Eclipsys Sunrise Clinical Manager Enterprise Electronic Medical Record (SCM) and Title 21 Code of Federal Regulations Part 11 (21CFR11)

The title 21 code of federal regulations part 11 deals with an institutions electronic medical record and electronic signature when submitting data to the Food and Drug Administration (FDA) for any reason.

The Sunrise Clinical Manager Enterprise Electronic Medical Record System meets the software requirements.
CRF 11

1. Access to SCM is limited to users with a unique user ID and a password
2. The system checks the authority to view, create, modify and delete the different components of the patient medical record.
3. Device data may be used to populate the patient record if information is sent by a qualified interface.
4. Eclipsys offers many types of educational classes however it is the responsibility of the owners of the system to ensure that all authorized users have taken advantage of the available education and training and passed proficiency test before allowing them to perform their assigned task.
5. Eclipsys Corporation offers training in best practices however it is the responsibility of the owners of the system to establish written policies on the use of electronic systems and enforce those policies that hold individuals accountable for actions initiated under their electronic signatures.
6. Eclipsys SCM is not an "Open System"
7. SCM meets all requirements for an electronic signature

21 CFR Part 11 applies to records in electronic format that are created, modified, maintained, archived, retrieved or transmitted under any records requirement set forth in Agency (FDA) regulations. Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service.

In August 2003 the FDA clarified the requirements in 21CFR11 ("final Guidance for Industry") related to manufacturers of electronic systems. "Under the narrow interpretation of the scope or part 11" specific requirements for "Validation", "Audit Trail", "Legacy Systems", "Copies of Records" and "Record Retention" were outlined.

The Eclipsys Corporation certifies that the Sunrise Clinical Manager Electronic Medical Record Systems and the Electronic Signature function meets the requirements in title 21 code of federal regulations part 11.

Eclipsys SCM meets the requirements to Specific Part 11 Requirements

1. Validation

Validation refers to verifying that the software manufacturer has a formal process for manufacturing quality software. Eclipsys follows a formal management process for software development and maintenance. The Eclipsys Sunrise Clinical Manager Software has been under development for more than 10 years. The Eclipsys Corporation uses a formal process based on the Microsoft Solutions Framework for software manufacturing. The Eclipsys name for this process is the Eclipsys Solution Framework (ESF). The ESF framework incorporates shared responsibility of the contributors throughout the release development cycle. End users of the software participate in the definition of the functional requirements for the software release. Planning for quality testing starts as business requirements are crafted into a vision/scope document. The software designers work with the requirement owners and the engineers to develop the designs. The software engineers perform estimates to allow the release definition to be "right sized" to the resources available for technical design, coding, and testing. The quality test plans are reviewed with engineering and design. The engineering teams comprised of senior engineers, engineers and junior engineers create the technical designs and create and modify the software code. An experienced team of database engineers review all data table designs with all of the teams to ensure efficient reliable database design for the electronic medical record. A formal process of code review by objective senior level engineers is enforced. A daily feedback loop exists between quality testing and coding. A professional database management system for defect tracking is deployed to collect defects, monitor their progress and resolution. Weekly meetings of the ESF team monitor the software development process. The development senior leadership team (SLT) reviews the weekly progress and assesses risk. When the software is ready for beta testing it is released to the development environment of carefully selected qualified clients. As these select clients find issues, the issues are recorded and corrective action taken as part of a formal process of software fixes, and service pack releases. Each Service pack release is thoroughly tested and incorporated into the current release which goes out to clients. The end of the beta-testing is associated with a service pack for the release. Each release including service packs contains documentation of all new features.

Eclipsys distributes the development team across three major population areas within the North America (Vancouver, Philadelphia and Boston) to take advantage of a large talent pool. Our development team members must go through a formal interview process with multiple engineers and members of the ESF team before they can be extended an offer. We are developing a complimentary large engineering department in two population centers in India and we are applying the same high standards.

Eclipsys SCM developers work with the latest Microsoft development environment technologies, operating systems, languages and database technologies. Eclipsys development uses source control software, and defect tracking software. Frequent meetings utilize web technologies to create the virtual meeting room. Web technology is used to create virtual folders which are frequently updated with artifacts related to the ESF process.

The Eclipsys ESF process is associated with high quality software that meets the needs of our diverse client base.

