/2012	6/11/2012	1	Yes
4	2062812956	Customer Number 5	Carrier 5	5/30/2012	6/01/2012	2	6/05/2012	6/05/2012	0	No
5	555555	Customer Number 5	My truck	6/10/2012	6/11/2012	1	6/15/2012	6/14/2012	-1	Yes
6	0	9 CUSTOMER	UPS	6/24/2012	6/24/2012	0	7/03/2012	7/03/2012	0	No
7	0	CUSTOMER 6	UPS	6/15/2012	6/21/2012	6	6/22/2012	6/22/2012	0	No
8	0	SEVEN		6/27/2012	6/28/2012	1	6/30/2012	6/30/2012	0	No
9	99999999	NINE	UPS	6/25/2012	6/26/2012	1	6/30/2012	6/30/2012	0	No
10	0	9 CUSTOMER		6/25/2012	6/26/2012	1	6/29/2012	6/29/2012	0	No
11	0	Customer Number 5		6/21/2012	6/22/2012	1	6/26/2012	6/26/2012	0	No
12	0	TWELVE		6/22/2012	6/25/2012	3	6/28/2012	6/28/2012	0	No
13	0	My New C		12	6/27/2012	0	/2012	7/01/2012	1	No
					Shipping Variances:	14			2	

and Totals

		Ship by Date vs. Shipped Date	< % >	Due Date vs. Actual Received Date	< % >
Total Shipments:	13				
Total Early Shipments:		2	15.38	1	7.69
Total On-Time Shipments:		3	23.08	1	7.69
Total Late Shipments:		8	61.54	2	15.38
Total Early + On-time Shipments:		5	38.46	2	15.38

44.3.4 On-time Delivery Calculator Form

The Calculator Form contains the following features:

- Author lookup table from the Employee file.
- Optional Customer Reference lookup from the Customer file.
- Optional User Defined field label and User Defined data lookup table.
- Optional Shipping Carrier lookup table.

On-time delivery is calculated by two mutually exclusive formulas.

1) The **Ship by Date** is subtracted from the **Actual Ship Date**.
   a) SBD vs. ASD field records the variance as a minus value, zero or a positive value.
   b) A minus value means the delivery was early by a variable quantity of days.
   c) A zero indicates the delivery was on-time.
   d) A positive number indicates the delivery was late by a variable quantity of days.
2) The **Customer Due Date** is subtracted from the **Actual Received Date**.
   a) CDD vs. ARD field records the variance as a minus value, zero or a positive value.

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b) A minus value means the delivery was early by a variable quantity of days.
c) A zero indicates the delivery was on-time.
d) A positive number indicates the delivery was late by a variable quantity of days.
e) The **Actual Received Date** is estimated by using the **Customer Due Date** and the results are not calculated until the **Actual Received Date** can be verified by checking the **Verified Actual Delivery Date**.

44.3.5 On-time Delivery Chart

QMSCAPA™ Quality Management System software includes an option to chart On-time Delivery performance.

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44.4 Purchasing Quality Metrics Calculator

The Purchasing Quality Metrics Calculator consist of:

1) A browse table and log of Purchasing activities.
2) A calculator form for recording Purchases.
3) An analysis report for Purchasing Quality Metrics.

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1) Set a Label Set to auto-populate the Metrics Labels (labels 1 through 5 and the 'Add To ... check boxes.')
2) The metrics labels are user defined and controlled by the Label Set look-up table.
3) By default the values of QM2, QM3 and QM4 are subtracted from QM1. Optionally the values of QM2, QM3 and QM4 may be added to QM1 if the check boxes are checked ☑.
4) The ☑ boxes are read only on the Purchasing Quality Calculator form and controlled by the Metrics Label Set look-up table

44.4.1 Purchasing Quality Charts

QMSCAPA™ Quality Management System software includes an option to chart Purchasing quality metrics.

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44.5 Sales Quality Metrics Calculator

The **Sales Quality Metrics Calculator** consist of:

1) A browse table and log of Sales activities.
2) A calculator form for recording Sales.
3) An analysis report for Sales Quality Metrics.

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1) Set a Label Set to auto-populate the Metrics Labels (labels 1 through 5 and the 'Add To ... check boxes.')
2) The metrics labels are user defined and controlled by the Label Set look-up table.
3) By default the values of QM2, QM3 and QM4 are subtracted from QM1. Optionally the values of QM2, QM3 and QM4 may be added to QM1 if the check boxes are checked ☑.
4) The ☑ boxes are read only on the Sales Quality Calculator form and controlled by the Metrics Label Set look-up table

44.5.1 Contract Review and Sales Quality Charts

QMSCAPA™ Quality Management System software includes an option to chart Contract Review and Sales Order quality metrics.

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45 Quality Targets Table

A) Quality Targets may be set for each customer to measure Customer Satisfaction and On-time Delivery. Click on the look-up button to select from the Customer Quality Targets Table or simply enter the Record Id number.
B) The Quality Targets may viewed by the Record Id or by a unique description.
C) Use the Quality Targets form to set the target as a percentage for ***On-time Delivery*** (***OTD***) and ***Customer Satisfaction*** (***CS***).

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46 Records Control Index Module

QMSCAPA provides an easy way to index electronic records that are stored on a computer network and/or server.

The Records Control Index may be accessed from the Icon Bar or from the Browse Logs main menu option.

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(A) In the table image above, the System Id refers to an identification number for an ISO Management System. The identification is user controlled. One or more management systems may be reference within the Records Control Index.
(B) The Records Control Index may be filtered and printed by a selected System Id.
(C) All entries in the Records Control Index may be printed.

Related Topics

- Document Control Index
- Document Version History
- Records Control Form
- Records Table Structure
- Records in the Group
- Records Approval Module

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46.1 Records Control Form

Menu Option

Main Menu > Browse Logs > 8) Records Control Index

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Records Control Index Form

The QMSCAPA Records Index module includes fields for:

1. A Record Group Name
2. Record requirements
3. Relationship to a Management System (ISO)
4. Date Created, Saved and Locked (optional)
5. Relationship to a Process and/or Department
6. Locations for Active and Archive retrieval & storage
7. Retention period required
8. Final disposition plan
9. Requirements for Authorized Approval (optional)
10. Authorized Job Title for Approval
11. Type of Record
12. If the record is locked then the Login Code of the user that executed the lock is recorded in the *Locked By field.*

In the image above:

A. Lock Record Check-box field: The Record Name Group may be locked to prevent unattended changes to the identification fields or from the Record Group from being deleted.

B. Locked by field: If the Record is locked then the Login Code of the user that executed the lock is recorded.

46.2 Records Table Structure

Records Control Index for ISO Management Systems

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46.3 Records in the Group

Control of Records Index Form

The Records in the Group is a 'many to one' relationship of records to the Records Group Name and includes information about …

1. Record Attachment Id, Record Index Group Id
2. Date Created, Last Saved, Last Approved, Locked, number of Approvals
3. Period Ending Date
4. Description of the record
5. The electronic folder path to the record
6. Tab 2) contains the Record Approval by one or more authorized persons (electronic signatures).

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Control of Records Index Form Tab 2) Records Attached and Approvals

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In the image below the Record Group shows two records. Record Id #2 contains approvals by two different authorized approvals.

A. The Attached Record and the Record Approval may be locked to prevent unauthorized changes or deletion.
B. The Print Record button shall print the highlighted record in the Record Attached browse table above.

46.4 Records Approval

The Authorized Approval list includes information about …

1. Date and Time the Record was approved
2. An electronic signature of Authorized Signers
3. Description and comments about the Record from the Authorized Signer.
4. The Authorized Approval may 'Lock' the record attachment to prevent unauthorized changes

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Authorized Approval Form

The Authorized Approval form includes information about …

1. Record Attachment Id, Approval Id
2. Date Created, Time Created
3. Description and/or comments by the Authorized Signer
4. Approved by electronic signature
5. Date and Time approved
6. An option to 'Lock' the record to prevent unauthorized changes to the record.

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46.5 Copy Records Index to Excel

QMSCAPA provides a **Copy the Records Index** to Excel feature, which copies the browse table to an Excel file in the same sequence of data that appears in the browse table.

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47 Recording Locking

The following types of QMSCAPA records my be locked by a QMSCAPA System Administrator or Supervisor users to prevent unapproved changes or deletions.

- ❑ Alert Information Messages
- ❑ Corrective & Preventive Actions
- ❑ Customer Feed-back
- ❑ Document Control Index (DCI)
- ❑ Non-conformance

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- ❑ Records Control Index (RCI)
- ❑ Task

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48 Register License

QMSCAPA provides support for multiple concurrent users, which requires a Registered License.

- ✓ Login & Password Control
- ✓ Access, Add, Edit and Delete Controls
- ✓ Control of Reports and Report Templates

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Under the Security Main Menu option select the **Register License option** to open the Register License Window.

Click here to acquire a License for 2 or more users.

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48.1 Register License Window

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QMSCAPA License files are typically distributed through email as an **XML file** attachment.

1. Download the License file to your desktop.
2. Select the Main Menu Security option and click on the Register License menu option.
3. In the Register License for QMSCAPA window click on the **Select License File button**.
4. Navigate to and select the license-file-name.XML

5. The license information will populate the window fields.

49 Relevant Interested Parties (RIP)

In ISO 9001:2015 (plus others), Append A.3 ... Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this (ISO 9001:2015) International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this (ISO 9001:2015) International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

QMSCAPA provides a module for identifying **Relevant Interested Parties** (RIP) and grouping them by their relationship to the Organization.

In addition, for each RIP, QMSCAPA provides a related database of the Expectations, Objectives and/or

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Requirements. Inside QMSCAPA the Expectations, Objectives and/or Requirements are referred to as **Exp/Obj/Req**.

Menu Option - Relevant Interested Parties

Main Menu > Edit Tables > Relevant Interested Parties > 1) Relevant Interested Parties

Browse Table - Relevant Interested Parties

1) In the Browse Table image below, section (1) shows the Relevant Interested Parties.
2) Number (2) shows the needs of the RIP, which are referred to as Expectations, Objectives and, or Requirements.
3) The RIP (1) button control will print the RIP highlighted RIP record and any related Exp/Obj/Req.
4) The RIP (All) button control will print all RIP records and any related Exp/Obj/Req.

Form - Relevant Interested Parties

1) The RIP Form, Tab 1) contains
   a. **User-defined Identification field** for an alpha/numeric identification of the RIP record.

b. **Relationship field** with a user-defined Relationship look-up table.

2) Tab 2) Expectations, Objectives or Requirements contains a browse table with the RIP's related Exp/Obj/Req.

Form - Relevant Interested Parties > Expectations, Objectives or Requirements

1. The **Row Number field** is used to control the order the **ExpObjReq text** appears on the ***RIP reports***. Each RIP may have 999 related records or rows.
2. The **EOR Look Up Id field**, if not zero (0), opens the **RIP ExpObjReq Lookup Table** of stored **ExpObjReq text examples**.
   a. The **ExpObjReq Description field** may be populated by the description information drawn from the **ExpObjReq Lookup Table.**
   b. Also, the **ExpObjReq Text field** may be populated by the text information drawn from the **ExpObjReq Lookup Table.**
3. The **ExpObjReq Text field** is used to record the needs of the RIP. Use the **ExpObjReq Text field** to record a single Expectation, Objective and/or Requirement.
4. **Checkbox Requires Risk Assessment** - If the Expectation, Objective and/or Requirement requires a Risk Assessment then check this box and associate the appropriate Risk Assessment and Impact Statement from the QMSCAPA Risk Assessment Module.
5. **Risk Assessment Id field** *lookup button* provides direct access to the Risk Assessment Table.

Sample Relevant Interested Party Report

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Relevant Interested Party
Page 1 of 1

Organization: ABCI CONSULTANTS
Address 1: 16835 ALGONQUIN STREET
Address 2: #236
City, State, Postal Code: Huntington Beach CA 92649

Relationship: Quality Audit & Consultants

Comments: Provides consulting and auditing services for:
[01] Quality
[02] EHS
[03] ISMS (NIST 800-171]

Expectations, Objectives and/or Requirements

0 RA Required: No

adjective, (of a person or their judgment) not influenced by personal feelings or opinions in considering and representing facts.
"historians try to be objective and impartial"

synonyms: impartial, unbiased, unprejudiced, nonpartisan, disinterested, neutral, uninvolved,

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49.1 RIP Expectations, Objectives or Requirements

QMSCAPA provides a lookup table for storing and reusing a **list of Expectations, Objectives and/or Requirements** of Relevant Interested Parties (RIP).

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Menu Option - RIP Expectations, Objectives or Requirements

Main Menu > Edit Tables > Relevant Interested Parties > 2) **RIP Expectation, Objectives and Requirements**

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Browse Table - RIP Expectations, Objectives or Requirements

1) List of Expectations, Objectives and/or Requirements in the order of the RIP EOR Id.
2) Use the Add, Edit or Delete buttons to maintain the table.
3) Print the Expectations, Objectives and/or Requirements table.

Form -RIP Expectations, Objectives or Requirements

1) The **Exp/Obj/Req Description field** is intended to be a brief description of the Expectation, Objective or Requirement.
2) The **Exp Obj Req Text field** may contain up to 2048 characters and spaces.

User Tip: Record one Expectation, Objective or Requirement per RIP Exp/Obj/Req Id.

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49.2 RIP Relationships

The **RIP Relationships lookup table** may be accessed inside the **RIP Form**.

Browse Table - RIP Relationships

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50 Request for Return Material Authorization

Return Material Authorization (RMA) information may be recorded into the Customer Complaint Table and Customer Complaint Form.

Customer Compliant Form

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(A) The RMA Number field is linked to a look-up table that provides an automatically generated unique number.
(B) The Return Location Id field is linked to a look-up table of Other Locations (aka Ship To locations).
(C) Comments may be recorded that are specific to the RMA.

50.1 RMA Numbers Generator

The RMA fields may be accessed through the Customer Complaint Form.

RMA Number Generator Table

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RMA Number Generator Form

1. The RMA No. field automatically increments the RMA Number.
2. The Customer No. field is populated from the the Customer Complaint form where the RMA number is assigned.

51 Risk Assessment Module

The QMSCAPA Risk Assessment (RA) module consist of:

1) Table of Risk Assessments (current and historical assessments)
2) A sub-table of specific aspects of the risk assessments
3) A look-up table of the risk impact values with regard to the
   a. Probability (P)
   b. Severity (S)
   c. Detection (D)
4) Five user-defined boundaries, e.g. Very Low, Low, Medium, High, Very High.

The impact values are used to calculate the *Risk Priority Number* (RPN) for each aspect.

RPN = (P * S * D)

The module is developed around the concepts typically found in a *Failure Mode Effects Analysis* (FMEA).

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See the [Terminology used in Risk Assessments](#).

51.1 Risk Assessments

The Risk Assessments browse table can store a large number of current and/or historical assessments.

1) The browse window contains *sort tabs* for instant viewing of data according to the key value of the Tab.
2) Risk assessments can be performed and recorded for virtually any type of risk related to the organization, relevant interested parties, product, service, staff, logistics, transportation, and cost, including environmental, health and safety.
3) **View RiskAspects button**: Opens a sub-table of related aspects to the highlighted risk assessment may be viewed, added, edited or deleted as needed.
4) **RIP icon button:** Access the Relevant Interested Parties table (RIP).
5) **Print Assessment button**: Use the button to print a Risk Assessment, which includes all aspects and impacts recorded.
6) **Copy Assessment or Template button**: The copy button control copies the currently highlight assessment record.
7) The tab 10) Templates applies a filter that only shows the Risk Assessments designed to be templates.

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See the [Terminology used in Risk Assessments](#).

51.1.1 Risk Assessment Form

The image below describes the Risk Assessment Form.

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A. The *Title* represents the title of the current Risk Assessment.
B. Describe the *Purpose of the Assessment*.
C. Standard can reflect the International Management Standard.
D. *RA SET ID* is the Risk Assessment Set Id for the template used to determine the boundaries and the values used to evaluate the risk based upon the Probability, Severity & Detection.
E. The Author Id indicates the person inputting the RA record. The Approval Id indicates the person approving the RA.
F. The RPN number is calculated from the data entered for the impact values of each Aspect.

See the Terminology used in Risk Assessments.

51.2 Risk Assessment Aspects

The Risk Aspects table shown below is attached to the Risk Assessment Form. This table can contain an infinite quantity of risk aspects. The RPN is calculated based upon the impact value of the probability (P Value) * severity (S Value) * detection (D value).

