



**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

## **Putting CSOS into Practice**

**ASAP Annual  
Industry and Technology Issues  
Conference**

**June 18, 2005**



**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

# Agenda

- Overview
- Scope of regulations
- Key Standards
  - Key Safeguarding
  - FIPS
  - Independent Certification
- Methods for ensuring compliance

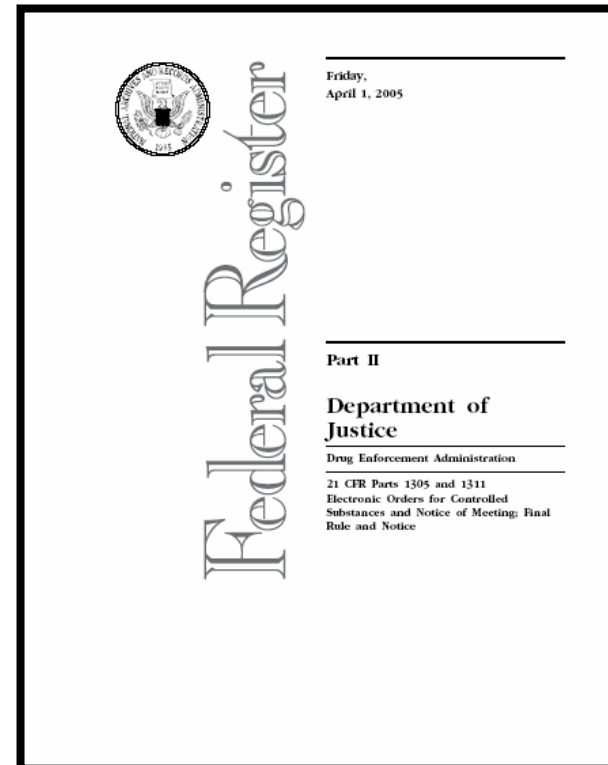


**BruckEdwards, Inc.**

Secure, Compliant,  
Process Improvement

# What's new since January 2005 ?

- Final Rule publication April 1<sup>st</sup>, 2005
- Public Meeting held May 18<sup>th</sup> 2005
- Production operation
- CSOS solutions available



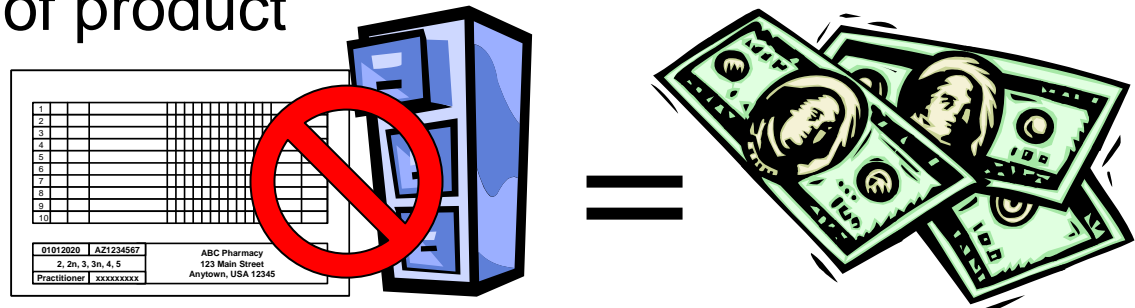


**BruckEdwards, Inc.**

Secure, Compliant,  
Process Improvement

# CSOS Value Proposition

- Economic impact analysis → 264 M annual savings
  - 7 Million controlled substance orders annually
  - Purchasers use overnight shipping
  - Burden of written signatures and paper files
- Savings associated with
  - Reduced inventory
  - Ordering Efficiencies (entering, annotating)
  - Faster receipt of product
  - Filing