2. Audit Trail

The SCM user must log into the system using a unique user name and password. Each contributor to the chart is uniquely identified and all information entered into the patient record is tagged with the user id, the date and time, the location of the workstation used and whether it is a new record or a modification of a record and therefore with a history of changes. The security required to view and/or contribute to the chart is very granular so that each user must be granted specific permission to add to specific areas of the patient record. This security extends beyond the document and flow sheet level to the specific question in a document or flow sheet. The SCM system records which user initiates and modifies every observation in a document, records a time stamp and keeps an audit trail of all changes to a document. The system keeps a record of all changes indefinitely. Any record that is "deleted" is not deleted at the database level and can always be retrieved by audit report. Reports of all changes to any document can be printed along with the date and time of all changes and the user who made the changes. Documents will be finalized when all required data and signatures have been applied. Addendums may be made to finalized documents. Any document that has been modified after having once been submitted to the medical record is clearly marked as a modified document with the authors identified as well as the time of the modification. Once finalized, a document may no longer be modified other than by appending a comment. Orders and results have the same level of security and auditing.

All patient data remains on-line. There is no requirement to archive patient data in our modern highly scalable Microsoft SQL Server database management system. All clients are advised to have redundant data storage (regular backups or real-time replication) and disaster recovery plans. The Eclipsys Corporation offers all clients remote hosting with database backup and disaster recovery. Many clients take advantage of this offering, other choose to take advantage of Eclipsys expert database administrative services to ensure proper planning for database maintenance, replication and disaster recovery plans.

3. Legacy Systems

Eclipsys Sunrise Clinical Manager is not a "Legacy System" and we do not claim an exemption from 21 EFR part 11 even though the current product had some early releases before 1977.

4. Copies of Records

The Eclipsys Sunrise Clinical Manager will produce copies of document in PDF format which complies with the copies of record requirement for 21 CFR part11. The copies "preserve the content and meaning of the record" as required by the regulation. Inspectors can be allowed to "inspect, review and copy records in a human readable form on site using local hardware" as required by the regulation.

5. Record Retention

Eclipsys Sunrise Clinical Manager is not purged of data. Although many clients opt to send patient information to a separate storage system to serve as the entire collection of the patient medical record, the records that are produced with SCM remain in SCM. The content and meaning of the records are not changed in SCM by this process.

In conclusion, the Sunrise Clinical Manager Electronic Medical Record System complies with requirements set forth in title 21 Code of Federal Regulations Part 11.

Appendix:

Guidance for Industry[1]

Part 11, Electronic Records; Electronic Signatures - Scope and Application

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to describe the Food and Drug Administration's (FDA's) current thinking regarding the scope and application of part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures (21 CFR Part 11).[2]

This document provides guidance to persons who, in fulfillment of a requirement in a statute or another part of FDA's regulations to maintain records or submit information to FDA,[3] have chosen to maintain the records or submit designated information electronically and, as a result, have become subject to part 11. Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations. Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act (the Act) and the Public Health Service Act (the PHS Act), even if such records are not specifically identified in Agency regulations (§ 11.1). The underlying requirements set forth in the Act, PHS Act, and FDA regulations (other than part 11) are referred to in this guidance document as *predicate rules.*

As an outgrowth of its current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics,[4] FDA is re-examining part 11 as it applies to all FDA regulated products. We anticipate initiating rulemaking to change part 11 as a result of that re-examination. This guidance explains that we will narrowly interpret the scope of part 11. While the re-examination of part 11 is under way, we intend to exercise enforcement discretion with respect to certain part 11 requirements. That is, we do not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of part 11 as explained in this guidance. However, records must still be maintained or submitted in accordance with the underlying predicate rules, and the Agency can take regulatory action for noncompliance with such predicate rules.

In addition, we intend to exercise enforcement discretion and do not intend to take (or recommend) action to enforce any part 11 requirements with regard to systems that were operational before August 20, 1997, the effective date of part 11 (commonly known as legacy systems) under the circumstances described in section III.C.3 of this guidance.

Note that part 11 remains in effect and that this exercise of enforcement discretion applies only as identified in this guidance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

In March of 1997, FDA issued final part 11 regulations that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect the public health.

