



## COMPENDIAL SPECIFICATION

FDA 21 CFR Part 11

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IDIS EE V2

Specification Compliance

For

Electronic Signatures

PRIVATE AND CONFIDENTIAL



# COMPENDIAL SPECIFICATION

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### 1 Revision History

Revision No.	Date	Author	Comments
1.0	31 <sup>st</sup> July 2000	K Wilkinson	Draft document
1.1	12 Mar 2001	J. Furner	Edited missing pictures
1.2	9 <sup>th</sup> Sep 2002	K Wilkinson	Added details of Icalis Graphics Printer and change tense throughout. Change reference to IDIS EE V2.
1.3	6 <sup>th</sup> Apr 2003	K Wilkinson	General editing



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## 2 Introduction

The document describes how the Icalis Data Systems IDIS EE software V2.0, meets the requirements as described by the FDA Code of Federal Regulations Title 21 part 11 (21 CFR Part 11).

The document (21 CFR Part 11) lists the procedures and how Icalis Data Systems Ltd IDIS EE software solution complies with this regulation.

This document describes how we implement features in the IDIS EE software to allow companies to comply with this regulation.



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### 3 References

Document Name	Date	Revision	Author
Federal Register Vol. 62 No. 54, Part 11	20 Mar 2000		
IDIS EE V1.27 Specification	31 <sup>st</sup> July 2000	1.11	K Wilkinson



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## 4 Implementation

**Icalis Data Systems** has approached this ruling by addressing the requirements listed below.

- i) Users can create working Groups, which can have different access rights as well as each individual within a Group.
- ii) Logging Off Times and Password expiry reuse are configurable to allow IDIS EE to meet each company compliant procedure.
- iii) If the company plans to implement Electronic Signing of record keeping and authentication, then the company must have the possibility to specify records or Groups of records that must be signed.
- iv) The company should have the possibility to specify which Users can sign records, which records and how many signatures are required.
- v) Records specified for signing will clearly show this requirement if printed and the status of the signing.
- vi) If a record previously signed is post edited, then the new post-edited record must have the signing status reverted to not signed.
- vii) An audit trail of all activity in the system will be kept and is user queryable to allow users to extract specific information.



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### 5 Meeting the Requirements

#### 5.1 11.1 (a) *Electronic Records Generally Equivalent to Handwritten Signatures*

IDIS EE provides unequivocal security so that each signature is unique.

#### 5.2 11.1 (e) *Computer Systems shall be readily available*

Icalis Data Systems Ltd software uses a Relational Database designed for long-term stability. The software is produced to a high standard of Version and Change control and upgrade paths are provided for an indefinite period of time to our customers.

#### 5.3 11.10 *Closed Systems used for Electronic Signatures must employ procedures to ensure Authenticity, Integrity and Confidentiality.*

IDIS EE employs a relational database with encrypted user passwords and access restriction. Once signed, the signature is written into the record rather than cross-referenced.

#### 5.4 11.10 (a) *Validation of systems*

Comprehensive Validation Test Scripts can be acquired and performed at the company's premises as an optional purchase.

The Test script addresses the issues of record integrity, relationship of Method and Data records, access restriction to records, Instrument Control and method sequencing, Post Editing records and Audi Trail traceability.

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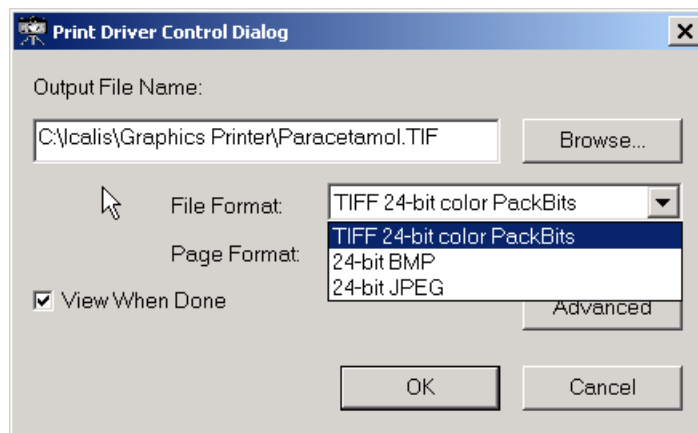
#### 5.5 11.10 (b) Ability to generate accurate and complete records for inspection

The IDIS EE software data structure ensures a unique record reference, which is never used again, and an international global record identifier.

Data records have a relational link to Methods, which prevent the method from being removed unless the data record is first deleted.

The IDIS EE software system will remove the signatures from any record if it is edited again while still retaining the information that the new edited record requires signing.