The Add, Edit and Delete controls are linked to the Risk Aspect Form.

See the Terminology used in Risk Assessments.

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51.2.1 Risk Aspect Module Form

The Risk Aspect module form is configured with 4 main Tabs or sections:

1. The General Tab contains information about the failure (generic for incident, breach, non-conformance). The ***assessment calculation tool*** (pre and post mitigation results) is designed for rating or assessing a specific aspect of the Risk identified and associated in the Risk Assessment Table. Therefore, a one to many relationship exist between the Risk (parent table) and the Aspects (child table).
2. Tab 2) contains fields for additional consequences.
3. Tab 3) contains fields for mitigation or risk treatment actions.
4. Tab 3) contains a method of generating risk impact statement based upon availability, confidentiality, integrity and financial effect.

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1) General tab

A. In the form image below, Describe the failure and the failure mode.
B. Describe what may cause the failure and the failure effect.
C. The impact values for calculating the Risk Priority Number (RPN) (pre-mitigation treatments); see the look-up table for impact values: RPN = Probability (P) * Severity (S) * Detection (D)
D. The impact values for calculating the Risk Priority Number (RPN) (post-mitigation treatments);
E. Look-up Tables for Response to Risk Aspect and the current/last Status of the Risk Aspect.
F. The RPN can report the pre or post-mitigation action [√] RPN Post Mitigation Action is check-box.

See the [Terminology used in Risk Assessments](#).

51.2.2 Risk Aspect Impact Statement

Aspect Assessment Form, 4) Impact on Business / Operations tab

A. In the image below, the Risk Aspect Assessment module form provides a tool to evaluate the impact of an aspect of the risk on the organization in relationship ...
   1) Availability (of assets, facility, personnel, process, outsource, supply chain, etc.)
   2) Confidentiality (information about contract, customers, intellectual property, personnel, stakeholders, etc.)
   3) Financial (information, cost of quality, cost of alternatives, cost of business continuity, etc.)
   4) Integrity (reputation and trust of customers, personnel, public, stakeholders, etc.)

B. Section (B) represents the evaluation of the impact after or post mitigation or treatment of the Risk Aspect.

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51.2.3 Copy an Aspect

Use the ***Copy Aspect button*** to copy the highlighted record in the Risk Aspect table.

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51.3 Risk Assessment Templates & Look-up Table for Impact Values

Risk Assessment Template Menu

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Risk Assessment Template Table

Risk Assessment Template Form

(A) Risk Assessment Record Id, template Name and its intended purpose.

(B) Tab 2) Probability, Severity and Detection Table
(C) Risk Assessment Boundaries, used to summarize the risk evaluation value of the Risk Priority Number (RPN).

The five Risk Assessment Boundaries are user-definable.

1) Check-box [ ] Use BLV # = Use the Boundary Level Value #1, 2, 3, 4 or 5
2) BLL# = Boundary Level Label
3) BLV# = Boundary Level Value
4) BLM# = Boundary Level Message

Form for the Values used for Evaluating the Impact from the probability, severity and the detection of an Risk Assessment Aspect.

1) RECID - This record identification is related to the Risk Assessment template.
2) Type of Evaluation - The type of evaluation is limited to the Probability, Severity and Detection.
3) Value - The impact value is user definable.

4) Description - The description is related to the probability of the occurrence, the severity of the impact or the detection ability.

See the Terminology used in Risk Assessments.

51.3.1 Example List of Impact Values

(P)robability (S)everity (D)etection	Value	Description
D	1	Certain - fault will be caught on test
D	2	Almost certain failure can be detected prior to reaching Operators or Maintainer
D	3	High probability failure can be detected prior to reaching Operators or Maintainers
D	4	Moderate probability failure can be detected prior to reaching Operators or Maintainers
D	5	Low probability failure can be detected prior to reaching Operators or Maintainers
D	6	Fault is undetected by Operators or Maintainers
P	1	Extremely Unlikely (Virtually impossible or No known occurrences on similar products or processes, with many running hours)
P	2	Remote (relatively few failures)
P	3	Occasional (occasional failures)
P	4	Reasonably Possible (repeated failures)
P	5	Frequent (failure is almost inevitable)
S	1	No relevant effect on reliability or safety
S	2	Very minor, no damage, no injuries, only results in a maintenance action (only noticed by discriminating customers)
S	3	Minor, low damage, light injuries (affects very little of the system, noticed by average customer)
S	4	Moderate, moderate damage, injuries possible (most customers are annoyed, mostly financial damage)
S	5	Critical (causes a loss of primary function; Loss of all safety Margins, 1 failure away from a catastrophe, severe damage, severe injuries, max 1 possible death)
S	6	Catastrophic (product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths)

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51.4 Applicable Controls

Menu Option

QMSCAPA provides a look-up and validation table for recording **ISO Applicable Controls & Programs**. These *controls* may be user-defined or loaded from an appropriate ISO Standard.

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ISO Controls Browse Table

Controls Form

Tags: quality management software, corrective action software, iso management software

51.5 Risk Responses

Menu Option

QMSCAPA provides a look-up and validation table for recording **Risk Responses**. These *responses* may be user-defined.

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Risk Response Browse Table

Tags: quality management software, corrective action software, iso management software

51.6 Risk Status

Menu Option

QMSCAPA provides a look-up and validation table for recording **Risk Status**. These *statuses* may be user-defined.

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Risk Status Browse Table

51.7 Risk Types

Menu Option

QMSCAPA provides a look-up and validation table for recording **Risk Types**. These *types* may be user-defined.

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Risk Types Browse Table

Tags: quality management software, corrective action software, iso management software

51.8 Terminology used in Risk Assessments

Definitions typically used in Failure Mode Effects Analysis (**FMEA**)

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1. **Failure**: The loss under stated conditions.
2. **Failure mode**: The specific manner or way by which a failure occurs in terms of failure of the item (being a part or (sub) system) function under investigation; it may generally describe the way the failure occurs. It shall at least clearly describe a (end) failure state of the item (or function in case of a Functional FMEA) under consideration. It is the result of the failure mechanism (cause of the failure mode). For example; a fully fractured axle, a deformed axle or a fully open or

fully closed electrical contact are each a separate failure mode.

3. **Failure cause** and/or mechanism: Defects in requirements, design, process, quality control, handling or part application, which are the underlying cause or sequence of causes that initiate a process (mechanism) that leads to a failure mode over a certain time. A failure mode may have more causes. For example; "fatigue or corrosion of a structural beam" or "fretting corrosion in an electrical contact" is a failure mechanism and in itself (likely) not a failure mode. The related failure mode (end state) is a "full fracture of structural beam" or "an open electrical contact". The initial Cause might have been "Improper application of corrosion protection layer (paint)" and /or "(abnormal) vibration input from another (possible failed) system".
4. **Failure effect**: Immediate consequences of a failure on operation, function or functionality, or status of some item.
    a. **Indenture levels** (bill of material or functional breakdown): An identifier for system level and thereby item complexity. Complexity increases as levels are closer to one.
    b. **Local effect**: The failure effect as it applies to the item under analysis.
    c. **Next higher level effect**: The failure effect as it applies at the next higher indenture level.
    d. **End effect**: The failure effect at the highest indenture level or total system.
5. **Detection**: The means of detection of the failure mode by maintainer, operator or built in detection system, including estimated dormancy period (if applicable)
6. **Probability:** Likelihood that a failure may happen.
7. **Risk Priority Number** (**RPN**) = Probability (of occurrence) * Severity (how severe is the impact) * Detection (ability to detect the failure)
8. **Severity**: The consequences of a failure mode. Severity considers the worst potential consequence of a failure, determined by the degree of injury, property damage, system damage and/or time lost to repair the failure.
9. **Remarks / mitigation / actions**: Additional info, including the *proposed mitigation* or actions used to lower a risk or justify a risk level or scenario.

51.9 Risk Assessment Template

Risk Assessment Browse Table

Tab 10) By RA Template shows a list of Risk Assessments that are designed to be templates to create new Risk Assessments.

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Risk Assessment Form

Create a New Risk Assessment from a Template:
Highlight a Risk Assessment record in the Tab 10) By RA Template and then click on the Copy Assessment Template button.

Click on the **Use As Template check-box** to *set the Risk Assessment as a template* to create new Risk Assessments.

52 Report Builder

A **Report Builder** is an end-user report writer tool for extracting information from a QMSCAPA database in a highly structured manner. Reporting styles can vary from simple columnar output to extravagant form letters and sales invoices. Some reports extract and/or manipulate data from a single database, while other reports may require several databases and complex formulae to generate information in the desired manner. (Report Builder is available with the Professional and Enterprise Licenses).

QMSCAPA contains menu options made available to the user for pre-defined reports. While these reports can usually fulfill the majority of end-user needs, times arise when a custom report has to be created. If the means to create/modify reports has not been included in an application, the programmer has to be hired to create the report for the user (usually at a substantial cost). The QMSCAPA Report Builder puts the power of creating/modifying reports into the users hands.

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As with any new tool there is a learning curve involved. However, a willingness to experiment can pay huge dividends to yourself and/or firm. You can create as many new reports as you want without paying a programmer to create them for you.

This **Report Builder** is an extremely powerful tool, comparable in features to software costing hundreds of dollars. Practically any type of report that you require can be created with this simple, yet highly effective tool.

Report Builder Overview

- What is a report builder?
- What are some features of this report builder
- Database fundamentals
- Database filters
- Expression and Formulas

Quick Tour

- The report manager screen - managing reports you create
- The report creation screen - Get acquainted!
- Bands- An overview on how they process database information
- Frames - How they print text and database information on reports
- Dictionaries - Stores database field information and other useful data

52.1 What is a report builder?

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A **Report Builder** is a tool for extracting information from a **database** in a highly structured manner. Reporting styles can vary from simple columnar output to extravagent form letters and sales invoices. Some reports extract and/or manipulate data from a single database, while other reports may require several databases and complex formulae to generate information in the desired manner.

Many computer applications have menu options made available to the user for pre-defined reports. While these reports can usually fulfill the majority of end-user needs, times arise when a custom report has to be created. If the means to create/modify reports has not been included in an application, the programmer has to be hired to create the report for the user (usually at a substantial cost). A report writer puts the power of creating/modifying reports into the users hands.

As with any new tool there is a learning curve involved. However, a willingness to experiment can pay huge dividends to yourself and/or firm. You can create as many new reports as you want without paying a programmer to create them for you.

This **Report Builder** is an extremely powerful tool, comparable in features to software costing hundreds of dollars. Practically any type of report that you require can be created with this simple, yet highly effective tool.

52.2 Features Of Report Builder

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Report Builder can do a lot more than simply print columns of data. While that would certainly meet the needs of a lot of users, there are times when specific detail is necessary to accomplish your task. Here is a short list of features you can use:

Accessing/Saving Report(s)

- Tree-styled Report Manager screen will help you to arrange your reports by means of classifying and grouping them by type and using several folders to store report files.
- You can create and manage an unlimited number of reports.

- Quickly create reports that are similar to an existing report by opening a file, then saving the report to a new file name.
- You can use Windows styled long filenames when saving reports.

QMSCAPA Report File Names

The QMSCAPA Report Builder will attempt to save your new reports with a name similar to "RPT00001.RPT." The second report that you save will be named "RPT00002.RPT" and the third will be named "RPT00003.RPT" and so on for additional reports. Therefore, end-users are recommended to **save report file names** using the automatic schema with the built-in serialized report file name.

If you makes changes to one of the QMSCAPA standard reports which are installed with the application, then you should save the changes using "**SAVEAS**" and let QMSCAPA suggest the appropriate name with the serialized naming schema as described above. If you save your changes with the same name as used by QMSCAPA to store its standard reports, then your changes will be overwritten each time QMSCAPA is upgraded.

Optionally, you may create your own report file names. If you elect to save your reports with your own naming convention, for example "MyQMSCAPAReport01" then it is not necessary to add the ".**RPT suffix**" at the end of the file name. The Report Builder will append the suffix to your custom file name. Once again, end-users should not use the QMSCAPA report file naming convention to save new or modified reports.

Data Creation/Manipulation

- Simultaneous processing of several data tables joined in an integrated structure

- Effective and high speed filters for records using any available fields from applications database file(s), including expressions and functions of the Report Builder's native programming language
- Sort data using any available fields, including expressions and functions of the Report Builder's native programming language
- You can easily build complex expressions with help of the built in Data Dictionary. The Dictionary contains all the field names, functions, operators, built-in variables and user defined total variables/calculated fields which are allowed for use in an expression. The Dictionary also shares a tree-style hierarchical structure.
- Supports end-user creation of total variables of type Sum, Counter, Average, Minimum, Maximum, Evaluate. Total variables can be reset on the end of appropriate sorting group as well as on the end of each page. These variables can be set up to be evaluated at the start of report, at the each record, at the end of a sorted group, at the end of page, at the end of report.
- Supports end-user creation of "Calculated fields". They are very similar to "Total variables" but always use the Evaluate type and never being reset. You can accomplish very complicated computations using any number of Total variables and Calculated fields.
- Print the current date and time on a page. The Picture can change the format of a date or time field to any desired format. For example, you can change 02/21/00 to read "21 February, 2000" at report runtime.

52.3 Report Builder - User Interface

User Interface

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- The **report formatter** or painter uses a word processing-styled interface, with buttons commonly found for formatting text (right align, left align, center align, etc)
- Supporting report sections (**bands**): Page header, Report header, Group break, Group header, Detail, Group footer, Report footer, and Page footer. Each band can contain an unlimited number of **Frames** to represent information.
- Frame contents may be a text string(s), or a formula. This is similar to Microsoft Excel usage: if the frame contents

begins with the equal sign "=" then it means the rest is the formula to evaluate. In that way you can reference the only one variable as well as the expression containing as many variables and functions as you want.

- Use borders around the Frames to make them standout. For example, you can place a border around dollar totals at the bottom of reports. You can also use all the Frames with borders and join Frames side-by-side to get grid-style report. Frame borders may have varying thickness and color. Also the whole frame can be filled by selected color.
- You may select a font typeface, size, style and color for the whole report or report section as well as for individual frame. Use different fonts and font types to make key data stand apart from other data.
- You can select multiple Frames at the same time for repositioning or alignment operations.
- Frame contents are placed and aligned both vertically and horizontally.
- Print the current page number as well as the total number of pages on each page header/footer.
- Print the number of database records printed on the current page (useful for page footer information).
- Ability to export report pages in WMF format to Microsoft Word for Print Preview, Edit, Save as *.doc format file, Printing purposes, etc.
- Add graphics to a report that are stored on your computer.
- Save one or more versions of a report for unique output and/or results.

QMSCAPA Report File Names

The QMSCAPA Report Builder will attempt to save your new reports with a name similar to "RPT00001.RPT." The second report that you save will be named "RPT00002.RPT" and the third will be named "RPT00003.RPT" and so on for additional reports. Therefore, end-users are recommended to **save report file names** using the automatic schema with the built-in serialized report file name.

If you makes changes to one of the QMSCAPA standard reports which are installed with the application, then you should save the changes using "**SAVEAS**" and let QMSCAPA suggest the appropriate name with the serialized naming schema as described above. If you save your changes with

the same name as used by QMSCAPA to store its standard reports, then your changes will be overwritten each time QMSCAPA is upgraded.

Optionally, you may create your own report file names. If you elect to save your reports with your own naming convention, for example "MyQMSCAPAReport01" then it is not necessary to add the ".**RPT suffix**" at the end of the file name. The Report Builder will append the suffix to your custom file name. Once again, end-users should not use the QMSCAPA report file naming convention to save new or modified reports.

52.4 Databases

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As simple to use as this report builder is, there are some **database** fundamentals that you should be comfortable with in order to get the most out of this powerful tool. It is one thing to blindly type information into a computer, but empowering yourself as to how a database program really works will greatly enhance the reports that you create.

A database is nothing more than a collection of information that is somehow related. A common phone book is a wonderful example of a database. A basic definition of a phone book would be a collection of names, addresses, phone number(s) for people and businesses in one physical area (usually a city, or a common area code number). So, a database would be all the names, addresses and phone numbers contained in a phone book.

A database file is comprised of two new terms: database records and database fields. going back to the phone book once again, each persons name listed in the phone book would be a database record - it contains all the information for one person or business (their name, address, phone number(s), etc). The next name shown in the phone book would be a separate database record, and so on.

A database record is made up of database fields. Using the phone book again as an example, we would have separate database fields for the following information:

- Individuals/business name
- Street address
- Phone number

A database can have only one field, or can have hundreds of fields - whatever it takes to store all the information required for one database record entry.

