

AutoSave

Document Approval & Audit Trails

Enterprise tools for automation source management & 21 CFR 11 Compliance

AUTOSAVE'S DOCUMENTS MODULE PROVIDES...

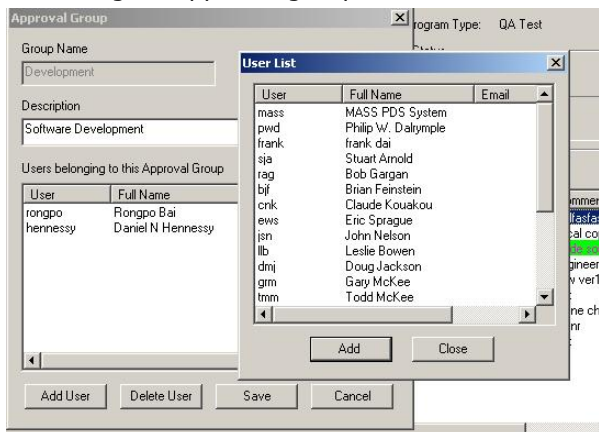
Using AutoSave's suite of office documentation modules for your plant procedures, drawings, and documents allows for the management of any mix of Word, Excel, PowerPoint, CAD drawing, PDF, CSV, and Windows files to provide:

- Central Repository for Critical Business Files
- Secured Access from any Client PC
- Launch by Extension for Variable Client Executables
- Historical Tracking
- Permanent audit trails: who, what, when, where, & why of changes
- Rapid, Minimal Program Configuration Steps
- And more...

ADD-ON MODULE'S APPROVAL AND AUDIT TRAIL FEATURES...

ELECTRONIC APPROVALS

- Configure approval groups of users



- Establish lists of required approval groups for specific documents or groups of documents
- Automatically e-mail approvers when changes ready for the process
- Electronic entry of each approval requiring comments and optional authorization number

- Electronic entry of approval rejection with comments during any status results in immediate demotion of the revision's status
- Automated maintenance of approval status and full history

ENHANCED LOGGING OF ALL EVENTS

- Augment AutoSave's already substantial tracking/audit trails to include logging of virtually all events including admin functions, providing both before and after images; ability to add manual log entries for clarification

MULTIPLE REVIEW STATUSES

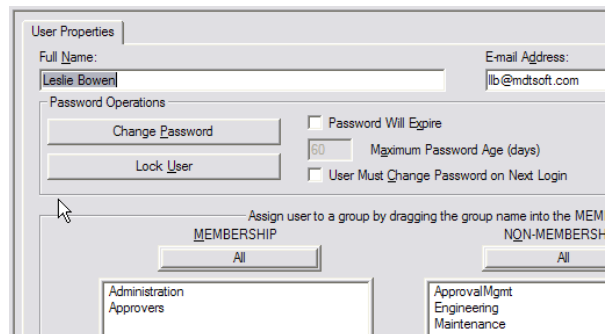
- Signify program versions that are in different statuses: Request for Approval, Test, Validate, Implement

VERIFY & CONFIRM PROCESSES

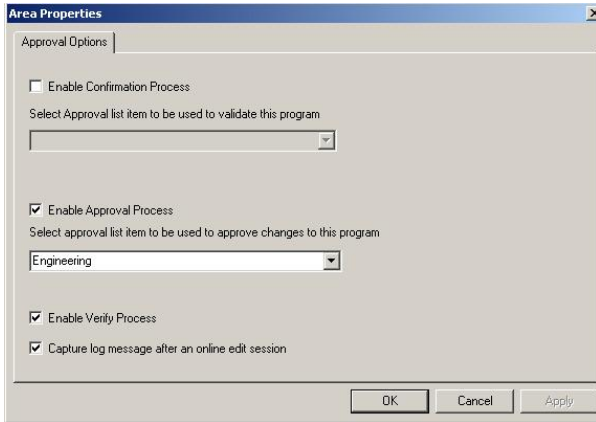
- Access to launch function requires user to re-enter password, thereby verifying individual is the logged in user
- Further inspection of critical functions can optionally require both the verification process and electronic confirmation by an approver to prove individual is the logged in user

SECURITY FEATURES

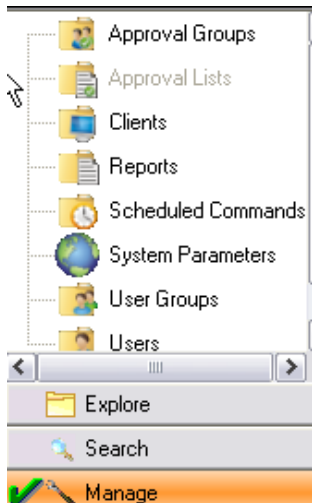
- Control expiring passwords and prior password re-use
- Capture e-mail addresses for AutoSave users for approval notifications



- Default classes for approvals, approval administration
- Unique privileges for the various approval process steps
- Customize required approval processes by document program or groups of documents



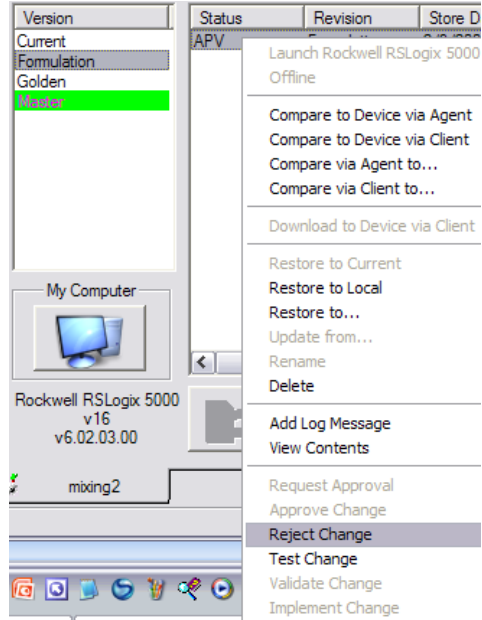
FUNCTIONS & FEATURES



- Document Approvals & Audit Trails add-on module's feature set is licensed separately and is applicable only to the Documents module suite of programs
- Configure approval groups and lists of groups applicable to entire directory or customize at document program level
- E-mail notification of approval process events
- License automatically includes the AutoSave Reports Module to provide access to historical logged data

LIFECYCLE OF A CHANGE

1. Create new version; automatic status of 'Edit'
2. Launch for edits and save
3. Request approval; automatic status to 'Request for Approval'
4. Status change triggers e-mails to all potential approvers in configured groups
5. Approvers determine whether or not to approve



If approve...

- Approver accesses **Add Approval** menu
- Verify & confirm processes performed
- Add Approval dialog completed
- Approval record stored; e-mail sent
- Approval process repeated by each group
- Partial approvals tracked, color coded

If Reject...

- Approver accesses Reject menu
- Verify & confirm processes performed
- Add Reject dialog completed
- Reject record stored, e-mail sent
- Automatic status change = Edit
- Change life cycle starts over

6. All approvals added; automatic status change to **Approved Pending Validation**
7. Validation testing, documentation, sign-offs performed
8. Manual change status to **Test**, then **Validated**
9. Manual change status to **Implemented**, put into production; previous Implemented version automatically demoted to Previously Approved