To comply with records in “human readable” form, IDIS EE is developed with a unique Graphics Printer capable of outputting records in TIFF (multiple pages), JPEG and Bitmap (BMP)



#### 5.6 11.10 (c) Protection of Records

The IDIS EE software ensures that only authorised personnel are able to amend records. A method may only be removed if there is no data associated with it.

Records can be archived and restored only by authorised personnel. The company’s administrator grants persons performing this task these rights as sub administrators..

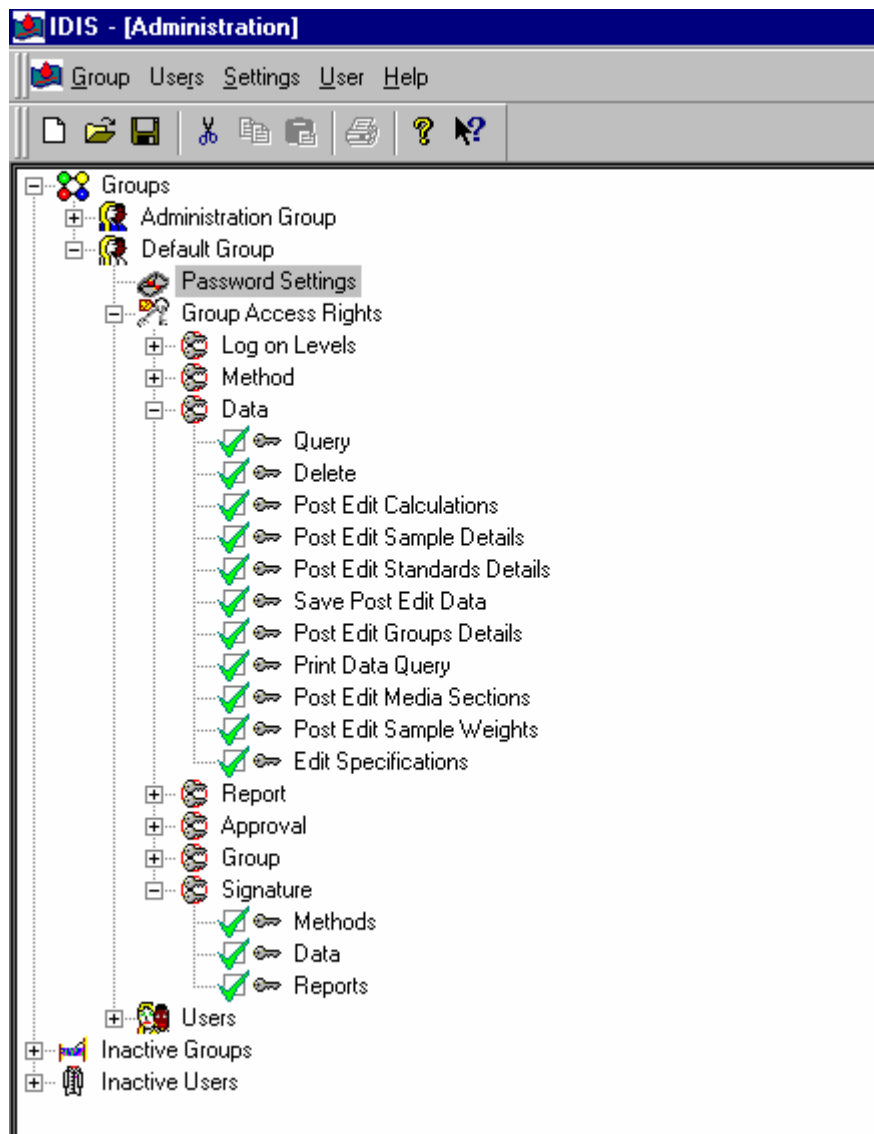
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#### 5.7 11.10 (d) Limiting access to unauthorised individuals

The IDIS EE software systems employ extensive restrictive access rights to all records either at Group level or by individuals. The confirmation of this feature is covered in the Validation Test script.



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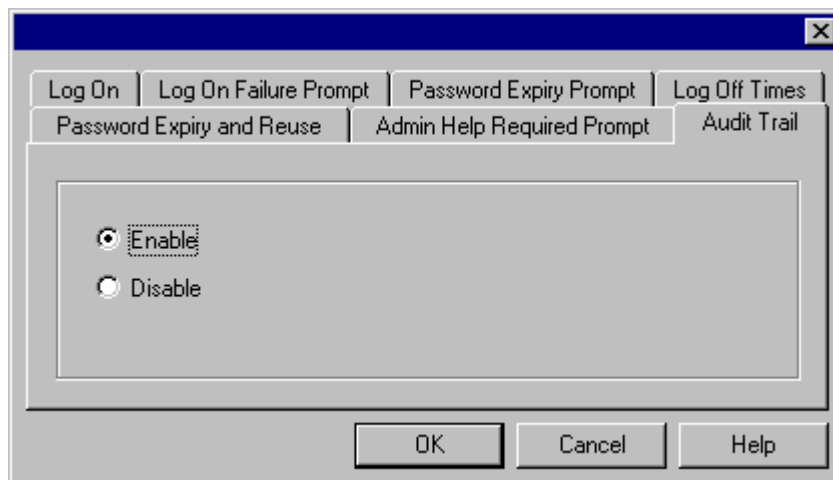
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#### 5.8 11.10 (e) Computer Generated Time Stamped audit trail