A phone book is usually sorted on the name of the individual/business, beginning with the number 0, and ending with the letter Z. This type of sort is known as ASCENDING sequence. If you started at the back of a phone book and worked your way to the front (going from the letter Z to the number 0) this sort is called DESCENDING sequence. Sorting a database requires the creation of a second type of file known as a database index, which can also be called a database key.

A database index is a file used by a database application to change the appearance of information stored by the database. Going back to the phone book example - every day the phone company creates phone numbers as people and businesses move into the city. Their name(s) are obviously not going to be in alphabetical order when the clerk creates their new phone number - a person named Jones may be first, then Joe-Bob's Barbeque is next, then Alpha-Beta Drugs may be third, and so on. Without a way of sorting this information a printed phone directory would be a total mess - names would jump around the alphabet! The index file's job is to regain some structure and order to the information being input into the database.

A database index file can be created using one database field, or several database fields. These file(s) are normally opened when the database is opened, and as each database record is added/deleted an identical action is performed on the index file. For the phonebook example, the desired sort would be the individual/business name to be sorted in ascending alphabetical sequence. The fieldname used for the index would be the individual/business name. If your phone company were really customer-oriented they could perhaps create section(s) in their phone book that were sorted on the street address - a new index created on that database field

would be created/used to print this new section of the phone book.

Index file(s) are most commonly used in browse screens (a screen where all the database records are displayed in columns, sorted alphabetically for easy location of information) and reports.

Index file(s) are also used to relate two or more database files together, which store different pieces of information that belong together. This type of database application is known as a relational database - two or more database file(s) relate to each other by means of a common database field, and an index file that links the two separate files together.

An example of a relational database could be your bank account. When you first joined your bank you filled out a form with your name, address, work history, etc. The clerk typed this information into the computer, handed you a bundle of blank checks and thanked you for joining their bank. All this "initial" information is stored in a database. As you start writing checks to pay for things a transaction is created for the date it was written, the dollar amount, the date the transaction was posted to your account, the check number, etc. These transactions are stored in a separate database file.

In the example above, we have one database that stores customer information (name, address, etc) and another database that stores transactions for each check cashed. In both database files is a field that contains the account number, and an index file is created for each database on this field. The two database files are related to each other by these index files created on the account number.

Not all database applications require a relational setup - if the information being tracked is simple then a single database file will contain all the data being monitored. However, all business type database systems rely on the relational database structure in order to keep track of a large quantity of information. Relational databases greatly reduce the amount of information being kept in database files, which keeps the size of the database file(s) small and increases the speed of the program in retrieving data.

This Report Builder can create reports from single database programs or relational database programs.

52.5 Fields

A database record is made up of database fields. Using the phone book again as an example, we would have separate database fields for the following information:

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- Individuals/business name
- Street address
- Phone number

A database can have only one field, or can have hundreds of fields - whatever it takes to store all the information required for one database record entry.

52.6 Database filters

A **database filter** enables you to extract information from database file(s) that you want to print on the report. The ability to use filters in database programs has always been one of the strongest features of database applications (dBase, Foxpro, Access, etc). While they can be a little confusing at first, if you understand some basic concepts of how to create a database filter you will find them to extremely helpful in creating useful reports.

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Filters do not change any information contained in database file(s); they don't copy information to another file either. A filter simply "hides" information that you don't want to see, which explains why they are called "Filters". No matter how many times you create or use a database filter, you are guaranteed that they will NEVER harm your database information. Hopefully this will give you the confidence to try creating filters for various purposes.

Reports may be filtered on the Report Property level and/or on a Report Band level. In the example below, the **Report Properties** are found inside the Report itself under the FILE > REPORT PROPERTIES menu option.

The **REPORT PROPERTIES** contains the master **Page layout** information, plus a field to store the **Report Builder Menu information and a Record filter.**

Related Topic: Expressions and Formulas

52.7 Expressions and Formulas

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Expressions

An expression is made up of two types of components: operands and operators. Operators perform an operation (such as addition, subtraction, etc.) on one or more operands of the expression. Operands are the components on which operations are performed. Operands either contain or return a value. Constants, data dictionary columns, memory variables, and functions are examples of operands. An operand can be made up of more than one component, such as a function and its parameters.

The Frame Editor lets you choose operators and operands, and then insert them into the Statement line.
The sections below lists all the components used in Clarion expressions.

Math Operators
+ Plus sign: Adds two operands together.
- Minus sign: Subtracts one operand from another.
* Asterisk: Multiplies one operand by another.
/ Slash: Divides one operand by another.
% Percent sign: Returns the remainder from a division operation (modulus division).

^ Caret: Raises one operand to the power of the other.
( ) Parentheses: Groups components together within an expression.

Logical (Boolean) Operators
= Equal: Evaluates whether one expression is equal to the other.
< Less Than: Evaluates whether one expression is less than the other.

> Greater Than: Evaluates whether one expression is greater than the other.
<> Not Equal: Evaluates whether one expression is not equal to the other.

>= Greater or Equal: Evaluates whether one expression is greater than or equal to the other.

<= Less or Equal: Evaluates whether one expression is less than or equal to the other.

AND Connects two logical expressions together. For an expression containing an AND to be true, both expressions of the AND must be true.
OR Connects two logical expressions together. An expression containing an OR is true if either expression of the OR is true.
XOR Connects two logical expressions together. An XOR expression is true if either expression is true, but not both.

NOT Reverses the evaluation of an expression.
~ Reverses the evaluation of an expression.

String Operators
& Ampersand: Appends one text string to another.

Operands

Data ~Includes data dictionary columns, global, and local memory variables.

Functions ~All of the built-in functions of the Clarion language. These functions all perform some operation on parameters (other operands) and return a value.
User ~Any FUNCTION in your application. These functions perform some operation on parameters (other operands) and return a value.
Constant Text ~You can type constant text surrounded in single quotes (‘A’) on the Statement line.
Constant Number ~You can type constant numbers on the Statement line. Constant numbers can be represented in any valid format, such as Decimal (1 or 1.2345), Scientific Notation (22e4), Binary (0101b), or Hexadecimal (1AFFh).

Example Expressions

Lastname & ‘, ‘ & FirstName	!concatenated string
constants & variables	
ABS(Amount) * 100	!function, numeric
variable & constant	
TaxCode = True AND Amount > .25	!Boolean with variables
& constants	

52.8 Report Formatter Screen

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Whenever you create a new report or modify an existing report you will be using a report formatter or "painter" to place item(s) in the desired location. The screen is very easy to use, with a toolbar of commonly used commands, a pulldown menu, and use of the right mouse button to modify item(s) on the screen. Here is a sample screen "painter"; place the mouse button over an item - if the mouse cursor changes to a hand you can left click the mouse to see what the item does.

52.8.1 Adding Text Frame

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After text to a frame is very easy; it is the default action for a new frame. As soon as the frame is added to the report band you can immediately start typing:

The above screen capture shows a report band with a Page Header report band; created inside is one frame, and the text string "Sample Report Title" has been entered. As you type information into the entry field for 'Contents' the screen is updated to reflect the information.

You can right click on the frame to change the characteristics of the information (in this case, the text string "Sample Report Title") will be printed.

Because the frame contains only a text string (Sample Report Title) you don't have to worry about the Picture tab, or the Picture pushbutton, since you are typing the text string as you want it printed.

52.8.2 Frames

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Frames are used to mark the boundaries of an object placed in a report band. A better explanation in "laymans terms" would probably be best described as a "box that will contain something". Frames are usable on certain report bands that you add to a report.

To define a new frame, you will:

- Left click inside the report band that you want something to be printed; this will select the report band to receive the empty frame

- Right click the mouse to display a popup menu; from this menu select 'New Frame'

A new empty frame is now displayed inside the report band where you had previously left clicked the mouse:

As shown above an empty frame was placed inside the Page Header Report Band; red blocks outline the frame, indicating that you can stretch any of the corners to meet your printing size requirement. You can also drag the empty frame to a different location inside the report band by left clicking inside the empty frame, then drag the empty frame to the desired location. When dragging the empty frame the border will turn completely red - release the left mouse button after moving the frame to set it's position.

A useful ruler bar to aid in positioning frames for the report. You can toggle the ruler bar style between the English system and Metric system by selecting the main menu option OPTIONS, then METRIC SYSTEM. If a checkmark is displayed to the left of the menu entry the ruler bar is displayed using the metric system, and vice versa.

Once you have moved and/or resized the frame you need to define what you want printed in this location. A frame can contain many things:

- A database field used in the application
- A text string (such as a report header, column header, etc)
- A calculated field that is generated at runtime
- A page counter
- The current date or time
- Total fields (such as total expenditure, dollar total, etc)

Frames can also contain MULTIPLE items - this is handy when you want to format database information to look a certain way. Here are some examples of combining multiple items inside a frame:

- Two or more fields: CUS:Fname &' ' &CUS:Lname [The &' ' places a blank space between the first and second name]
- Two or more fields; remove empty space at end of each field: clip(CUS:Fname) & ' ' & clip(CUS:Lname)

- Two or more fields; highly formatted: clip(CUS:Lname) & ', ' & clip(CUS:Fname)
- Fields and text: '* ' & clip(ITE:Description) & ' *'

Notice that the function clip() was used with text information (remember to ALWAYS surround any text information with the ' symbol). Any of the report builder functions may be used to format database information (such as the Upper() and Lower() functions).

To change the contents of a frame and/or it's properties you will use the Report Formatter Frame Edit Box.

Related Topic: Expressions and Formulas

52.8.2.1 Frame Properties

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In many ways, a **FRAME** is very much like a **CELL** inside a spreadsheet. However, a **FRAME** may be placed at any position inside a **BAND** and is not constrained by a ROW or COLUMN in a spreadsheet. This dialogue box allows you to modify the appearance of information stored inside a frame. You can display this popup window by double clicking on a frame, or right click on the frame and select from the popup menu the choice titled Properties:

You can change any aspect of the frame contents by using this dialogue box. Here is a breakdown of the various options:

- Contents: If you are going to use the frame to contain text you can simply type it into this entry field. If you want the frame to contain database information click on the Dictionary button to select a database field, or alternatively format the information using the built in functions. You can modify the contents at any time by selecting the frame and re-editing.
- **FRAME TYPES**: A frame type can be **CUSTOMARY**, **MAIL MERGE** OR **IMAGE FILE**.
- **CUSTOMARY FRAME**: Use the CUSTOMARY FRAME for most fixed length data fields and field report labels.
- **MAIL MERGE:** Use the MAIL MERGE FRAME to place multiple fields with various sizes into a particular BAND.
- Contents - **Image File** Name: Include the Path and the Image file name (frameproperties,jpg or logo.bmp)

- Picture: If using database information inside the frame you can use a "picture" to modify it's appearance. Optionally, for large text fields leave the picture token blank.
- Appearance Group:

1. [ ] **Multiline Text** (Use this option if you want to wrap text content inside the FRAME. The contents of the field will conform to the size of the FRAME.
2. [ ] **Auto Resize Bottom** (Use this option to flow text from fields with large contents that may vary is size. This feature works best when the FRAME is placed alone on the last line of the BAND. Therefore, the FRAME may be set to .20 but with this feature enabled the FRAME will automatically adjust to a height that is needed for the inflow of text.
3. **ROTATION ANGLE:** Use the **ROTATION ANGLE** on a CUSTOMARY Frame to show field variable data or text on a slant.

- Align Horizontal: A drop list of different positions that the frame contents are aligned horizontally inside the frame.
- Align Vertical: A drop list of different positions that the frame contents are aligned vertically inside the frame.
- Left Margin: Define in increments of 0.5mm the gap between the edge of the frame and it's contents from the left edge of the frame.
- Right Margin: Define in increments of 0.5mm the gap between the edge of the frame and it's contents from the right edge of the frame.
- Top Margin: Define in increments of 0.5mm the gap between the edge of the frame and it's contents from the top edge of the frame.
- Bottom Margin: Define in increments of 0.5mm the gap between the edge of the frame and it's contents from the bottom edge of the frame.
- Between Margin:
- Border Color: Displays a standard Windows color selection box to choose a color for the border drawn around the frame.
- Left Border: A checkbox that allows for displaying (checkbox is check marked) or not displaying (checkbox is empty) a border on this side of the frame. The default setting for the report builder is to display a solid black border around the contents of the frame.
- Right Border: A checkbox that allows for displaying (checkbox is check marked) or not displaying (checkbox is

empty) a border on this side of the frame. The default setting for the report builder is to display a solid black border around the contents of the frame.

- Top Border: A checkbox that allows for displaying (checkbox is check marked) or not displaying (checkbox is empty) a border on this side of the frame. The default setting for the report builder is to display a solid black border around the contents of the frame.
- Bottom Border: A checkbox that allows for displaying (checkbox is check marked) or not displaying (checkbox is empty) a border on this side of the frame. The default setting for the report builder is to display a solid black border around the contents of the frame.
- Border Width: This is a spin box with a range of 0-9 which changes the border line width.
- Font: Displays a standard Windows dialogue box to change the font characteristics of the frame contents.
- Fill Enable: A checkbox allowing you to fill in a frame with a solid color. When check marked the button to the left of the checkbox is made available to select a color from a standard Windows color selection dialogue window.
- Save: Save changes made to the selected frame.
- Cancel: Abandon all changes made to the selected frame.

52.8.3 Report Bands

There are 8 types of report bands, plus **frames**, that can be defined in a report:

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1. **Page Header** - Your report can contain only one page header. This report band is printed at the top of the output on each generated report page.
2. **Report Header** - Your report can contain only one report header. This report band is printed at the top of the output on only the FIRST generated report page.
3. **Sorting Band** - Your can have multiple Sorting Band details on a report. A sorting band may contain it's own header, footer and/or additional breaks. A sorting band is the mechanism for SORTING a report.
4. **Group Header** - This band is printed at the top of each page when the group break value has changed.
5. **Detail** - You can have multiple DETAIL bands in a report. A detail band is responsible for retrieving database

information required for the report and printing the data onto the report.

6. **Group Footer** - This band is printed at the bottom of each page when the group break value has changed.
7. **Report Footer** - This band is printed at the bottom of the last generated page in the report.
8. **Page Footer** - This band is printed at the bottom of each page in the generated report.

52.8.4 Sorting Bands

This band is used to print a header above a group. Let's examine a real world situation for using a sort band header.

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Let's use a mailing list as an example. Your organization has members all over the United States in each of the fifty states. When your mailing list prints you want the output to be nicely formatted with a title above each state to be make locating people in a specific state very quick and easy. An example output without a group header may resemble:

```
AL   Bob McKinley
AL   Chuck Connors
AL   David Spinley
AZ   Alan Sockworth
AZ   Frank Sputz
AZ   Henry Rollins
```

And an example output with a fancy sort band header:

```
_____________
State: AL
_____________
             AL   Bob McKinley
             AL   Chuck Connors
             AL   David Spinley
_____________
State: AZ
_____________
             AZ   Alan Sockworth
             AZ   Frank Sputz
             AZ   Henry Rollins
```

Obviously a group header can be as simple or fancy as required. Different font types and colors can be used to help

separate groups of data as needed. Aside from bring far more visually appealing for the user, they also aid in locating data that is grouped together much more efficiently.

A group header can contain a mixture of text and database field information. Use the frame charactistics dialogue box to help you build the group header.

52.8.5 Group Band Properties

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Sample Output:

Notice that the Group Footer was printed only after the state code changed from FL!

USER TIP: To force the FL data to begin printing on a new page click on the **Explicit Page Overflow** checkbox [ ] **Before Band Printing, which forces a New Report Page.**

52.8.6 Concatenation Symbol

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Concatenation is a fancy word that means "join together"; it is most often used in the computer programming world, which is why you've probably never heard of it.

The ampersand symbol (&) is used to join together one string field or string variable to another. The length of the resulting string is the sum of the lengths of the two strings. Numeric data types may be concatenated with strings or other numeric variables or constants. In many cases, the CLIP() function should be used to remove any trailing spaces from a string being concatenated to another string.