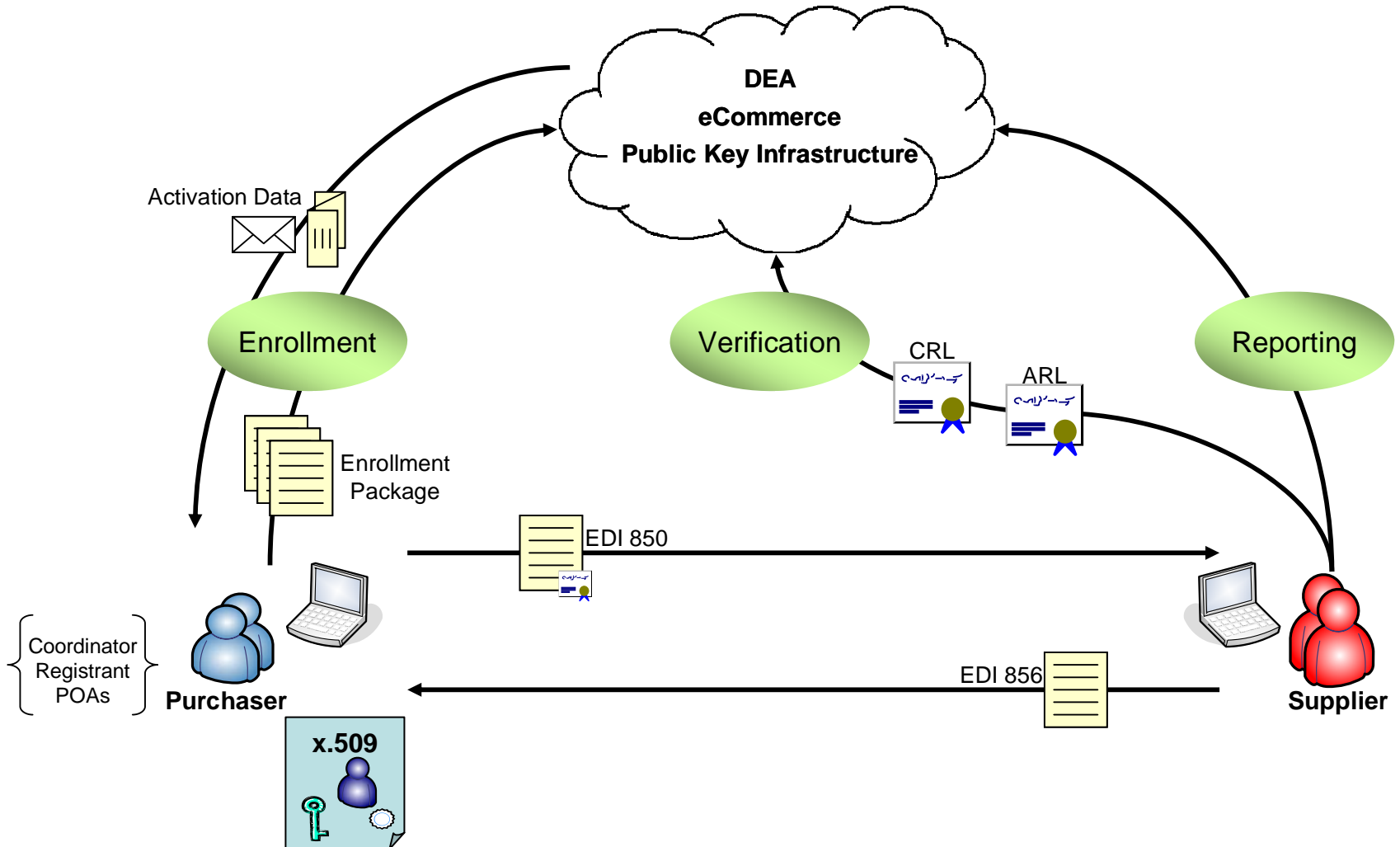




BruckEdwards, Inc.

Secure, Compliant,  
Process Improvement

# Diversion Control e-commerce PKI





**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

## Implementing CSOS demands...

- Understanding all relevant requirements
- How these map to your system
- Mechanism to validate compliance across all systems
- Ongoing process for ensuring staff adherence to certificate management provisions



**BruckEdwards, Inc.**

Secure, Compliant,  
Process Improvement

# CSOS Regulatory Framework §1305



## (C) Electronic Orders

- .21— Requirements for E-orders
- .22— Procedure for Filling E-orders
- .23— Endorsing E-orders
- .24— Central processing of orders
- .25— Unaccepted or defective E-orders
- .26— Lost E-orders
- .27— Preservation of E-orders
- .28— Canceling and voiding of E-orders
- .29— Reporting to DEA

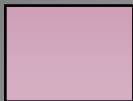
### LEGEND



Purchaser



Supplier



Purchaser &  
Supplier



**BruckEdwards, Inc.**

Secure, Compliant,  
Process Improvement

# CSOS Regulatory Framework §1311



## **(B) Obtaining & using digital certificates for E-orders**

- .10— Eligibility to obtain a CSOS certificate
- .15— Limitations on CSOS certificates
- .20— Coordinators for CSOS certificate holders
- .25— Requirements for obtaining a CSOS certificate
- .30— Requirements for storing and using a private key
- .35— Number of CSOS certificates needed
- .40— Renewal of CSOS Certificates
- .45— Requirements for registrants that allow POAs to obtain CSOS certificates under their DEA registration

- .50— Requirements for recipients of digitally signed orders
- .55— Requirements for systems used to process digitally signed orders
- .60— Recordkeeping

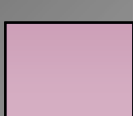
### LEGEND



Purchaser



Supplier



Purchaser &  
Supplier





**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

# Federal Information Processing Standards

- Wide range of FIPS approved modules available
- FIPS is relevant to:
  - Cryptographic module (140-2)
  - Signing algorithms (186-2)
  - Hash algorithms (180-2)
- Best achieved by selecting commercial solution



BruckEdwards, Inc.