The IDIS EE software has an audit trail. The audit trails logs all activity to the system based on the Record ID, the User and Logging On access.

Access to the system is logged using Creation, Deletion and Modification to generate other records in the Audit Trail.

All activity is date and time stamped and access to the audit trail details is user queryable by Administrators only.



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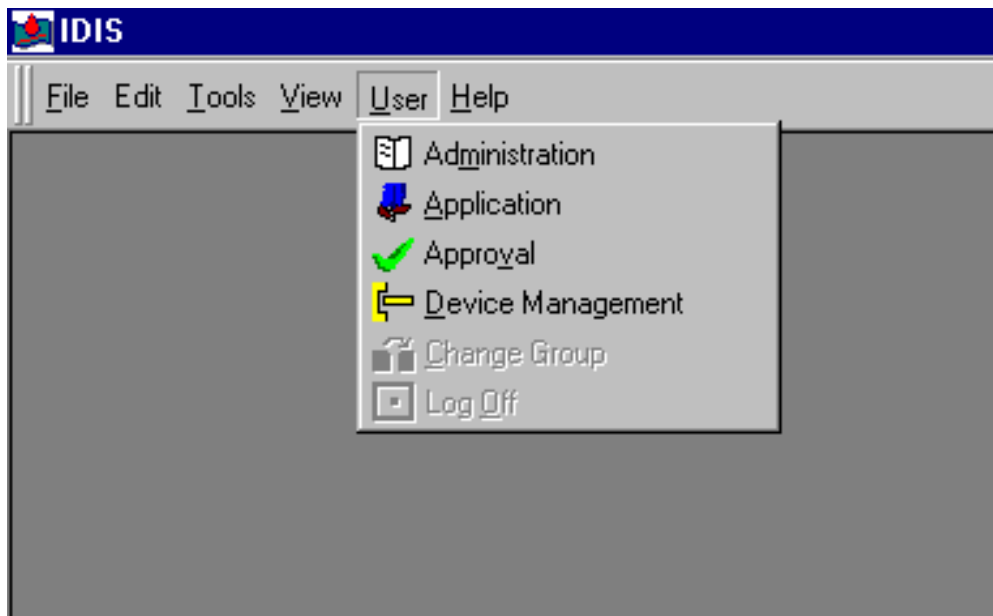
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#### 5.9 11.10 (g) Use of Authority Checks to ensure only authorised individuals can use the system

IDIS EE uses Administered configuration, where specific user(s) can take overall responsibility of the system.

The administrator makes changes in order to decide which users access the system and at what level.



A main administrator has over all control to delegate administrative tasks to other users (sub administrators).

All individuals accessing the IDIS EE system are restricted to specific number of tries and attempts which can eventually lock the workstation in question necessitating an administrator to unlock the workstation.



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#### **5.10 11.30 Persons using open systems shall employ document encryption and digital signatures**

The system can be configured so Users logging are requested to enter a Name and a Password. The User's full name is used on all documentation for authentication.

The system files used for the Names, Passwords (System Database) and the company's details such as Serial Number, are encrypted.

#### **5.11 11.5 Signatures shall contain Printed name, date and meaning of the approved signature**

IDIS EE appends non-removable electronic tags to records clearly showing the signer, Date and Time and meaning of the signature as well as a signer's "activity".

#### **5.12 11.7 Signatures assigned to records shall be linked to ensure signatures cannot be excised, copied, transferred or falsified.**

Record and User's ID integrity is maintained by unique reference ID. User ID's once created can never be deleted from the system, only made inactive.

Users will be configured by the administrator and linked to Groups for signing.

The company can also specify Groups whose records will need to be signed rather than relying on ad hoc signing by Users.

Records that have been signed are electronically tagged, even if the record is Archived or Restored from and to another destination.