Examples: clip(NAM:Lastname) & ', ' & clip(NAM:Firstname)
'$' & ITM:UnitCost

Related Topic: Expressions and Formulas

52.9 Dictionary

QMSCAPA Report Builder Features

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The dictionary is the "heart" of the report builder - it contains information on all the database fields used by your program, as well as internal variables and functions that you can use to customize your output. The **dictionary** may be accessed through a **FRAME**. Here is a sample dictionary:

Shown above is a sample dictionary. The dictionary uses an expandable "tree" format to access the different types of information that can be placed inside a frame. The tree above is shown in collapsed form for a better overall view. To gain insight into what the different dictionary categories are, left click on one of the following items in the above screen capture:

- Processed Files
- Functions
- Built-In Variables
- Standard Operators
- Standard Functions
- Calculated Fields
- Gather Totals

A dictionary stores all the data used in this application in an easily accessed format. It also provides access to powerful tools for manipulating data required for fancier reports. You can even create new variables to contain data that is extracted at report generation time!

52.9.1 Dictionary - Built in Variables

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QMSCAPA Report Builder Features

As shown below there are 5 available built-in variables that can be used in a QMSCAPA report. Double left click an entry to select the choice to insert the value into the Contents window of the FRAME properties entry field.

52.9.2 Dictionary - Calculated Fields

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QMSCAPA Report Builder Features

The screen capture above shows a new calculated field being added to the dictionary. A new variable named "TotalCost" is being created that will contain the sum of two database fields (INV:Quantity + INV:Cost). The evaluation process is performed at the end of the page.

The new variable was created by clicking the blue '+' button after highlighting Calculated Fields.

Calculated fields can be looked upon as temporary storage in the computers memory to perform calculations on one or more database fields. This is primarily used for (but not restricted to) calculating invoice totals, inventory balances, etc. By changing the Picture you can have the output modified to better suit your needs. For example, if you are calculating a dollar total you could use the picture @N$-10.2 to display a dollar sign in front of the calculated field.

You can also change where the evaluation process occurs. There are 4 different methods to how fields are calculated:

- On the start of the report
- On each record
- On the end of the report
- On the end of the page

Related Topics: Expression and Formulas

52.9.3 Dictionary - Funtions

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QMSCAPA Report Builder Features

These functions are different than those found in the Standard Functions. These functions are designed by the programmer especially for this pc application. The screen above may be totally blank, with no functions developed at all. Or, it could contain a dozen or more specialized functions that perform a specialized task.

The above screen shows four functions available to this application. You could select one of these functions for your report from this dictionary location.

Some examples of different functions that a programmer could create and store here would be:

- Convert a text string to a propercase statement
- Calculate true cost of an item, to include it's sales tax
- Calculate tariff costs for outbound sales
- Convert a standard date (mm/dd/yy) to a julian formatted date (yyyyddd)

52.9.4 Dictionary - Processed Files

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QMSCAPA Report Builder Features

This section of the Dictionary will be the most heavily used section by you - it contains references to all the databases

and their fields. Depending on your application you may have only one database listed under "Processed Files" or many entries. The screen capture below shows three database files (Inventory History, Vendors and Products):

The above screen capture shows the Processed Files section of the dictionary. In this example there are three databases in this application:

- Inventory History
- Vendors
- Products

For each database you can expand the "tree" to view the database fields that it is made up of. The above example shows the Inventory History tree expanded to show it's database fields. The description for the field is shown under the database name - it is a more "english" looking name for the database field name, which is shown in the second column titled 'Name'. Notice that the database fields shown in the Name column have a prefix (INV:); this prefix is used to identify the database field at it's lowest level. Prefixes allow a programmer to use the same database field name in other database(s) used by this application.

The Processed Files section of the dictionary is used to select database field(s) for use in frames, calculated fields, etc. To select a field simply double click the desired field to insert it into the frame or calculated field.

52.9.5 Dictionary - Standard Functions

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QMSCAPA Report Builder Features

The language used to create this Report Builder has some extremely useful "functions" that programmers use to generate applications. Some of these functions are made available to you to use with your reports.

A function could be described as a means of converting something to something else. Data is manipulated using a

function to generate a desired result. Kind of like a car going through a carwash - it looks one way going in, and another way coming out.

Functions are broken into four "groups":

Here is a more detailed breakdown of the categorized function types:

String Functions

- ALL() - Returns a text string that replicates itself a defined number of times. For example, ALL('A',5) would return the text string 'AAAAA'.
- CAPITALIZE() - Returns a text string with the first letter in uppercase and the remainder in lowercase.
- CHR() - Returns the ANSI character from an ASCII code. For example, CHR(122) would return 'z'
- CLIP() - Returns a string with the trailing spaces removed. Commonly used to properly format names and addresses into a more aesthetic appearing text string; multiple database fields are combined together using the concatenation symbol (&) to form a formatted string. For example, the database field ADR:City that contains the city name 'Tucson' could be combined with the ADR:State field that contains 'Az'. Because the ADR:City database field has 30 spaces allocated to it, and only 6 positions were used for 'Tucson', you would normally have 24 blank spaces:
  Tucson Az
  not exactly appealing! Using the CLIP() function and the concatenation symbol you
  can convert this to: Tucson, Az
  EX: CLIP(ADR:City) & ', ' & CLIP(ADR:State)
  Note that there is a blank space after the comma to "push" the state over one
  position to avoid crowding the comma character.
- DEFORMAT() - Returns a string that contains the unformatted characters of a numeric string. For example DEFORMAT('999-53-9954') returns 999539954
- FORMAT() - Returns a formatted string; knowledge of the PICTURE command is mandatory to make best use of this function. For example SSN = FORMAT(Emp:SSN,@P###-##-####P), which would properly format the database field EMP:SSN to a standard social security number.

- INLIST() - Returns the position of an item in a comma delimited list. For example, INLIST('D','A','B','C','D','E') returns a value of 4
- LEN() - Returns the length of a string. For example, LEN('Scott Daughtry') would return a value of 14.
- LOWER() - Returns the lowercase version of a string. For example LOWER('SCOTT Daughtry') would be returned as 'scott daughtry'.
- NUMERIC() - Returns a true or false. If a string contains only numbers a true is returned. For example NUMERIC('123') would be true, and NUMERIC('1,23') would be false.

SUB() - Returns a portion of a string. You define where the starting and stopping positions are in the string. For example, SUB('Scott Daughtry', 1, 5) would extract positions 1-5 of the string, returning 'Scott'. SUB('Scott Daughtry', 7, 3) extracts 'Dau' - the starting position is 7, and the next 3 positions are extracted from that starting point. You can also work backwards on a string by assigning a negative starting position. For example, SUB('Scott Daughtry', -1, 3) would return 'try'.

- UPPER() - Returns an uppercase version of a text string. For example, UPPER('scoTT') is returned as 'SCOTT'.
- VAL() - Returns the ASCII character numeric equivalent for an ANSI entry. For example, VAL('A') would return 65.

Mathematical Functions

- ABS() - Returns an absolute value from an expression. The absolute value of a number is always a zero. For example, C = ABS(A-B). C would contain the absolute value of the difference of B subtracted from A
- INRANGE() - Compares a numeric expression for an inclusive range of numbers. Returns a value of true if the scope is met, and false otherwise. For example, INRANGE(variablename, 1, 5) would check if the variablename is with the numbers 1-5, and return true if so. The starting number is 1, and ending number is 5.
- INT() - Returns an integer value from a numeric expression. For example, INT(8.5) would return a value of 8.
- LOGE() - Returns the natural algorithym. The natural logarithm of a value is the power to which e must be raised to equal that value. The value of e used internally for these

calculations is 2.71828182846. For example LOGE(2.71828182846) returns 1; LOGE(1) returns 0

- LOG10() -Returns base 10 logarithm. If the value of the expression is zero or less, the return value will be zero. The base 10 logarithm is undefined for values less than or equal to zero. The LOG10 procedure returns the base 10 logarithm of a numeric expression. The base 10 logarithm of a value is the power to which 10 must be raised to equal that value. For example, LOG10(10) returns 1; LOG10(1) returns 0
- RANDOM() - Returns random integer.Returns a random integer between the low and high values, inclusively. The low and high parameters may be any numeric expression, but only their integer portion is used for the inclusive range. For example, RANDOM(22, 80) would return a random number between the numbers 22 and 80.
- ROUND() - Returns a rounded number. For example, ROUND(5163, 100) would return the rounded number of 5163+100 (which is 5200); ROUND(657.50,1) returns 658; ROUND(51.63594,.01) returns 51.64
- SQRT() - Returns the square root of a number.

Trigonometric Functions

- SIN() - Returns the trigonometric sine of an angle measured in radians. The sine is the ratio of the length of the angle's opposite side divided by the length of the hypotenuse. For example, eturns the trigonometric cosine of an angle measured in radians. The cosine is the ratio of the length of the angle's adjacent side divided by the length of the hypotenuse. For example, sineAngle = SIN(45 * 3.142498712
- COS() - Returns the trigonometric cosine of an angle measured in radians. The cosine is the ratio of the length of the angle's adjacent side divided by the length of the hypotenuse. For example, cosineAngle = COS(45 * 3.142498712)
- TAN() - Returns the trigonometric tangent of an angle measured in radians. The tangent is the ratio of the angle's opposite side divided by its adjacent side. For example, TanAngle = TAN(45 * 3.142498712)

ACOS() - Returns the inverse cosine. The inverse of a cosine is the angle that produces the cosine. The return value is the angle in radians. p is a constant which represents the ratio of

the circumference and radius of a circle. There are 2p radians (or 360 degrees) in a circle. For example, acos = ACOS(45 * 3.142498712)
ASIN() - Returns the inverse sine. The inverse of a sine is the angle that produces the sine. The return value is the angle in radians. p is a constant which represents the ratio of the circumference and radius of a circle. There are 2p radians (or 360 degrees) in a circle. For example, asine = ASIN(45 * 3.142498712)
ATAN() - Returns the inverse tangent. The inverse of a tangent is the angle that produces the tangent. The return value is the angle in radians. p is a constant which represents the ratio of the circumference and radius of a circle. There are 2p radians (or 360 degrees) in a circle. For example, TanAngle = ATAN(45 * 3.142498712)

Date/Time Functions

- TODAY() - Returns the operating system date as a standard date. The range of possible dates is from January 1, 1801 (standard date 4) to December 31, 2099 (standard date 109,211). You can use a picture command to change the appearance of the return value. For example, cToday = format(TODAY(), @d01B)
- CLOCK() - Returns the current time based upon your pc bios time.
- DATE() - Returns a standard date for a given month, day, and year. The month and day parameters do allow positive out-of-range values (zero or negative values are invalid). A month value of 13 is interpreted as January of the next year. A day value of 32 in January is interpreted as the first of February. Consequently, DATE(12,32,97), DATE(13,1,97), and DATE(1,1,98) all produce the same result. The century for a two-digit year parameter is resolved using the default "Intellidate" logic, which assumes the date falls in the range of the next 20 or previous 80 years from the current operating system date. For example, assuming the current year is 1998, if the year parameter is "15," the date returned is in the year 2015, and if the year parameter is "60," the date returned is in 1960. For example, HireDate = DATE(Hir:Month,Hir:Day,Hir:Year); FirstOfMonth = DATE(MONTH(TODAY()),1,YEAR(TODAY())) would compute the first day of month

- DAY() - Returns day of month. Computes the day of the month (1 to 31) for a given standard date. For example, OutDay = DAY(TODAY()) to get the day from today's date; DueDay = DAY(TODAY()+2) to calculate the return day
- MONTH() - Returns the month of the year (1 to 12) for a given standard date. For example, PayMonth = MONTH(DueDate) to get the month from the date
- YEAR() - Returns a four digit number for the year of a standard date (1801 to 9999). For example, YEAR(today())
- AGE() - Returns a string containing the time elapsed between two dates. The age return string is in the following format: 1 to 60 days - 'nn DAYS'; 61 days to 24 months - 'nn MOS'; 2 years to 999 years - 'nnn YRS'. For example, nAge = AGE(EMP:Birthday, TODAY()) would compare the database field EMP:Birthday against the computer date to return the persons age.

52.9.6 Dictionary - Standard Operators

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QMSCAPA Report Builder Features

The language used to create this Report Builder allows you to use 'operators' to create and/or compare values stored in your database file(s). Operators are broken into two different groups:

Arithmetic

Addition - Add two variables together to produce a value. The addition sign (+) is used.

Subtraction - Subtraction one variable from another to produce a value. The minus sign (-) is used.

Multiplication - Multiply one variable against another to produce a value. The asterisk symbol (*) is used.

Division - Divide one variable into another to produce a value. The slash character is used (/).

Exponentiation - Raises one variable to the value of a second variable. The carat symbol (^) is used.

Modulus Division - Returns the remainder of one variable divided by another variable. The percentage character (%) is used.

Logical

Choose() - This function is used to perform a logical evaluation and return a value based upon the result. When a condition is evaluated to true the first return value is returned. If a condition is evaluated to false the second return value is returned. For example, CHOOSE(1 > 2, 'A', 'B') would return 'B'; CHOOSE(INV:Sex = 'M', 'Male', 'Female') would return the text string 'Male' if the database field INV:Sex contained a value of 'M'.

And - A boolean operator; used to combine 2 or more logical statements together. Used when you need/want multiple logical expressions to equal TRUE in order for something to occur. For example: INV:Sex = 'M' AND INV:State - 'Az' would require the database field INV:Sex to equal 'M' AND the INV:State database field to equal 'Az' for a value of true to be returned. If either database field did not contain these values then a return value of false is returned. The expressions are evaluated from left to right; if a value of false is returned then the subsequent expressions are skipped over, since a value of false has already been reached. If the INV:Sex database field did not contain a value of 'M' then the INV:State field wouldn't be processed at all - a value of false has already been returned. If the INV:Sex database field contained an 'M', but the INV:State database field contained something other than 'Az', then a value of false is returned, since both items must return a value of true. You can a very long expression with the AND operator. For example: INV:Sex = 'M' AND INV:State = 'Az' AND INV:Birthdate > '01/01/60'.

Or - A boolean operator; used to combine 2 or more logical statements together. Used when a condition can evaluate to a value of false but processing is still desired. For example: INV:Sex = 'M' AND Inv:State = 'Az' OR INV:State = 'Ak' would evaluate INV:Sex; if it equals a 'M' the INV:State field is evaluated. If it contained 'Az' an overall return value of true is reached. If it didn't contain 'Az' it is then checked for a value of 'Ak'. If it did, a an overall value of true is reached.

Not - A boolean operator. Used in conjunction with the Greater Than, Equal To or Less Than operators. For example, INV:State NOT = 'Az'; INV:Age NOT < 45; INV:Income NOT > 30000.

Xor - A boolean operator. Used when an expression can evaluate to true on one side of the equation, but not both. For

example: A XOR B; true is returned if A is true OR B is true, but not both.

Greater Than - The symbol (>) is used for this operator. When you want the left side of an equation to return a value of true. For example, INV:Quantity > 5 would return a true if the INV:Quantity database field was greater than 5.

Lesser Than - The symbol (<) is used for this operator. When you want the right side of an equation to return a value of true. For example, INV:Age < 15 would return true if the database field INV:Age is less than 15.

Equal To - The symbol (=) is used for this operator. When you want an exact match in an equation for a value of true to be returned. For example, INV:State = 'Az' would return a value of true if the database field INV:State contained 'Az'

Not Equal To - The symbol (<>) is used for this operator. When you want a value of true returned when a variable does NOT contain a particular value. For example, INV:State <> 'Az' would return a value of true when it did not contain 'Az'

Greater Than Or Equal To - The symbol (>=) is used for this operator. When you want a value to be equal to or greater than something. For example: INV:Sold >= 325 would return a value of true if the INV:Sold database field was equal to or greater than 325.

Less Than Or Equal To - The symbol (<=) is used for this operator. When you want a value to be equal to or less than something. For example, INV:Sold <= 325 would return a value of true if the INV:Sold database field was equal to or less than 325.

Standard operators can be used to build complicated expressions when you want to "drill down" to highly specific data (which is normally the case). Make sure that the most important criteria is placed first that would (in theory) eliminate the majority of data when the database is scanned. This will speed up the remainder of the operational string when they are executed. Some expression examples:

EMP:Sex = 'M' AND LOC:State = 'Az' OR Loc:State = 'Nv' AND EMP:Haircolor = 'Brown'

STO:Location = 'Iowa' AND PAR:Vendor = 'Hasbro' AND PAR:Onhand <= 100

SAL:Total = INV:Itemprice * SAL:Quantity * SAL:Salestax

53 Report Preview Features

Most QMSCAPA reports include options to print ...
- To printers
- Excel
- PDF
- Rich Text Formatted file (RTF)
- Word document as Windows Meta File

All print options may be previewed to the monitor window.