After part 11 became effective in August 1997, significant discussions ensued among industry, contractors, and the Agency concerning the interpretation and implementation of the regulations. FDA has (1) spoken about part 11 at many conferences and met numerous times with an industry coalition and other interested parties in an effort to hear more about potential part 11 issues; (2) published a compliance policy guide, CPG 7153.17: Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures; and (3) published numerous draft guidance documents including the following:

- *21 CFR Part 11; Electronic Records; Electronic Signatures, Validation*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records*
- *21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records*

Throughout all of these communications, concerns have been raised that some interpretations of the part 11 requirements would (1) unnecessarily restrict the use of electronic technology in a manner that is inconsistent with FDA's stated intent in issuing the rule, (2) significantly increase

the costs of compliance to an extent that was not contemplated at the time the rule was drafted, and (3) discourage innovation and technological advances without providing a significant public health benefit. These concerns have been raised particularly in the areas of part 11 requirements for validation, audit trails, record retention, record copying, and legacy systems.

As a result of these concerns, we decided to review the part 11 documents and related issues, particularly in light of the Agency's CGMP initiative. In the *Federal Register* of February 4, 2003 (68 FR 5645), we announced the withdrawal of the draft guidance for industry, *21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records*. We had decided we wanted to minimize industry time spent reviewing and commenting on the draft guidance when that draft guidance may no longer represent our approach under the CGMP initiative. Then, in the *Federal Register* of February 25, 2003 (68 FR 8775), we announced the withdrawal of the part 11 draft guidance documents on validation, glossary of terms, time stamps,[5] maintenance of electronic records, and CPG 7153.17. We received valuable public comments on these draft guidances, and we plan to use that information to help with future decision-making with respect to part 11. We do not intend to re-issue these draft guidance documents or the CPG.

We are now re-examining part 11, and we anticipate initiating rulemaking to revise provisions of that regulation. To avoid unnecessary resource expenditures to comply with part 11 requirements, we are issuing this guidance to describe how we intend to exercise enforcement discretion with regard to certain part 11 requirements during the re-examination of part 11. As mentioned previously, part 11 remains in effect during this re-examination period.

III. DISCUSSION

A. Overall Approach to Part 11 Requirements

As described in more detail below, the approach outlined in this guidance is based on three main elements:

- Part 11 will be interpreted narrowly; we are now clarifying that fewer records will be considered subject to part 11.

- For those records that remain subject to part 11, we intend to exercise enforcement discretion with regard to part 11 requirements for validation, audit trails, record retention, and record copying in the manner described in this guidance and with regard to all part 11 requirements for systems that were operational before the effective date of part 11 (also known as legacy systems).

- We will enforce all predicate rule requirements, including predicate rule record and recordkeeping requirements.

It is important to note that FDA's exercise of enforcement discretion as described in this guidance is limited to specified part 11 requirements (setting aside legacy systems, as to which the extent of enforcement discretion, under certain circumstances, will be more broad). We

intend to enforce all other provisions of part 11 including, but not limited to, certain controls for closed systems in § 11.10. For example, we intend to enforce provisions related to the following controls and requirements:

· limiting system access to authorized individuals

· use of operational system checks

· use of authority checks

· use of device checks

· determination that persons who develop, maintain, or use electronic systems have the education, training, and experience to perform their assigned tasks

· establishment of and adherence to written policies that hold individuals accountable for actions initiated under their electronic signatures

· appropriate controls over systems documentation

· controls for open systems corresponding to controls for closed systems bulleted above (§ 11.30)

· requirements related to electronic signatures (e.g., §§ 11.50, 11.70, 11.100, 11.200, and 11.300)

We expect continued compliance with these provisions, and we will continue to enforce them. Furthermore, persons must comply with applicable predicate rules, and records that are required to be maintained or submitted must remain secure and reliable in accordance with the predicate rules.

B. Details of Approach - Scope of Part 11

1. Narrow Interpretation of Scope

We understand that there is some confusion about the scope of part 11. Some have understood the scope of part 11 to be very broad. We believe that some of those broad interpretations could lead to unnecessary controls and costs and could discourage innovation and technological advances without providing added benefit to the public health. As a result, we want to clarify that the Agency intends to interpret the scope of part 11 narrowly.

Under the narrow interpretation of the scope of part 11, with respect to records required to be maintained under predicate rules or submitted to FDA, when persons choose to use records in electronic format in place of paper format, part 11 would apply. On the other hand, when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to

perform their regulated activities, FDA would generally not consider persons to be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11.

2. Definition of Part 11 Records

Under this narrow interpretation, FDA considers part 11 to be applicable to the following records or signatures in electronic format (part 11 records or signatures):

· Records that are required to be maintained under predicate rule requirements and that are maintained in electronic format *in place of paper format*. On the other hand, records (and any associated signatures) that are not required to be retained under predicate rules, but that are nonetheless maintained in electronic format, are not part 11 records.