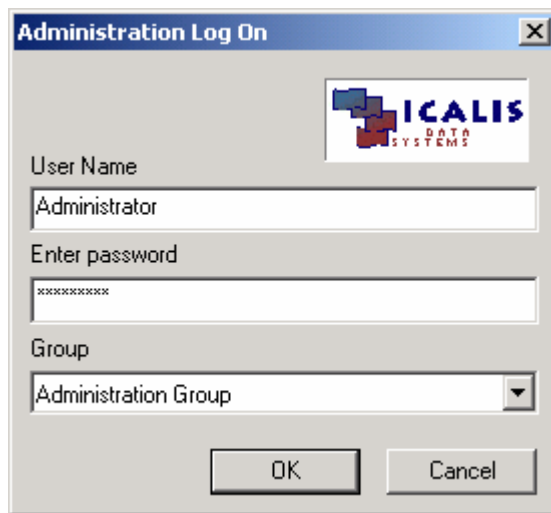
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#### **5.13 11.100 Each unique signature shall be unique to one individual**

Our software systems employ a unique User name, a unique Password and a Full User name.



The image shows a Windows-style dialog box titled "Administration Log On". It features the ICALIS logo in the top right corner. The dialog contains three input fields: "User Name" with the text "Administrator", "Enter password" with masked characters "\*\*\*\*\*", and "Group" with a dropdown menu showing "Administration Group". At the bottom, there are "OK" and "Cancel" buttons.

#### **5.14 11.200 Individuals exercising multiple signings shall enter both components of signatures**

Users performing signatures are requested to enter their User Name and Password at the time of signing even though they have logged onto the signing level.

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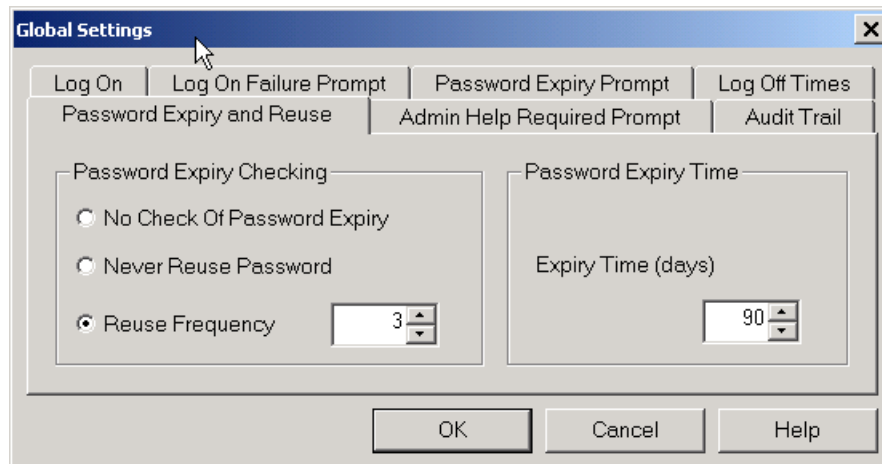
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#### 5.15 11.300 No two individuals have the same user name and password

The User name, User's Full name and the Password for a user are unique. A system prompt is provided when the user logs on to display the user's full name.

This assists in validation of the system.

The User passwords are also subject to review as shown below which is configurable by the administrator.



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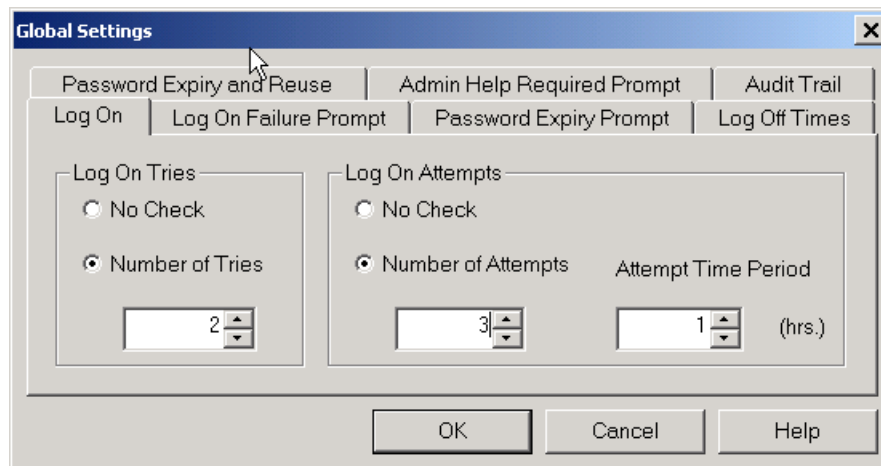
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#### 5.16 11.3000 (d) Transaction safeguards to prevent unauthorised attempts to access system

The IDIS EE software monitors and checks unauthorised access to the system.

The number of User attempts to log on to the system satisfactorily is set by the administrator as shown.

After a specified number of attempts, the system shuts down requesting administrator access.



Only Administrators can perform restoring locked workstations, a task which can be performed remotely when systems are networked.