Report Review Window

A. The **Select Printer button** controls the default or selected printer options.
B. The **Print button** executes the output to the selected printing application or device.
C. The **Zoom in/out button** controls the image magnification levels.
D. The **Layout button** options are 1 page, 2 pages, 3 pages, 4 pages and 6 pages.
E. All pages to be printed may be selected or unselected with a single **Select All** or **Select None** button click. (See the checkbox at the upper left corner of each individual pages.)
F. The **preview navigation controls** advance or retreat a page, a group of pages in the layout or from the beginning or to the end of the document.
G. Previewed documents may be Saved as a PDF.

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Report Preview Window

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53.1 Save-As PDF

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The ***Save as PDF button*** on the Print Preview window opens the following dialog:

☑ ISO 9001:2015 Implementation & Templates Kit

A. First set the *file name and folder location* by clicking on the **1st Click to Save the Folder PDF Name button**. The Users Default folder may be set in the Users Profile options.
B. The Document Name may be edited during the Save function.
C. The Create PDF and View button is not available (dimmed) until the file and folder have been set

The Windows File Explorer will open into the default location, which may be set by the QMSCAPA User's profile.

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D. Once the File Name and location have been saved the **Create PDF and View button** becomes active.

The PDF is created and a shortcut hyperlink is displayed . Click on the **Done button** to exit the Preview module or the **Return to Preview button** for more options.

Tags: quality management software, corrective action software, iso management software

54 Security Aspects Table

Menu Option

A)The Company Security Aspects and the Security Access for each affiliated person may be accessed through the ...

1)Main Menu > File option
2)Company Setup >
3)Company Security Access Table
4)Company Security Aspects Table

Security Aspects Browse Tables

In the image shown below ...

A)Add Physical, Logical and Virtual Security Aspects to the Table.
B)Add, Edit and Delete controls for the Security Aspects Table.

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C)Print the Security Aspects Journal.

Related Topics:

•Security Access Table

Tags: quality management software, corrective action software, iso management software

55 Supply Chain Management

The QMSCAPA Supply Chain Management Tools consist of ...

- ❑ A database for **Supplier Survey Questionnaires** that may easily edited or copied to modify as an additional set of Supplier Survey Questionnaires.
- ❑ A Supplier/Vendor Table with relationships for ...
  - ❑ Supplier Survey Questionnaires sent to specific Supplier/Vendors;
  - ❑ Records for Surveys completed;
  - ❑ Supplier/Vendor worksheets for internal evaluations and scoring.

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Related Topics

- Supplier Survey Questionnaires
- Supplier Survey Question Form

55.1 Supplier Survey Questionnaires

Menu Option

Main Menu > Edit Tables > Vendor / Supplier Survey Questionnaires

Browse Table for Supplier / Vendor Survey Questionnaires

- Create one or more Supplier / Vendor Survey Questionnaires that are appropriate for your business and Management System.
- Print the Question Set for sharing or editorial review. (Prints the highlighted record in the Table)
- Create a New Question Set by Duplicating and editing an existing Question Set.
- Assign the Survey Questionnaire to one or more suppliers.

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Form for Supplier /Vendor Survey Questionnaires

1) General tab

A. QMSCAPA assigns the Supplier Question Set a numeric Id. The end-user may create a List Name and the Title for the Supplier Survey Questionnaire. The Department using the Survey and the version of the Survey Questionnaire may be recorded. Also, Survey Questionnaires may contain questions that require a Pass or Fail response (e.g. Yes or No) and written text response.

B. Approval and Use of the Survey may be recorded.

C. Record the intended purpose of the Survey and other instructions to end-users. By default setup this field is not printed on Surveys that are to be sent to Supplier /Vendors.

2) Questionnaire Text

A. The **Text for Top of Form** is user-defined and intended to print on Surveys that are to be sent to Supplier /Vendors.

B. The **Text for Bottom of Form** is user-defined and intended to print on Surveys that are to be sent to Supplier /Vendors.

3) Questions in the Questionnaire Set

A. The **Survey Questions** in the Questionnaire Set may be ordered by a **Section Sequence Number** that is independent of the Section Name.

B. The Row Number may be used to control the order of questions within the **Section Sequence Number**.

Related Topic:

- Supplier Survey Question Form

Tags: quality management software, corrective action software, iso management software

55.1.1 Survey Question Form

Menu Option

Main Menu > Edit Tables > Vendor / Supplier Survey Questionnaires

The Supplier Survey Question Form may be accessed from the Supplier Survey Questionnaire Set form.

Browse Table

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I. Supplier Survey Question Form

A. The Survey Question may be phrased for a question that requires a response that is ...
   1. Pass or Fail question
   2. True of False
   3. Yes or No; Y or N
   4. Text
   5. Both Pass or Fail and Text

B. Question Placement Controls allow the end-user to ...
   1. Position the Question anywhere in the Questionnaire by entering the appropriate Section Sequence Number, Section Name and Row Number within a Section.

C. Question Response Requirements are controlled by the end-user ...
   1. Enter the appropriate text for Pass or Fail;
   2. Check the check-box if a Pass or Fail (Yes or No) response required;
   3. Check the check-box if a Text response is required;
   4. Provide the Survey Respondent with additional guidance for answering the question.

Tags: quality management software, corrective action software, iso management software

55.2 Assign Survey Questionnaire Set

Menu Option

Main Menu > Edit Tables > Vendor / Supplier Survey Questionnaires

Supplier Survey Questionnaires may be assigned to a Supplier /Vendor by first clicking on the **Copy to Vendor button** shown in the Browse Table below.

Browse Table

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1. Step (1) highlight in the table show below a Survey Question Set that should be assigned (related to a supplier). Multiple Survey Sets may be assigned to a single Supplier.
2. Step (2) Click into the Vendor Id field and the Supplier /Vendor look-up table will open. Select a Supplier from the table.
3. Step (3) Click on button (3) Click here to Copy Question Set to Vendor Table.
4. Repeat these steps above to assign Survey Questionnaires to other Supplier /Vendors.

Tags: quality management software, corrective action software, iso management software

56 Supplier/Vendor Evaluations

The QMSCAPA Supplier/Vendor Evaluations tool consist of a Vendor Table, Evaluation Criteria Template Set and a Supplier/Vendor evaluation worksheet.

1) The Vendor Criteria Evaluation Sets menu option opens a Supplier/Vendor Criteria Evaluation Table.
2) The Vendor/Supplier Evaluations menu options opens a table of the actual Supplier/Vendor Evaluations, which have been performed and recorded.
3) Also, the Vendor/Supplier Evaluations may be accessed from the Quality Measurements main menu option.
4) *Supplier Evaluations are intended for internal use.*

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56.1 Supplier/Vendor Criteria Evaluation Table

The ***Supplier/vendor Criteria Evaluation Table*** may be accessed through the ***Edit Tables main menu*** option. The Supplier /Vendor Evaluation methods includes setting a criteria for the evaluation and then scoring the supplier or vendor on a scale of 1 to 10 for 10 individual criteria.

1) Identify the Author and Approval Person for the Supplier /Vendor Evaluation Criteria.
2) Set the minimal score for an 'Approved' vendor; set the minimal score for a 'Conditional' vendor.
3) Optionally you may include or exclude 1 or more criteria items.
4) Use the Criteria field to describe the aspect to be evaluated.
5) The evaluation criteria 1 through 5 appears in the 1) By Evaluation Set Identification and the 2) Evaluation Criteria

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6 through 10 Tab.

Related Topics:

- Supplier /Vendor Evaluation Table
- Supplier /Vendor Evaluation Form
- Printing Supplier/Vendor Evaluations

56.2 Supplier/Vendor Evaluation Table

1) The Supplier/Vendor Evaluation upper table shown below provides direct access to the Vendor file, including controls for adding, editing and deleting supplier/vendor information.
2) The evaluations recorded for the Supplier/Vendor appear in the lower browse table.

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Related Topics:

Supplier/Vendor Evaluation Form
Printing Supplier/Vendor Evaluations

56.3 Supplier/Vendor Evaluation Form

1) The ***Supplier/Vendor Evaluation Form*** is linked to the Supplier/Evaluation Criteria sets file. Therefore, you must select the criteria that is to be used for evaluating the supplier/vendor.
2) The criteria for an evaluation is designed for ten elements, which may be scored with a value of 1 to 10 and 10 being the highest score.
3) The ***Supplier/Vendor Evaluation Score*** may entered or adjusted with the spin control.

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Related Topics:

Printing Supplier/Vendor Evaluations

Supplier/Vendor Criteria for Evaluation

56.4 Printing Supplier/Vendor Evaluations

Vendor /supplier evaluations may be accessed from the ***Quality Measurements main menu*** option.

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1) The ***Print Supplier Evaluations button*** starts the Report Builder and displays a window to select the Vendor Id and to enter a date range for the evaluations to be printed.

A sample ***Supplier/Vendor Evaluation Report*** is shown below.

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SUPPLIER /VENDOR EVALUATION

Supplier /Vendor Evaluations by Selected Vendor Id#

From 1/01/2014 Through 1/30/2014

ABCI Consultants 16835-236 Algonquin Street Huntington Beach CA 92649 USA	Status: Active Certification: ISO 9001:2008 | Certification: 8006442056 Expiration Date: 12/31/2015
Date of Evaluation: 1/24/2014 Evaluation Set: 1 Author: Allison Hwang Evaluator(s): Jack T. Bogle	Description of Evaluation Criteria: Example for QMSCAPA

Evaluation Criteria	Score
Rate your experience of the quality of service provided by the suppliers / vendor personnel personnel.	10
Rate your experience of orders being correct as ordered?	10
Rate your experience of on-time delivery. Did you consistently receive the product on-time as expected?	10
Rate your experience of the quality of the products ordered.	10
Rate your experience with the value received for the products ordered.	10
Rate your experience with the packaging and intact delivery condition.	10
Rate your evaluation of the results of Supplier Quality Survey. Enter zero if the supplier/vendor was not responsive.	10
Rate your experience with the supplier's Customer Services.	10
Rate your experience with product realization compared to product specification.	10
Rate your over-all experience with the supplier/vendor.	10

Minimum Score for APPROVED Supplier Status: 85 | Minimum Score for CONDITIONAL Supplier Status: 70 | Total Score: 100

Comments: Comments about Vendor 1

57 Task Table

Action Task list may be created as independent tracking records or linked to a CAPA or an Non-conformance report.

When the Window is opened the table will show the open or incomplete Task that have been assigned to the User that has logged into QMSCAPA.

See the User Profile Options to automatically open this window upon login.

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Task list may be added within the CAPA form or the AIMNCR form as shown in the image below.

QMSCAPA Task list inside the Non-Conformance form.

57.1 QMSCAPA Task Linked to Outlook

Menu Option

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The TASK table may be accessed from the Icon Menu Bar or the Main Menu option > Browse Logs > CAPA Task Assignments. Also, TASK assigned to a specific CAPA may be accessed directly form the CAPA record.

Browse Task Table

A TASK entered into QMSCAPA that may be copied into the Microsoft Outlook TASK table. A TASK may be associated (linked to) with a CAPA or a Non-conformance.

Form to Copy a QMSCAPA Task to the Outlook Task Table

To copy the QMSCAPA TASK to Outlook access the TASK Table and open the TASK RECORD.

To copy the the TASK record to a **Microsoft Outlook Task Table** simple click on the **Create Outlook Task button**.

Tags: quality management software, corrective action software, iso management software

57.2 Create Outlook Task

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A. When Microsoft Outlook is active click on the **Send to Outlook button** to complete a copy.
B. The **Refresh Log button** may be used to verify a that copy was successful.
C. The Outlook Task will appear in the Outlook TASK log when the OUTLOOK connection is active.
D. Points the the **Outlook TASK Log TAB** and shown below:

Tags: quality management software, corrective action software, iso management software

58 Training

QMSCAPA provides a method of ...

- Creating a personnel training plan;
- Documenting mgtremgtraining programs;
- Recording Student training;
- Recording training effectiveness.

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- The **Training Programs** menu option opens a table of training courses and training elements (components of the course).
- The **Trained Students** menu option opens a table of personnel that have been trained on specific Training Programs.
- The **Training Schedule** menu option opens a table of the Training Programs, which have been scheduled for specified students.

58.1 Training Programs

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To *create or edit a Training Program* select ..

Edit Tables > Training > Training Programs

1) Section (1) shows a browse table of Training Programs. Training Programs is intended as a generic term for training course, training workshop and, or training class.
2) Section (2) shows a window form for adding or editing a Training Program.
3) Section (3) shows a browse table of the Training Elements that are part of or components of the Training Program. For example, a training course may be extended over multiple weeks and each weekly class may be defined within the training element.

58.1.1 Training Program Elements

Training Elements are sub-components of a Training Program. Training Elements may be used to represent:

a) Workshops
b) Chapters
c) Days
d) Assignments
e) You name it!

1) Section (1) shows a browse table of Training Programs.
2) Section (2) shows a browse table of Elements of a highlighted record in the Training Programs browse table.
3) Section (3) shows the window form for adding or editing a training element.

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58.2 Training Schedule Reports

Training Schedule Reports include:

1. All Training Programs that are scheduled with a user-defined date range, which includes the enrollment.
2. A single selected Training Program schedule and enrollment.
3. A single selected Training Program sign-in and sign-out sheet.

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Training Schedule Table from QMSCAPA v1.29.15

58.3 Trained Students

To *create a Training Record* select ..

Browse Logs > Training > Trained Students

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The Trained Students browse table is designed for enrolled students and students who complete a Training Program.

1) Section (1) shows a browse table of enrolled students.
2) Section (2) shows a window form for adding and editing *training records*.

58.4 Training Schedule

To *schedule a Training Program* select ..

Browse Logs > Training > Training Schedule

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1) Section 1 shows the browse table for Training Programs, which have been scheduled.
2) Section 2 shows the window form for recording or scheduling a Training Program.

58.4.1 Adding Students to a Schedule

To *enroll students* and *schedule a Training Program* select ..

Browse Logs > Training > Training Schedule

1) Section 1 shows the browse table for Training Programs, which have been scheduled by the date scheduled and Training Id.
2) Section 2 shows the browse table for Students that have been enrolled into the Program that is highlighted in

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table (1). Use the [Add Student] button to record a student enrollment.

3) Section 3 shows the window form for the enrolled student and the status of their training outcome.

58.4.2 Adding a Personnel Group to a Schedule

Menu Option

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Browse Table

The ***Add by Group button*** opens a tool to assist with adding multiple persons to a scheduled training.

By Selection Form

A. Select the Training Program scheduled and an appropriate Status.
B. The ***Search button*** opens a window with Fast text search options. For example, search the 'Quality Department' and the window will display everyone in the Quality Department.
C. Use the ***+ Person (Selected) button*** to schedule the selected personnel record.

By Group Form

- 1st Select a Scheduled Training Program and Status
- 2nd Search and/or Tag a Person in the table
- 3rd Click on the Process Tagged button to copy the tagged person records to the the selected Schedule Id.

Tags: quality management software, corrective action software, iso management software, iso 9001

58.5 Training Schedule Calendars

QMSCAPA provides options to display the Training Schedule in a Monthly or Weekly Calendar.

The calendars feature a 'drag-drop' shuffling feature for rescheduling.

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58.5.1 Training Schedule Month

QMSCAPA Monthly Training Schedule Calendar options:

- ✓ The Calendar display may be resized to fit the monitor.
- ✓ Toggle between the monthly or weekly views.
- ✓ Click on an entry then drag and drop to a new date for rescheduling.
- ✓ Right-mouse click for Edit, Print or View details.
- ✓ Refresh the Window to adjust the resized window.

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✓ Refresh the Data to check of additional records that may have been added by other users.

58.5.2 Training Schedule Week

QMSCAPA Weekly Training Schedule Calendar options:

- ✓ The Calendar display may be resized to fit the monitor.
- ✓ Toggle between the monthly or weekly views.
- ✓ Click on an entry then drag and drop to a new date for rescheduling.
- ✓ Right-mouse click for Edit, Print or View details.
- ✓ Refresh the Window to adjust the resized window.
- ✓ Refresh the Data to check of additional records that may have been added by other users.

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59 Utilities

59.1 Export to Excel

Menu Option

QMSCAPA includes an option to export commonly used files to an Excel file.

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Export Menu Form

A. As shown in the image below, to export a QMSCAPA file simply select the appropriate Export Control button. The Export Folder and File fields shows the default export file folder (path) and Excel file name.

Tags: quality management software, corrective action software, iso management software

59.2 File Manager (Internal)

The internal FILE Manager, which is embedded within QMSCAPA™, is designed to keep QMSCAPA™ database files working in top form.