Secure, Compliant,  
Process Improvement

# Provisions for Key Management

- 1311.30 Requirements for storing & using a private key
  - a) Only the certificate holder may access a private key
  - b) FIPS approved private key storage is required
  - c) No person other than the certificate holder can use the private key. Unauthorized use must be prevented.
  - d) No backup copies
  - e) Must report loss or theft within 24 hours of substantiation
- 1311.55 Requirements for Systems
  - FIPS
  - User ID or biometric activation
  - 10 minute inactivity timeout
  - Plaintext key must be cleared from system memory



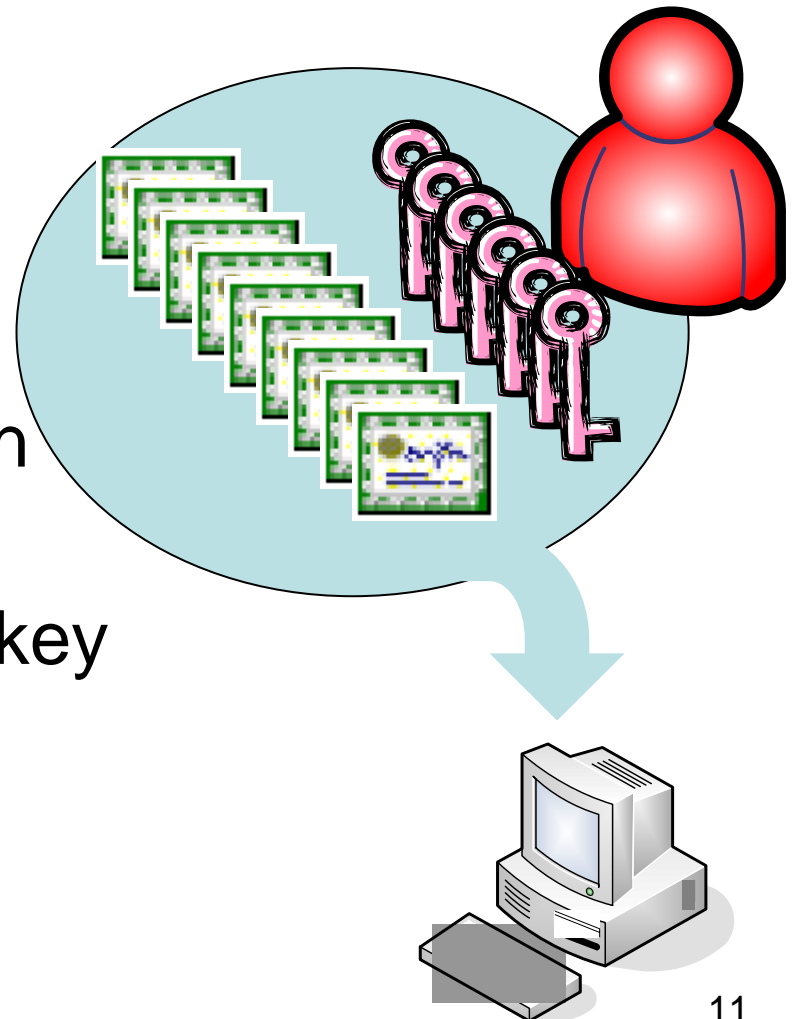


**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

# Technical Key Management Challenges

- Secure Retrieval
  - Individual or bulk
  - Certificate naming
  - IT/ Pharmacy coordination
- Certificate protection within OS
- Preventing loss of private key
- Scalable to support centralized purchasing / POAs
- Portability





**BruckEdwards, Inc.**

Secure, Compliant,  
Process Improvement

# Ongoing Training Needs

- Certificate Management
  - Rolls (Registrant, Coordinator, POA)
  - Forms
  - Agreements
  - Deadlines
- Key Safeguarding





**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

# Independent Certifications

- 1311.55 (d) – For systems used to process CSOS orders, the system developer or vendor must have an initial independent third-party audit of the system and an additional independent third-party audit whenever the signing or verifying functionality is changed to determine whether it correctly performs the functions listed under paragraphs (b) and (c) of this section.





