

## Auditing and Security – 21 CFR 11b

### Auditing Features

- Audit any Sage MAS 500 ERP tables or 3<sup>rd</sup> party tables for tables updates, inserts and deletes
- Include extended data for a table, such as "ItemID" and "Description" in tables that store only the "ItemKey"
- Audit changes done through the Sage MAS 500 ERP interface as well as any other program such as Access or Query Analyzer
- Recover deleted or revised records from audit history

### Security Features

- Idle timeout enforced from the server, in the event that users walk away from their desktop.
- Track document revision notes
- Track authorship functions such as Authorship, Revision and Approval
- Enforce password expiration

Auditing and Security are currently hot topics in Information Technology. O2 facilitates compliance with government auditing and security regulations, including the Sarbanes-Oxley and the FDA 21CFR part 11b. There are many systems that can process your data, O2 goes one step further by helping you validate and audit your data.

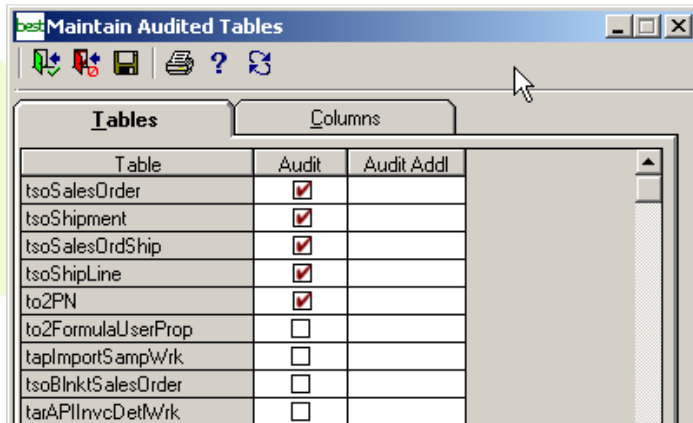
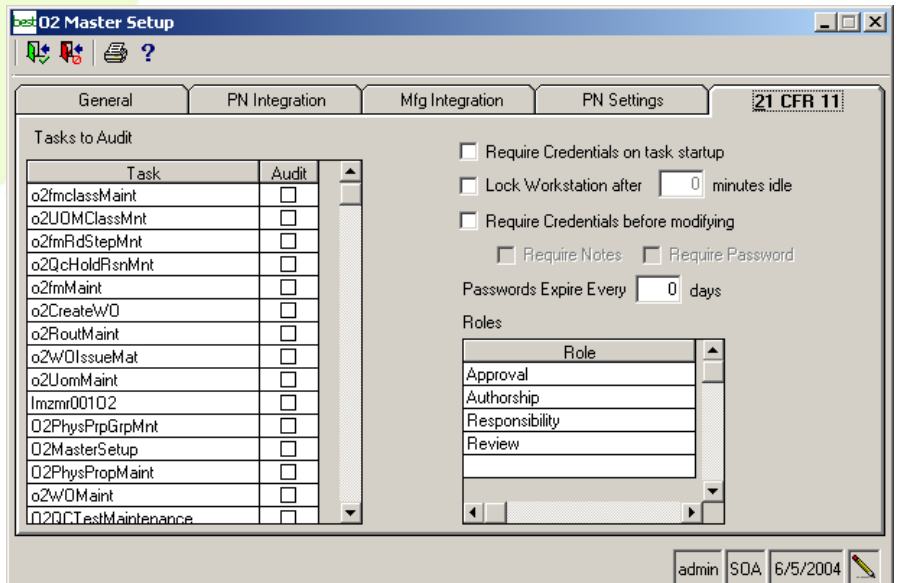


Table	Audit	Audit Addl
tsoSalesOrder	<input checked="" type="checkbox"/>	
tsoShipment	<input checked="" type="checkbox"/>	
tsoSalesOrdShip	<input checked="" type="checkbox"/>	
tsoShipLine	<input checked="" type="checkbox"/>	
to2PN	<input checked="" type="checkbox"/>	
to2FormulaUserProp	<input type="checkbox"/>	
taplImportSampWrk	<input type="checkbox"/>	
tsoBlnkSalesOrder	<input type="checkbox"/>	
tarAPIInvcDetWrk	<input type="checkbox"/>	

21 CFR 11b is the FDA's regulation regarding the security and audit-ability or electronic records. O2 provides the tools necessary for compliance.



**O2 Master Setup**

General | PN Integration | Mfg Integration | PN Settings | **21 CFR 11!**

Tasks to Audit

Task	Audit
o2fmcClassMaint	<input type="checkbox"/>
o2UOMClassMnt	<input type="checkbox"/>
o2fmRdStepMnt	<input type="checkbox"/>
o2QcHoldRsnMnt	<input type="checkbox"/>
o2fmMaint	<input type="checkbox"/>
o2CreateW0	<input type="checkbox"/>
o2RoutMaint	<input type="checkbox"/>
o2W0IssueMat	<input type="checkbox"/>
o2UomMaint	<input type="checkbox"/>
Imzmr00102	<input type="checkbox"/>
O2PhysPipGrpMnt	<input type="checkbox"/>
O2MasterSetup	<input type="checkbox"/>
O2PhysPropMaint	<input type="checkbox"/>
o2W0Maint	<input type="checkbox"/>
O2QCTestMaintenance	<input type="checkbox"/>

Require Credentials on task startup  
 Lock Workstation after  minutes idle  
 Require Credentials before modifying  
 Require Notes    Require Password  
 Passwords Expire Every  days  
 Roles:

Role
Approval
Authorship
Responsibility
Review

admin SOA 6/5/2004