It most cases if QMSCAPA™ encounters a file error the 'error message' to the user will include the file name. Write down the file name and go to the File Manager as shown below. You may need to restart the application.

USER TIP: Use the FILE MANGER as a single user only!

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Select the appropriate file with the offending error by using the mouse pointer select or deselect a specific file. Left click on the file name places a check-mark to the left of the file name. First use the Freshen button to correct the file problem. Other options are described below:

- [Tag All] is used to select all files.
- [UnTag All] is used deselect all files.
- [Build] is used to 'Re-index' the selected file(s).
- [Pack] is used to remove previously 'deleted' records from the selected file(s).
- [Fix] is used to repair the selected file(s). Fix must only be used if the file doesn't come right with Freshen. Don't use Fix on working files, as it can sometimes corrupt them. Fix is your last resort.
- [Freshen] is used to create a new file and copy all the old records out the old file and put them in the new file. Freshen is the best for fixing files, for getting rid of deleted records, and re-building keys all in one. This effectively removes all duplicate entries (which might be causing the Build to fail) and also can act as an effective fixing of possibly corrupted files.
- [Info] is to look-up the quantity of records in the selected file(s) and show the File Path.
- [Create] is used to create a non-existent file.
- [Done] closes the File Manager.

Some database Build, Freshen and Repair functions may need to be done using the standalone File Manager (External).

59.2.1 File Access Error

If QMSCAPA ENCOUNTERS FILE ACCESS Error message (QMSCAPA may or may not close down?

Unfortunately, magnetically stored data files can get tweaked and or damaged due to break-downs of hardware and network interruptions.

1. Make sure that you are the only user in QMSCAPA when you attempt to correct a file access problem.
2. Identify the offended file name, which typically appears in a window similar to the one that appears to below.

3. Navigate to FILE > COMPANY SETUP > FILE MANAGER.
4. Locate the offended file file name in the File Manager browse table and mouse-click or check in the empty space left of the file name.
4. Click on the [FRESHEN] button, which will launch a utility application that will compare the file and attempt to recover and/or correct it. The process make take a few moments to a few minutes depending upon the size of the file and the type of corruption that may have occurred. Please wait until the process is complete.
5. Resume using QMSCAPA to learn if the problem reoccurs. If the problem persist return to the File Manager and repeat the steps above but using the [FIX] button.

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59.2.2 File Manager Info Button

The File Manager Info button is a tool to inspect the current location and health or status of QMSCAPA files.

1) To use the Info button first click on the Tag All button.

2) With all files or selected files 'checked' click on the (i) Info button.
3) A file with a good status will be shown at the end of the file path.
4) A file with another status will be display with an error message.

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59.3 File Manager (External)

The External FILE Manager is a standalone application that must be installed in the same directory as your QMSCAPA™ database files (filename.tps). Therefore, to install **FM3QMS.exe**, most Windows computers will require:

1. An Administrative User login to the computer or server where the QMSCAPA™ database files (filename.tps) are located.
2. All QMSCAPA users should be logged out of the application and all of the databases should not be in use.

It most cases if QMSCAPA™ encounters a file error the 'error message' to the user will include the file name. Write down the file name and go to the File Manager as shown below. You may need to restart the application.

USER TIP: Use the FILE MANGER as a single user only!

When **FM3QMS.exe** is launched:

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1. The select the folder where data files are stored will open.

2. Once the 'Data Path' is selected all databases are scanned for errors and an attempt is made to automatically correct any problems found.

Once the scan and repair process has completed the application will pause momentarily allowing the user to manually inspect the files.

If you intend to inspect the files manually then click on the **Use the File Manager button**.

Select the appropriate file with the offending error by using the mouse pointer select or deselect a specific file. Left click on the file name places a check-mark to the left of the file name. First use the Freshen button to correct the file problem. Other options are described below:

- [Tag All] is used to select all files.
- [UnTag All] is used deselect all files.
- [Build] is used to 'Re-index' the selected file(s).
- [Pack] is used to remove previously 'deleted' records from the selected file(s).
- [Fix] is used to repair the selected file(s). Fix must only be used if the file doesn't come right with Freshen. Don't use Fix on working files, as it can sometimes corrupt them. Fix is your last resort.
- [Freshen] is used to create a new file and copy all the old records out the old file and put them in the new file. Freshen is the best for fixing files, for getting rid of deleted records, and re-building keys all in one. This effectively removes all duplicate entries (which might be causing the Build to fail) and also can act as an effective fixing of possibly corrupted files.
- [Info] is to look-up the quantity of records in the selected file(s) and show the File Path.
- [Create] is used to create a non-existent file.
- [Done] closes the File Manager.

59.4 IMPEX for QMSCAPA

Caution: IMPEX for QMSCAPA is for System Manager Use Only

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IMPEX for QMSCAPA is an external file import utility for importing Customers, Items, Employees and Suppliers. A user may map a separate Excel file for customers, items, employees and vendors. The program provides a method to match data fields from Excel fields to QMSCAPA fields by mouse click, drag and drop actions. The matrix of mapped fields may be saved and reused.

QMSCAPA files names that may be imported:

socustomers.tps
soitems.tps (the NAME field is the part number field)
employee.tps

vendors.tps

Default data location of QMSCAPA files

c:\users\public\public documents\ABCI\QMSCAPA

Caution: Backup your QMSCAPA data prior to using using IMPEX.

- An import will append to existing data
- If you don't like your first results imported, then quit IMPEX
  - delete the files above,
  - restore these files from your back-up
  - restart IMPEX and try again

IMPEX for QMSCAPA may be downloaded from [ABCI-Software.com]

59.5 Import from Excel Wizard

Menu Option

QMSCAPA provides an *Excel file import utility* for the most common files used in other external programs.

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Wizard Forms

Import Tips

Preparing the Excel file for Import

1. First export sample data to an Excel file from each file that you wish to import.
2. The exported file may be used as a template for arranging your data for import.
3. Each QMSCAPA file contains at least one *unique record identifier field*. Opening the exported Excel file will help you identify the Record Id field. These fields must be prepped to contain a unique numeric value. In Excel you can use a formula in the appropriate field column to automatically number each row in Excel.
4. Arranging your Excel column data into the same sequence of the appears in the exported template can also reduce the amount of field mapping that may be necessary inside the QMSCAPA import wizard.

The ***Excel Import Wizard*** opens to a table of previously saved File Import Setups. The Import Setup show *Excel Columns* that are mapped to the QMSCAPA table fields

A. In the image below, 'The Table Name & Description' identifies the QMSCAPA file that will receive the Excel file.
B. The saved Import setup may be used or a new Import Setup may be created.
C. Select a saved Import Setup or create a new setup and then click on the Next button.

A. In the image below, the details of the Excel file to be imported are needed to proceed. Enter the Excel file name and path or use the [...] navigation button to locate the file. The 'Start importing at row' may be used to skip a header row that may exist in the Excel file. The 'Rows to Import' may be used to limit the import to a specific quantity of rows or records in the Excel file; set to zero (0) to import all rows).
B. The' Table to import to' contains the QMSCAPA tables that may accept imported data from Excel.

A. In the image below the field mapping window is shown. The 'Sample from the Excel file' section shows the first few rows of the Excel file that has been selected for import.
B. The the table in the (B) section shows the QMSCAPA fields. The Excel columns may be mapped to the QMSCAPA table fields by click and dragging from the Excel section and column to the QMSCAPA table and column.
C. The table in section (C) shows the results of the mapping activity. Click on the Import button once the column/field mapping has been completed.

Related Topics: Export to Excel Options

Tags: quality management software, corrective action software, iso management software

59.6 Moving QMSCAPA

Moving QMSCAPA from a single user, local computer, to a Windows Remote Desktop Server with Multiple Users.

PLEASE READ ALL THE WAY THROUGH THE PROCESS BEFORE BEGINNING STEP 1.

1. First make a back-up copy of the ABCI directory structure in the local computer.
   a. The default location is C:\Users\Public\Documents\ABCI
2. Next UPDATE the QMSCAPA application on the local computer to the latest version prior to moving, and
   a. run the application, login, open the CAPA log and print the CAPA log before moving to verify the UPDATE was successful
3. Next, after logging in as a Server Administrator, install the latest version of the QMSCAPA DEMO on the new **Windows Remote Desktop Server** location. It should be the same version as the UPDATE used in Step 2.
   a. ***DO NOT USE the UPDATE for a new installation on the SERVER.***
   b. We recommend installing to the DEMO to the default location to easily apply future UPDATES.
4. Start the newly installed DEMO on the SERVER and allow the setup process to continue, which may take a few minutes before the QMSCAPA login window appears.
   a. The default login and password for the DEMO 'mgtrep';
   b. Open the CAPA log and open a CAPA record;
   c. Save and Close the record.
   d. Quit QMSCAPA.

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5. From the local computer, copy the entire previous ABCI sub-directory to the same location on the new **Remote Desktop Server** location.
   a. The default location is C:\Users\Public\Documents\ABCI
6. Restart QMSCAPA on the **Remote Desktop Server** and test QMSCAPA for proper operation.
   a. Open the CAPA log browse table.
   b. Print the CAPA log report (assuming you have configured a default printer or print-to-PDF driver.
7. Under the QMSCAPA *top menu option* select **Security** > **Register License**; the Register License window will open.

   a. Apply the XML license file to the new **QMSCAPA** installation on the **Remote Desktop Server**.
   b. ***DO NOT OPEN THE XML license file with your Email client.***

59.7 Remote Desktop Connection

The Remote Desktop Connection feature in Windows

Remote Desktop Services (RDS) is one of the core virtualization technologies available in Windows Server (2008/2012/2016). Microsoft is progressing in its vision to provide the best virtualization platform for accelerating and extending desktop and application deployments from the secure data center to any device. In addition to the traditional session virtualization scenario (formerly known as “Terminal Services”) Remote Desktop Services is expanding its role to provide an extensible platform for a Virtual Desktop Infrastructure (VDI).

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Advantages and Benefits of Using a Remote Desktop Server

- Remote Desktop Services allows a user to access applications data and even an entire desktop running on a remote computer over a network.
- The client access device can either be a full rich Windows personal computer or a thin client (such as Windows CE device).
- Remote Desktop Services works by allowing individual applications or an entire desktop to run on a server rather than on the user's workstation.
- Remote Desktop Services simply sends screen images to the users and the user's machine in turn sends keystrokes and mouse movements back to the server. By doing this Remote Desktop Services allows clients to run applications or desktop environments that they might otherwise not have the hardware or bandwidth to support.
- On the server applications and desktop environments can either run as shared sessions or in the context of a virtual machine environment (aka virtual desktop infrastructure or VDI).

Windows Server Remote Desktop User CAL

A Windows Server Remote Desktop User CAL permits one user (using any device) to access or use the server software. User CALs are likely to be more cost effective than Device CALs if there are multiple devices per user (for example a

user has a laptop and handheld computer accessing Windows Remote Desktop Services)

QMSCAPA User Configuration Tips:

1. Remote Desktop Connections can be fine-tuned to create a seamless user experience between the Remote Desktop Server and the users local computer. It is easy for the RDP User to switch from the local computer to the remote desktop.
2. Add Microsoft Office to enhance the users experience and to interact with QMSCAPA.
   a. QMSCAPA can use the Spell Check features in Microsoft Word.
   b. QMSCAPA can copy many of the browse tables to an Microsoft Excel file.
   c. QMSCAPA can launch the default Email client on the Server and copy data directly into the Email composition window from the Customer Feed-back, CAPA and the AIM-NCR Logs.
3. Add a 'print to PDF' driver or application for printing.

a.

Related Topic: Using Local Drives in an Remote Desktop Connection

59.7.1 RDC: Using Local Drives

Remote Desktop Connections (RDC) can be fine-tuned to create a seamless user experience between the Remote Desktop Server and the users local computer.

Inside the RDC Local Resources Tab local computer options can be configured, including:

- Audio
- Clipboard
- Drives
- Keyboard
- Printers

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- Storage Devices

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59.8 Spell Check

F7 = Spell Check

***Spell Check** is available on many of the window forms that contain text fields:

1) Click inside the text field and then press the **'F7 key'**;
2) The 'F7 key' will open the spelling suggestions window with options to Ignore, Change, Add, Ignore All, Change All and/or Cancel. Optionally a word can be typed directly into the [Replace with] field.

***Spell Check** requires Microsoft Office installed on the client computer.

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59.9 User-Defined Help

Viewing help when your application runs

To view a help tip when your application is running, do one of the following...

- Click on the Windows "?" button at the top right corner of the window, and then click on the control that you want to see the tip for. So if you wanted to see the help for say an OK button, then you would click on the "?" button and then on the OK button.
- Right click on the interesting control, and then choose "What's This'.
- Give the interesting control the focus (by selecting it with the mouse, or tabbing to it) and then press F1.

After you've just started using the **User-defined Help** (**UDH**) there will obviously be no tips entered, and you will see a message saying there is no help for that control. To see how to add, and format the help, read the next section.

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Editing Help Tips at runtime

To edit the tips at runtime, you need to bring up the tip (using Right-Click What's This, F1 or the Question Mark icon) and then use the following hot-keys to do the necessary editing:

Alt-E - to edit the tip

Alt-C - to format or configure the tip Editing Tips

To get to the first screen press Alt-E (for Edit) while viewing a tip. You will see a regular looking memo box which contains the tip for the text. Apart from typing in the actual text, this is where you can also place buttons, hyperlinks, web links, highlighted text, horizontal lines etc. Each of these items is discussed below.

Bullets
To place a bullet in the text use <T>. Note: You must have a space after the bullet (before entering text) otherwise you will get a **? Control** not completed **Line xx?** message.

Buttons
To place a button inside the text, put the following in the text. <**B1**> For the second button use <B2> etc.
To configure the action of the button. Go to the Format/Configure window (**Alt-C**) and then left click on the button, then right click to see the menu, choose Properties and then configure what you would like the button to do.

For more options on how to configure button see the Configuration information.

Horizontal lines
You can break up your tip using horizontal lines. To place a horizontal line in your tip, place the following on a line by itself <**HR**>

Internet Web Page links
To place an active hyperlink to a web page place the page's URL inside sharp brackets, like this:

<www.abci-software.com>
<http://www.abci-consultants.com>
<C:\users\public\documents\myHtmlPage.htm>

Formatting or Configuring Tips

To get to the screen press Alt-C (for Control) while viewing the tip. You can then set the color and font of text, the actions for buttons, the destinations of links etc.

Important: To select the control you want to edit properties for, left click on the control so it becomes highlighted and then right click on the control to see the menu. When you have finished setting all the properties right click anywhere on the window to Save and Exit, or Cancel.

Highlighting & Formatting Text
To format the text, select the text (left click) and then right-click to get the Popup menu. Choose Properties. You can then edit the font, color and style of the text by pressing the ... button.

You can also repeat the last format by choosing the Repeat Last Format option in the Popup menu.

You can also:
Separate a piece of text from the surrounding text, so that it can be formatted later, place "pipes" around it. Pipes are vertical line characters (often of the backslash key on the keyboard). They look like this |. Only do this for highlighting single words or short phrases. To highlight an entire line, use the formatting method mentioned above.

So for example if you had the sentence "Click on the OK button to save the record", then you could prepare the OK button for highlighting by placing pipes around it, like this -

Click on the **|OK|** button to save the record

Note that placing pipes doesn't highlight the word, but it allows you to format that word separately from the text around it later.

Remember you can use the Windows Character Map to copy Wingdings characters and paste them into the Help Tip text. While formatting the control you can set the font to Wingdings and suddenly you will have all sorts of useful pictures!

Buttons
To place a button inside the text, put the following in the text. <B1> For the second button use <B2> etc.
To configure the action of the button. Go to the Format/Configure window (Alt-C) and then left click on the button, then right click to see the menu, choose Properties and then configure what you would like the button to do.

60 Vendor Table

The Vendor Table may be accessed through the Main Menu > Edit Tables option

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The Vendor Table window is displayed below:

Related topics:

- Vendor Edit Window;
- Vendor Reports.

60.1 Vendor Edit Window

1) The General tab shows Vendor name, address and contact information.

2) The Quality Management System tab shows ISO certification information.

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3) Evaluations tab contains a journal of evaluations for the specific Supplier/Vendor record.

4) Survey tab contains a journal of Survey Questionnaires for the specific Supplier/Vendor record.