We recommend that you determine, based on the predicate rules, whether specific records are part 11 records. We recommend that you document such decisions.

· Records that are required to be maintained under predicate rules, that are maintained in electronic format *in addition to paper format,* and that *are relied on to perform regulated activities*.

In some cases, actual business practices may dictate whether you are *using* electronic records instead of paper records under § 11.2(a). For example, if a record is required to be maintained under a predicate rule and you use a computer to generate a paper printout of the electronic records, but you nonetheless rely on the electronic record to perform regulated activities, the Agency may consider you to be *using* the electronic record instead of the paper record. That is, the Agency may take your business practices into account in determining whether part 11 applies.

Accordingly, we recommend that, for each record required to be maintained under predicate rules, you determine in advance whether you plan to rely on the electronic record or paper record to perform regulated activities. We recommend that you document this decision (e.g., in a Standard Operating Procedure (SOP), or specification document).

· Records submitted to FDA, under predicate rules (even if such records are not specifically identified in Agency regulations) in electronic format (assuming the records have been identified in docket number 92S-0251 as the types of submissions the Agency accepts in electronic format). However, a record that is not itself submitted, but is used in generating a submission, is not a part 11 record unless it is otherwise required to be maintained under a predicate rule and it is maintained in electronic format.

· Electronic signatures that are intended to be the equivalent of handwritten signatures, initials, and other general signings required by predicate rules. Part 11 signatures include electronic signatures that are used, for example, to document the fact that certain events or actions occurred in accordance with the predicate rule (e.g. *approved*, *reviewed*, and *verified*).

C. Approach to Specific Part 11 Requirements

1. Validation

The Agency intends to exercise enforcement discretion regarding specific part 11 requirements for validation of computerized systems (§ 11.10(a) and corresponding requirements in § 11.30). Although persons must still comply with all applicable predicate rule requirements for validation (e.g., 21 CFR 820.70(i)), this guidance should not be read to impose any additional requirements for validation.

We suggest that your decision to validate computerized systems, and the extent of the validation, take into account the impact the systems have on your ability to meet predicate rule requirements. You should also consider the impact those systems might have on the accuracy, reliability, integrity, availability, and authenticity of required records and signatures. Even if there is no predicate rule requirement to validate a system, in some instances it may still be important to validate the system.

We recommend that you base your approach on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity. For instance, validation would not be important for a word processor used only to generate SOPs.

For further guidance on validation of computerized systems, see FDA's guidance for industry and FDA staff *General Principles of Software Validation* and also industry guidance such as the *GAMP 4 Guide* (See References).

2. Audit Trail

The Agency intends to exercise enforcement discretion regarding specific part 11 requirements related to computer-generated, time-stamped audit trails (§ 11.10 (e), (k)(2) and any corresponding requirement in §11.30). Persons must still comply with all applicable predicate rule requirements related to documentation of, for example, date (e.g., § 58.130(e)), time, or sequencing of events, as well as any requirements for ensuring that changes to records do not obscure previous entries.

Even if there are no predicate rule requirements to document, for example, date, time, or sequence of events in a particular instance, it may nonetheless be important to have audit trails or other physical, logical, or procedural security measures in place to ensure the trustworthiness and

reliability of the records.[6] We recommend that you base your decision on whether to apply audit trails, or other appropriate measures, on the need to comply with predicate rule requirements, a justified and documented risk assessment, and a determination of the potential effect on product quality and safety and record integrity. We suggest that you apply appropriate controls based on such an assessment. Audit trails can be particularly appropriate when users are expected to create, modify, or delete regulated records during normal operation.

3. Legacy Systems[7]

The Agency intends to exercise enforcement discretion with respect to all part 11 requirements for systems that otherwise were operational prior to August 20, 1997, the effective date of part 11, under the circumstances specified below.

This means that the Agency does not intend to take enforcement action to enforce compliance with any part 11 requirements if all the following criteria are met for a specific system:

- The system was operational before the effective date.
- The system met all applicable predicate rule requirements before the effective date.
- The system currently meets all applicable predicate rule requirements.
- You have documented evidence and justification that the system is fit for its intended use (including having an acceptable level of record security and integrity, if applicable).

If a system has been changed since August 20, 1997, and if the changes would prevent the system from meeting predicate rule requirements, Part 11 controls should be applied to Part 11 records and signatures pursuant to the enforcement policy expressed in this guidance.