5) Attachments tab contains a journal of electronic documents related to eh Supplier/Vendor

6) Additional Information for Supplier /Vendors

60.1.1 Quality Management System

QMSCAPA includes fields for tracking survey information about supplier or vendor Quality Management Systems.

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60.2 Vendor Reports

The default Vendor List may be printed from the Vendor Table window.

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Additional Vendor Reports may be accessed through the Reports > Report Builder and Reports Menu as shown below:

60.2.1 Sample Vendor Report

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Vendor List (By Tier Level)

Printed 2/11/2012

Tier Level 1 Vendors

ABCI Consultants 16835-236 Algonquin Street Huntington Beach CA 92649 USA Contact Information: ---------- Jack Bogle, Director of Business Development Phone 1: Main:800-644-2056 jacktbogle@abci-consultants.com , Phone 2: Fax:714-442-9994	Vendor Id Number: 1 Vendor Approved: No Vendor Status : Active Vendor Tier Level: 1 Vendor QMS : ISO 9001:2008 ISO Certification # : 8006442056 Certification Expiry: 78530

Comments: The is the commment/notes field in the Vendor record.

Tier Level 2 Vendors

AAA Quality Systems 222 East Clinton Street Suite W9 Anaheim CA 92870 USA Contact Information: ---------- Jim Beam, President Phone 1: Office:800 840 9439 jimbeam@qualitymanagementsystems.us , Phone 2: Cell:800 675 2415	Vendor Id Number: 2 Vendor Approved: No Vendor Status : New Vendor Tier Level: 2 Vendor QMS : None ISO Certification # : None Certification Expiry: 0

Comments: ISO Standards and certifications are very sound management systems recognized worldwide for giving a business the competitive edge, client confidence and market place leverage.

All whom are concerned about providing excellent Customer Satisfaction for a product or service.
All whom are concerned about improving quality of a product or service.
All whom are concerned about reducing the cost and waste of providing a product or service.
All whom are concerned about the environment and the carbon footprint of providing a product or service.
All whom are concerned about the occupational health and safety of their citizenry in providing a product or service.
All whom are concerned about business continuity in the event of an emergency or disaster.
All whom are concerned about the security of intellectual property, proprietary trade secrets and privacy of its customers.

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61 Version History

QMSCAPA for Workgroups, 1.48.1 < What do the version numbers mean?

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QMSCAPA™ is quality management software designed by a user group of quality professionals, including assessors, auditors, consultants and quality managers for quality management systems. If you have an idea or new feature that you would like to see in **QMSCAPA** please join our user group by completing our web form.

Do you have an idea for a new feature in **QMSCAPA**? Let is know by sending an email with your feature request to our support group. (sherlock @ abci-software.com). Click here to see what is planned on our list of new features.

10/09/2015 v1.32.16

- Enhanced the AIM NC Reporting Module, which includes new report templates
- Enhanced the Quality Dashboard
- Enhanced the CAPA Task List report template
- Added a new Export to Excel feature for key files
- Added a new Import from Excel Wizard
- Added batch entry feature for the On-time Delivery data from external programs
- Added a copy to Excel feature to the Document Control Index
- Added a copy to Excel feature to the Records Control Index
- Enhanced the Customer Table
  - Activated a Customer Type field and validation table for classification of customers.
- Enhanced the Risk Assessment and Management Module
  - Added Risk Impact Statements to the Risk Aspect module
  - Added Risk Response and Risk Status fields to the Risk Aspects module
  - Added Risk Type field to the Risk Assessment module
  - Added a Applicable Control Table to the Risk Assessment module
- Enhanced the default Monitoring & Measurement Device reports.

06/01/2015 v1.31.5

- Adjusted CWG group filter for CAPA display
- Restored copy feature in the On-time Delivery Calculator
- Enhanced the Supply Chain Management module

- Added a sample Supplier /Vendor Survey Questionnaire
- Click here to download a PDF copy of the QMSCAPA Supplier Survey Questionnaire

04/10/2015 v1.30.03

- Enhanced the Document Version History log to sync with the document Current Revision date.
- Enhanced the Monitoring & Measuring Device/Equipment Table to include intervals for scheduling calibrations and maintenance
- Added two new reports for scheduling Monitoring & Measuring Devices for calibration or maintenance
- Task may be linked to the AIM-NCR form
- Added additional AIM-NCR reports
- Added a Training Sign-in & Sign-out sheet
- Added the Job Title to the employee training look-up table
- Added spell checking to the Customer Satisfaction Survey Sets
- Report templates have been updated

03/20/2015 v1.29.14

- Updated the QMSCAPA CAPA Window Form to provide an expanded Root Cause and Corrective Action fields.
- Updated the Vendor Table to include fields for tracking surveys.
- Added **Reference Id fields** (use as batch #, lot#, etc.) to Non-conformance Reporting, KPI forms and the Manufacturing/Production forms.
- Enhanced the Document Control Index Table and Form
  - The System Document Id can be changed
  - Documents may be sorted by Document Status tab and Document Level
  - Author Id added to the Document Revision History Log
- Enhanced the Records Control Index Table and Form

02/25/2015 v1.28.5

- Added additional CAPA charts
- Added additional Performance Charts
- Added a Monthly & Weekly Training Schedule Calendars
- Enhanced Security Controls on Browse Tables

- Transitioned references to Customer Complaint to Customer Feed-back

01/24/2015 v1.27.8

Added graphical charting options for the ...

- Corrective & Preventive Actions
- Contract Review and Sales Quality Metrics
- Customer Feed-back Table
- Manufacturing / Production Quality Metrics
- On-time Delivery Table
- Performance Dashboard
- Purchasing Quality Metrics
- Process KPI Table

01/15/2015 v1.26.2

- Enhanced calculations for used for evaluating suppliers and vendors.
- Enhanced the Process Key Performance Indicator (KPI) data entry form.
- Updated the File Manager.

01/07/2015 v1.25.1

- Added active hyperlink to access documents and, or images from the Records Control Index.
- The Document Control Index, numeric version field accepts two decimal places.
- Corrected Dashboard calculation for rounding errors; now displays percentages with two decimal places.
- Improved the Dashboard Label Set controls to simply use and setup.
- Updated the File Manager.

11/24/2014 v1.24.4

- Added a feature to save most reports as an HTML Output from reports.
- Added an Email Assistant feature to send **ALERT MESSAGES** from CAPA Request, Customer Complaints or Non-Conformance Reports.
- Enhanced the Performance Dashboard by adding optional Target Percents.
- Limit the EXE to run only 1 session at a time.

11/18/2014 v1.23.1

- Added a feature to save most reports as an Excel compatible file.

11/09/2014 v1.21.5

- Added Browse Table for messages related to:
  - Alerts for Quality, Environment, Health & Safety
  - Employee Initiatives
  - Non-conformance Reporting
- Enhanced the Process KPI Log and Reporting module.
- Enhanced the format of the CAPA Table (set to descending date order)
- Enhanced the format of the Customer Complaint Table (set to descending date order)
- Enhanced Controls for Current Work Group (CWG) filtering
- Login is optional if a user name and login code are not created.
- Enhanced the Training Schedule Table (set to descending date order)

11/01/2014 v1.20.8

- Enhanced the Management System Performance Dashboard
  - Added *Percent of Achievement field* to record 'actual attainment'.
- Enhanced the browse table windows for the Training Programs and Training Schedule.
- Corrected Training Program attachments.
- Updated the field validation method on the Task List form.
- Updated the method for free license deployment.
  - Click here to download ***FREE LICENSE***
  - Click here to learn how to install the license.
- Added new report template for Document Edit History Log.

10/24/2014 v1.19.3

- Added a feature to the Document Control Index that provides an option to synchronize the Current Revision Date in the Document Index Record with the Version History Table.
- Added a new Document Version History Report Template.

- ❑ Added a copy feature to allow the Management System Standard clauses and elements to be directly copied to an Audit Plan.
- ❑ Added a copy feature to allow a single Aspect of a Risk Assessment to be copied into the same Risk Assessment.
- ❑ Updated the Document Index report.

10/9/2014 v1.18.3

- ❑ In this version special attention has been focused on enhancing our Risk Assessment module, which now includes additional boundary controls that are user definable. Our default boundaries are Very Low, Low, Medium, High and Very High.
- ❑ These boundaries can be triggered by user-defined values for evaluating Probability (P), Severity (S) and the Detection (D) of risk. A Risk Priority Number (RPN) is calculated at the Risk Aspect level and the Risk Assessment level. At the Aspect level the RPN equals P * S * D. The RPN at the Risk Assessment level equals the sum of all Aspect RPNs within a single Risk Assessment. Essentially, QMSCAPA can create and store thousands of Risk Assessments and related Aspects.

9/29/2014 v1.17.3

- ❑ Enhanced the Risk Assessment module to by adding risk evaluation of boundaries.
- ❑ Enhanced the Risk Assessment reporting.
- ❑ Enhanced the Document Control Index.
- ❑ Added Document Index Revision Log report template.

9/21/2014 v1.16.3

- Enhanced the Risk Assessment module to track the results of mitigation
- Added new Report Template for Audit Results.
- Added a summary report for Customer Complaints.

9/10/2014 v1.15.1

1) Added Supplier /Vendor Evaluation Criteria Set Report (requested by user group).
2) Added Customer Satisfaction Survey Set Report (requested by user group).
3) Enhanced the Supplier /Vendor Table and Form.
4) Updated the default CAPA reports.

5) Enhanced the KPI browse table.
6) When Customer Complaints are copied to the CAPA log the Complaint 'Status' is posted with 'Copied to the CAPA log'. (requested by user group)

9/03/2014 v1.14.2

1. Activated the Quality Key Performance Indicators (KPI) database for public users (demo and upgrade).
2. Enhanced the Quality Calculators for:
   a. Production
   b. Purchasing
   c. Sales and Order Entry

8/26/2014 v1.12.2

1) Added to the CAPA browse table a feature button control to copy the CAPA log to Excel.
2) Added to the Customer Complaint browse table a feature button control to copy the Complaint log to Excel.
3) Enhanced the copy Complaint to CAPA log feature.
4) Enhanced the Vendor Evaluation table.
5) Added fields to save default file folder locations for management system documents and records.
6) Added an Elements Table related to the Management Systems Table.
7) Added a Sub-processes Table related to the Processes Table.
8) Added a Process and Element interaction report.

8/17/2014 v1.11.2

1) Added a Customer Survey Browse Table inside the Customer Form
2) Enhanced the Risk Assessment module by expanding the copy Risk Assessment Template feature, which allows any Risk Assessment to be copied.
3) Added a copy feature to the Risk Priority Number factor table.
4) Enhanced the CAPA Form for field completion.
5) Enhanced the Customer Complaint Form for field completion.
6) Added a method for auto-calculating response due dates for customer complaints based upon the type of complaint.

7) Added a method for auto-calculating response due dates for CAPAs based upon the type of CAPA.

8/10/2014 v1.10.4

1) Enhanced the Risk Assessment module by adding a copy Risk Assessment Template feature.
2) Added new feature to ImpExQMS for importing suppliers/vendors.
3) Enhanced the Supplier Evaluation Criteria Sets by adding a copy set feature.

8/4/2014 v1.10.2

1) Enhanced Customer Complaint Table and Form
2) Added Check-boxes for Request for RMA and Orders Canceled prior to Shipping.
3) Added RMA number field
4) Added Return Location Id field
5) Added Comments field for RMA
6) Added Other Locations Table (Ship To Locations) that is related to the Company (user's Company)
7) Separated the Records Control Index from the Document Control Index

7/21/2014 v1.9.12

1) Added 'Client Name' Order Sort Key and Tab for the CAPA Table.
2) CAPA file attachment look-up changed to allow 'All Files'.
3) Enhanced the Monitoring & Measuring Device Table and Form.
4) Enhanced the Training Table & Form.
5) Enhanced the Customer Complaint Table & Form.
6) Added option to print Customer Complaints by Date range and Status.
7) Enhanced the Risk Assessment module.

7/8/2014 v1.9.5

1) Corrected CAPA table display for Preventive Action Classifications.
2) Removed display filters on CAPA table.
3) Corrected Client search name field in Client Table.
4) Updated the default CAPA form to conditionally include fields for vendors, items, parts and other batch/lot information.

5) Added a related table for attachments in the Training Program Schedule.
6) Added group reference field to Customer Complaint and CAPA forms for batch, lot, run, etc.
7) Added security control to Customer Complaint Table for the ***Copy to CAPA button***.
8) Added Transaction Id field to the Customer Complaints and CAPA tables.
9) Activated Shipping Carrier table.
10) Added Carrier Id fields to the field to Customer Complaints and CAPA tables.
11) Added Vendor Id field to the Customer Complaint table.
12) Provided direct access from the Edit Menu to the Product and Services table.

5/27/2014 v1.8.134

1) Includes support to allow the Windows OS Control Panel to control the QMSCAPA date field format; e.g. MM/DD/YYYY or DD-MM-YY and others.
2) Enhanced the Vendor Table and Form.
3) Added a Vendor Status look-up table.
4) Added horizontal control to CAPA task table.
5) Corrected display for Monitoring and Measuring table.
6) Update Training Schedule report
7) Updated display for Training Program Attachments
8) Added Section Sequence # to the Checklist Items Table.
9) Updated the Checklist default report.
10) Updated the Measuring and Monitoring Device default report.
11) Updated the Customer Complaint form to include estimated and actual cost fields, plus a user-defined Reference Field.

5/18/2014 v1.8.95

- CAPA Log Table enhanced
- Added Training Tab to Employee Form
- Added Checklist Items Tab to the Checklist Form

5/2/2014 1.8.62

- Corrected write-delay for auto-increment of the CAPA log.
- Corrected Quality Purchasing Report Template.
- Expanded Training Programs description field.

4/26/2014 v1.8.59

1) Made some tweaks to the Windows manifest to improve compatibility with Windows 8.1 (some users reporting the need to 'run-as-an-adminstrator';
2) Added two fields to the CAPA log, Estimated Cost and Actual Cost, to assist with measuring the cost of Corrective and, or Preventive Actions. The tally of these fields is based upon Estimated and Actual cost entered into a CAPA Task record. (requested by user group)
3) In the Company Setup, added the ability to change the Company Id; somehow users started out with a Company Id of zero.
4) Added a 'Document Name' field to the User Defined Guidance Table. (requested by user group)

4/21/2014 v1.8.43

1) Released user-definable help system (**F1 Key**) and question-mark button **[?]**. (requested by user group)
2) Enhanced browse tables to allow users more options to arrange and sort columns. (requested by user group)
3) Increased user-defined Document Id field to 40 characters. (requested by user group)
4) Added a feature to allow users to edit the window field names for language translation or an industry specific vocabulary. (requested by user group)
5) Added CAPA Task List table linked to each CAPA. (requested by user group)
6) Added CAPA Task Reporting.

3/15/2014 v1.7.2

- Risk Assessment Module in the style and functionality of an FMEA risk assessment.
- Enhanced the CAPA module with product/service fields with a standardized look-up table. (requested by user group)
- Enhanced the Customer Complaint log providing a complete copy to the CAPA log when needed.

3/8/2014 v1.6.745

1) Added security controls to the Monitoring and Measuring device table. (requested by user group)
2) Added security controls to the Document Type look-up table.
3) Added a new report for the selected Training Program. (requested by user group)

2/23/2014 v1.6.739

1) Corrected the re-size window strategy on Internal Audit Plan and associated auditor tables.
2) Updated sorting tabs on the Training Program table. (requested by user group)
3) Added an assortment of window enhancements based upon feed-back by the user group.
4) Updated Staff Training Plan reports.

2/14/2014 v1.6.716

1) Enhanced Training Schedule with Calendar Look-up Date Selector. (requested by user group)
2) Enhanced the Training Schedule report by adding a Date Selection Range.
3) Quality Dashboard for measuring continual improvement.
4) Internal audit findings form and database have been enhanced.
5) Integrated Microsoft Office spell check feature into the audit form. (requested by user group)
6) Additional functionality to the External Document Manager.

2/3/2012 v1.6.2

1) Added Microsoft Office spell check module for the Document RTF Editor (beta).
2) Added CAPA Issued Date field and Table sorting Tab. (requested by user group)
3) Additional table for CAPA attachments, which essentially provides unlimited attachments and respective management of attachments.
4) Enhances made to Training Programs and Training Schedules.

1/31/2014 v1.5.11

1) QC Checklist generator
2) Enhanced Document Control Index
3) Document Management Table with Document Editor, which supports Rich Text Format (RTF).
4) Supplier /Vendor evaluation and scoring system.

1/14/2014 v1.4.2

1) Added new Icon Quick Access Tool Bar
2) Added new Monitoring and Measurement Device Table (requested by user group)

, including:
   a) Brand table
   b) Calibration & maintenance frequency table
   c) Calibration standards table
   d) Device types
   e) Device location names
   f) Device owners
   g) Device status
   h) Monitoring and Measurement reports
3) Added an option to change the CAPA number.
4) Security Controls added to ...
   a) Audit Results Table.
   b) Audit Plan Table.
   c) CAPA Log Table.
   d) CAPA Log by filtered by CWG Table.
   e) Customer Complaints Table.
   f) Human Resource Table
   g) Training Programs Table.
   h) Training Schedule Table.
   i) Training Students Table.
5) Added more fields to the CAPA browse tables.
6) Added new attachment field to the HR (Employee file)

09/12/2013 v1.2.45

1) Made adjustments to CAPA entries copies from Customer Complaints.
2) Made esthetic changes to the Quality Dashboard.
3) Enhanced the File Manager.

06/20/2013 v1.2.31

1) Further enhances to the Document Control Index.
2) A PDF viewer was added to the Document Control Index editor window. (requested by user group)
3) A User Defined Guidance table was added to the Help menu options. (requested by user group)

06/16/2013 v1.2.17

1) Added new features to the Document Management Module;
   a. Moved the Document Control Index to the **'Edit Table'** menu option.
   b. Added Approved Date field;
   c. Added Effective Date field;
   d. Added Numeric Version counter field;

e. Added File Path & Name field;
f. Added a Document Version History table;
g. Updated Document Index by Document Id (report);
h. Updated Document Index by Title (report);
i. Added Document Index by Path & File Name (report).

05/05/2013 Version 1.1.7

1) Added support for the Windows 8 manifest;
2) Added support for the Windows Server 2012 Edition (requested by user group);
3) Corrected and tweaked user interface.

10/27/2012 Version 1.0.635

1) Added a Customer Complaint browse tables and reports. (requested by user group)

10/09/2012 Version 1.0.607

1) Corrected the way MS Word is loaded for Spell Checking. MS Word is loaded in the background when the F7 Key is depressed.

10/06/2012 Version 1.0.598

1) Added Training Programs browse tables and reports, includes training courses, training schedule and trained student records. (requested by user group)
2) Added a process for identifying ***Audit Plans*** to Copy the annual *internal audit schedule* for one or more standards from year to year.
3) Added ' *Spell Check* ' for 'text fields' on most of the primary window forms.

7/20/2012 Version 1.0.498

1) Added framework and databases for new **Dashboard for Monitoring Quality**, which includes Quality Measurement Dashboard table, Dashboard window and a Quality Dashboard report.
2) Corrected look-up for the Company file when printing reports. Company logo and name print correctly again.
3) Created standalone File Manager bot for external database maintenance.

7/3/2012 Version 1.0.418

1) Manufacturing and Production Quality Calculator

   a) Added a Manufacturing and Production table and form for calculating the over-all quality score as a percentage.
   b) Added Mfg. and Production Analysis report for monitoring Manufacturing and/or Production quality.
2) Purchasing Quality Metrics Calculator
   a) Added a Purchasing table and form for calculating the over-all purchasing quality score as a percentage.
   b) Added a Purchasing Analysis report for monitoring Purchasing quality.
3) Sales Quality Metrics Calculator
   a) Added a Sales Contract table and form for calculating the over-all Sales quality score as a percentage.
   b) Added a Sales Analysis report for monitoring Sales quality.

6/24/2012 Version 1.0.362

4) Added Department Name lookup table to the Employee table and form. (requested by user group)
5) Added a Customer lookup table in the CAPA form. (requested by user group)
6) Corrected the Vendor lookup in the CAPA form.
7) Added Customer Survey & Satisfaction Calculator
   a) Added a table for multiple Customer Survey Questions sets, which provides flexibility for many different industry and business types.
   b) Added Survey table and form for calculating customer satisfaction.
   c) Added Survey form printing.
   d) Added Survey results reports for monitoring customer satisfaction.
8) On-time Delivery Log & Calculator
   a) Added Delivery table and form for calculating delivery and shipping results.
   b) Added On-time Delivery Analysis report for monitoring on-time delivery.

3/12/2012 Version 1.0.247

1) Moved security file to user selected data folder.
2) Made login optional for first time users.
3) Minor window and tab sequence adjustments.

2/18/2012 Version 1.0.239

1) Added to horizontal and vertical scroll bars to the main window document frame to allow easier navigation on smaller computer screens.
2) Fixed tab order on the CAPA form window.
3) Added cwhhla.dll to installation wizard.

2/11/2012 Version 1.0.219

1) Added vendor table
   a) Added vendor field to CAPA window and printed form
   b) Added two Vendor reports
      i) By vendor name in alphabetical order
      ii) By Tier Level and vendor name in alphabetical order

1/18/2012 Version 1.0.201

1) Internal Audit Schedule
   a) Internal Audits Log
   b) Internal Audit Reports
2) Fixes
   a) The Reports Directory now follows the user select Data Directory.

62 Appendix

ISO Registration

Accredited ISO Certifying Bodies

Consulting for International Management Systems

ISO Lead Auditor Training

- ISO 9001 Training
- ISO 14001 Training
- ISO 18001 Training
- ISO 27001 Training

Quality Management Resources

- Quality Management Software
- ISO 9001 Quality Manual Template
- ISO 14001 Requirements Guide

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- ISO 18001 Requirements Guide
- ISO 27001 Requirements Guide

62.1 Amazon Web Services

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Amazon Web Services provides a wide range of hosting services that can provide a robust environment for QMSCAPA, including Workspaces that creates virtual desktops for remote clients such as:

- ✓ Apple OS devices
- ✓ Android OS devices
- ✓ Chromebooks
- ✓ Database File Sharing for 1 to 5 QMSCAPA users
- ✓ Windows Virtual Servers for 1 to 100 QMSCAPA users

Click here for more about Amazon Workspaces ...

Tags: quality management software, corrective action software, iso management software

62.3 Framework & Layout

Menu Option

☑ AS9100 D Implementation & Templates Kit

☑ ISO 9001:2015 Implementation & Templates Kit

Browse Table

Form

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Tags: quality management software, corrective action software, iso management software

☑ AS9100 D Implementation & Templates Kit

☑ ISO 9001:2015 Implementation & Templates Kit

62.4 Statement of Conformance to ISO 13485 and US FDA 21 CFR

About ACCESS BUSINESS COMMUNICATIONS, INC. (ABCI)

ABCI produces software solutions that enable non-regulated and regulated companies improve the quality of their products through providing collaborative tools for monitoring quality objectives, process efficiency and corrective actions for non-conformances.

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The intended use and general purpose of its **QMSCAPA™** software is to aid in the administrative management of quality management systems, including AS9100 for the Aerospace industry and ISO 13485 for Medical Device industry.

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QMSCAPA™ is an *off-the-shelf software* that's easy to use, configure, install, implement, and validate. The different **QMSCAPA™** modules — Document Control Index, integrated forms, CAPA logging, Training Programs, Non-conformances, Risk Management, and Records Control Index — can be used as standalone applications or as an integrated system under a single Internet-based portal using Microsoft's Remote Desktop Services.

ABCI offers real-time support services that include hands-on software training, installation assistance, optional validation services, and continuing customer and technical support. The **QMSCAPA™** solution helps medical device manufacturers' quality processes stay compliant, connected, and complete.

Also, QMSCAPA is known for being easy to implement, easy to use and easy to configure.

Many users have found that QMSCAPA v1.34 offers an effective software solution to medical device manufacturers' needs pertaining to compliance with 21 CFR Part 11 & 820 and ISO 13485.

QMSCAPA solutions include:

- ❑ Audit Management
- ❑ Corrective & Preventive Actions
- ❑ Customer Feed-back
- ❑ Document Control Index with Revision History and Authorized Approval Log
- ❑ Management for Monitoring & Measuring Devices
- ❑ Records Control Index with Records Approval Log
- ❑ Risk Management and Risk Treatment Programs
- ❑ Supplier Management
- ❑ Training management.

Related Topics

Q & A QMSCAPA, ISO 13485 and US FDA 21 CFR

Comparison of QMSCAPA, ISO 13485 and US FDA 21 CFR

62.4.1 Q & A QMSCAPA, ISO 13485 and US FDA 21 CFR

QUESTION: What is 21 CFR 820 and what is ISO 13485:2003

ANSWER: Title 21 of the Code of Federal Regulations (CFR) covers the broad area of food and drugs, but Part 820 pertains to quality systems for medical devices. It outlines Current Good Manufacturing Practice (CGMP) regulations that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. These requirements are meant to ensure that medical devices are safe, effective, and in compliance with the Federal Food, Drug, and Cosmetic Act.

ISO 13485:2003 is an international standard that specifies requirements for regulatory purposes for medical device manufacturers. It provides a framework for companies to meet their customer and regulatory requirements. The main goal is to provide a harmonized model for quality management system requirements in the international market since different countries might have different standards. ISO (derived from the Greek word 'isos', meaning equal) refers to the International Organization for Standardization, a non-governmental organization based in Geneva.

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QUESTION: Who is covered by 21 CFR 820 and who is covered by ISO 13485?

ANSWER: 21 CFR 820 is applicable to manufacturers of finished medical devices sold in the United States, including foreign manufacturers who import devices. Some manufacturers might be subject only to certain requirements, depending on the operations they are engaged in Medical device manufacturers that sell their products in the global market find it advantageous to get ISO 13485 certification because ISO standards are recognized worldwide. Certain countries require such certification. Many customers also prefer medical devices that are ISO 13485 Certified.

QUESTION: What's the relationship between 21 CFR 820 and ISO 13485?

ANSWER: Although the two are similar, they have significant differences. For example, complaint handling and reporting requirements are integral to the

FDA's quality systems regulation (QSR), but the FDA thinks they are not adequately addressed in ISO 13485. In this case, conformity to the ISO standard would not suffice to demonstrate conformity with the QSR and the FDA's Center for Devices and Radiological Health will not recognize the standard for this particular purpose.

QUESTION: Who enforces 21 CFR 820 and ISO 13485?

ANSWER: The Food and Drug Administration enforces 21 CFR 820.
Third parties usually conduct assessment of a manufacturer's system and processes to make sure they are in accordance with the requirements of ISO 13485.

QUESTION: What's the connection between 21 CFR 820, ISO 13485, and QMSCAPA?

ANSWER: Developed more than five years ago, the QMSCAPA™ quality management software solution was designed to help companies adhere to ISO standards for tracking customer feed-back and corrective actions. Many QMSCAPA™ users compelled with FDA regulations found the software to be a cost effective and efficient tool for assisting with quality management. Today hundreds of companies worldwide rely on ABCI to help them analyze, document, control, interconnect, log and manage their quality processes, customer feed-back and corrective actions.

QUESTION: What are some of QMSCAPA™ features and how can they help medical device manufacturers comply with 21 CFR 820 and ISO 13485?

ANSWER:

- Audit Management
- Corrective & Preventive Actions
- Records Control Index
- Risk Management
- Supplier

- Customer Feed-back
- Document Control Index
- Management for Monitoring & Measuring Devices
- Management
- Training management

62.4.2 QMSCAPA FDA 21 CFR Sub-Chapter A, Part 11

PART 11: ELECTRONIC RECORDS; ELECTRONIC SIGNATURES	**Addressed by or with QMSCAPA (+Part11 Module)**
Subpart B--Electronic Records	
Limiting System Access (21 CFR, Section 11.10(d))	Limiting System Access may be controlled by the QMSCAPA standard Security Module
Program Time-Outs (21 CFR, Section *11.10(d))*	QMSCAPA requires Windows Vista or higher; program time-outs may be controlled by the OS.
Authority Checks (21 CFR, Section *11.10(g))*	Authority Checks may be controlled through the QMSCAPA standard Security Module. QMSCAPA (v1.33) provides support for ... (a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: *1) The printed name of the signer;* *2) The date and time when the signature was executed; and* *3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.* *(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls*

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PART 11: ELECTRONIC RECORDS; ELECTRONIC SIGNATURES	**Addressed by or with QMSCAPA (+Part11 Module)**
	as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).
Signature/record linking (21 CFR, Sec. 11.70)	*QMSCAPA provides a method for* ***electronic signatures and handwritten signatures*** *executed to electronic records so they may be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.*

62.4.3 Comparison of QMSCAPA, ISO 13485 and US FDA 21 CFR

The following table highlights 21 CFR 820 and ISO 13485 and the relevant **QMSCAPA™** modules and features that are crucial in conformance.

ISO 13485	21 CFR 820	QMSCAPA™
(Clause 4) Quality management system requirements were developed to satisfy international medical device regulations.	(Subpart B) Quality system refers to a medical device manufacturer's responsibilities, procedures, processes, and resources for	Conforms with 21 CFR parts 11, 210, 211, 820, 821, and quality standards like AS9100, AS9110, AS9120, ISO 9001, ISO 13485, ISO 14001, ISO 16949, ISO

ISO 13485	21 CFR 820	QMSCAPA™
	implementing quality management.	17025, ISO 18001, ISO 20000, ISO 22000, ISO 27001, TL9000
(Clause 4) Requires establishment of a quality management system for medical devices. A manufacturer must have quality procedures that are documented, controlled, and effectively implemented and maintained.	(Subparts C, D, E, G) Require controls in design, document, purchase, and production process. This entails establishment of processes to ensure that a medical device conforms to specifications. Requirements stress maintenance of records of document changes, documentation of instructions of production processes and SOPs, and monitoring of process parameters.	The QMSCAPA suite of modules, automates, controls, and manages quality processes to improve efficiency and compliance. It can handle all types of documents, regardless of the software used to create them. It offers advanced routing, approval, escalation, and revision control.
(Clause 6) A manufacturer must ensure that its personnel have the right experience, education, training, and skills. Acceptable levels of competence must be defined. Training needs must be established and assessed. A record of competence must be maintained.	(Subpart B, Sec. 820.25) Each manufacturer must have sufficient personnel with the necessary background, training, and experience. It must have established procedures for identifying training needs and ensuring that employees are adequately trained to perform their jobs. Training should be documented.	QMSCAPA training controls role-based training requirements and employee competencies. It allows creation and deployment of training courses, requiring users to learn their duties and also demonstrate proficiency.
(Clause 8) Remedial processes are required. Quality should be monitored and measured by gathering customer feedback, setting up internal audits, establishing a non-conformance procedure, and analyzing quality information. Non-conformances must be corrected, recorded, and prevented.	(Subparts I, J) Require establishment and maintenance of nonconformance and corrective and preventive action (CAPA) procedures. Nonconformances relating to product, processes, and quality system should be investigated. Actions needed to correct and prevent recurrence must be identified. Corrective action has to be validated to ensure effectiveness. All activities pertaining to nonconformance and CAPA must be documented.	QMSCAPA provides an integrated database for corrective and preventive action processes based on input of complaints or incidents, audits or investigations, out of specifications, deviations, non-conformances, and safety and defects issues. It accumulates data from multiple sources, manages trends, and automatically triggers subsystem processes to solve production issues before or after they arise. This module offers a pre-

ISO 13485	21 CFR 820	QMSCAPA™
		packaged, best practice set of electronic forms, and business analytics. QMSCAPA forms, a closely related module, offers the capability to create electronic forms that look identical to existing forms or create new ones altogether. This module integrates workflow processes, data entry, and form or data approval.
(Clause 7) Requires development of procedures to identify and track products.	(Subpart F) Requires procedures for identifying products.	QMSCAPA includes a feature for searching and identification of product items. A search can be made using the key fields associated with the database like type, description, or item name, or any user-defined field created by the customer.
(Clause 7) Requires validation of monitoring and measuring software before use. Revalidation should be conducted when necessary.	(Subpart G, Sec. 820.70) When computers or automated data processing systems are used as part of production or the quality system, the manufacturer should validate computer software for its intended use according to an established protocol. Validation activities and results should be documented.	When appropriate, QMSCAPA may be validated in accordance with FDA General Principles of Software Validation Guidance for Industry and FDA Staff.

62.5 What do the software version numbers mean?

QMSCAPA Version and Release Numbers

The first one or two numbers from the left (##.###.###) indicate a new version, which adds new and significant functionality and, or features.
The middle numbers (##.###.###) indicates new features, reports and, or tables were added.

The last one, two or three numbers from the left (##.###.###) indicates something was fixed or enhanced.

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