4. Copies of Records

The Agency intends to exercise enforcement discretion with regard to specific part 11 requirements for generating copies of records (§ 11.10 (b) and any corresponding requirement in §11.30). You should provide an investigator with reasonable and useful access to records during an inspection. All records held by you are subject to inspection in accordance with predicate rules (e.g., §§ 211.180(c), (d), and 108.35(c)(3)(ii)).

We recommend that you supply copies of electronic records by:

- Producing copies of records held in common portable formats when records are maintained in these formats
- Using established automated conversion or export methods, where available, to make copies in a more common format (examples of such formats include, but are not limited to, PDF, XML, or SGML)

In each case, we recommend that the copying process used produces copies that preserve the content and meaning of the record. If you have the ability to search, sort, or trend part 11 records, copies given to the Agency should provide the same capability if it is reasonable and technically feasible. You should allow inspection, review, and copying of records in a human readable form at your site using your hardware and following your established procedures and techniques for accessing records.

5. Record Retention

The Agency intends to exercise enforcement discretion with regard to the part 11 requirements for the protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10 (c) and any corresponding requirement in §11.30). Persons must still comply with all applicable predicate rule requirements for record retention and availability (e.g., §§ 211.180(c),(d), 108.25(g), and 108.35(h)).

We suggest that your decision on how to maintain records be based on predicate rule requirements and that you base your decision on a justified and documented risk assessment and a determination of the value of the records over time.

FDA does not intend to object if you decide to archive required records in electronic format to nonelectronic media such as microfilm, microfiche, and paper, or to a standard electronic file format (examples of such formats include, but are not limited to, PDF, XML, or SGML). Persons must still comply with all predicate rule requirements, and the records themselves and any copies of the required records should preserve their content and meaning. As long as predicate rule requirements are fully satisfied and the content and meaning of the records are preserved and archived, you can delete the electronic version of the records. In addition, paper and electronic record and signature components can co-exist (i.e., a hybrid[8] situation) as long as predicate rule requirements are met and the content and meaning of those records are preserved.

IV. REFERENCES

Food and Drug Administration References

1. *Glossary of Computerized System and Software Development Terminology* (Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs, FDA 1995) (http://www.fda.gov/ora/inspect_ref/igs/gloss.html)

2. *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (FDA, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, 2002) (http://www.fda.gov/cdrh/comp/guidance/938.html)

3. *Guidance for Industry, FDA Reviewers, and Compliance on Off-The-Shelf Software Use in Medical Devices* (FDA, Center for Devices and Radiological Health, 1999) (http://www.fda.gov/cdrh/ode/guidance/585.html)

4. *Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach; A Science and Risk-Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach* (FDA 2002) (http://www.fda.gov/oc/guidance/gmp.html)

Industry References

1. *The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems, GAMP 4* (ISPE/GAMP Forum, 2001) (http://www.ispe.org/gamp/)

2. ISO/IEC 17799:2000 (BS 7799:2000) Information technology - Code of practice for information security management (ISO/IEC, 2000)

3. ISO 14971:2002 Medical Devices- Application of risk management to medical devices (ISO, 2001)

1 This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in consultation with the other Agency centers and the Office of Regulatory Affairs at the Food and Drug Administration.

2 62 FR 13430

3 These requirements include, for example, certain provisions of the Current Good Manufacturing Practice regulations (21 CFR Part 211), the Quality System regulation (21 CFR Part 820), and the Good Laboratory Practice for Nonclinical Laboratory Studies regulations (21 CFR Part 58).

4 See *Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach; A Science and Risk-Based Approach to Product Quality Regulation Incorporating an Integrated Quality Systems Approach* at www.fda.gov/oc/guidance/gmp.html.

5 Although we withdrew the draft guidance on time stamps, our current thinking has not changed in that when using time stamps for systems that span different time zones, we do not expect you to record the signer's local time. When using time stamps, they should be implemented with a clear understanding of the time zone reference used. In such instances, system documentation should explain time zone references as well as zone acronyms or other naming conventions.

6 Various guidance documents on information security are available (see References).

7 In this guidance document, we use the term *legacy system* to describe systems already in operation before the effective date of part 11.

8 Examples of hybrid situations include combinations of paper records (or other nonelectronic media) and electronic records, paper records and electronic signatures, or handwritten signatures executed to electronic records.