**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

# Independent Certifications

- Buyers must make informed purchasing decisions
- For organizations building customized CSOS solution, provision still applies.
- Not applicable to all system changes only for signing and verification.
- Not all commercial solutions will address all CSOS requirements.
- Read the certification !!!

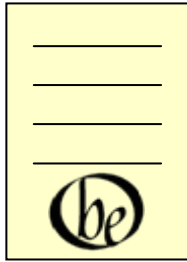


BruckEdwards, Inc.

Secure, Compliant,  
Process Improvement

# CSOS Compliance Management Methodology

## Questionnaire



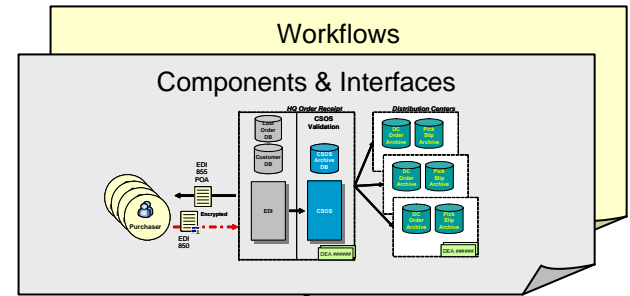
## Training & Discovery



Functions  
Components  
Interfaces  
Constraints  
Legal Instruments



## "As-is" Definition & Schedule



## Phase 1

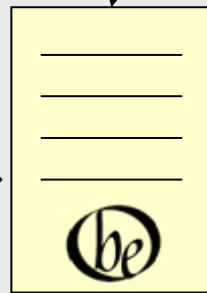
Satisfaction  
Mechanisms

## CSOS BLUEPRINT

- Flow Diagrams
- Architecture Diagrams
- Inputs/outputs
- Interfaces
- Validation Logic
- Event Handling
- Std. Ops. Procedures
- Legal Issues
- Questions

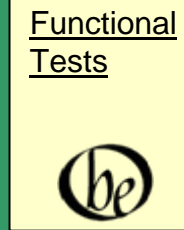


## RTM



## TESTING

Use Cases  
(850)



## OUTCOMES



## TEST REPORT



## Phase 2

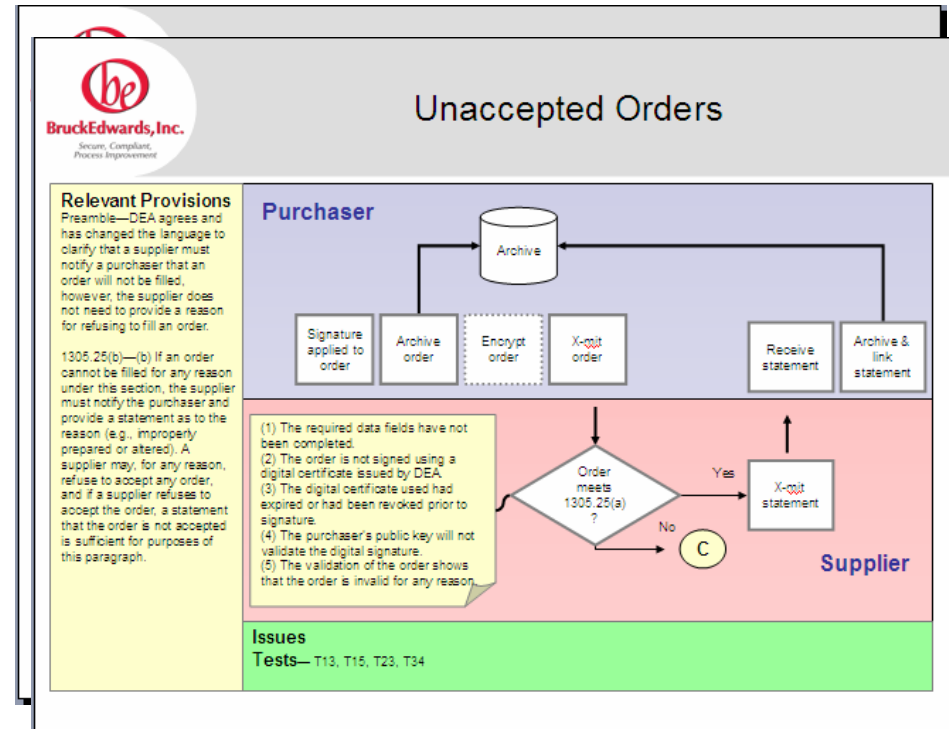


BruckEdwards, Inc.

Secure, Compliant,  
Process Improvement

# Implementation Workflows

- Relevant Provisions
- Processing Logic
- Error handling
- System Component
- Interfaces
- Standard Procedures
- Test Cases



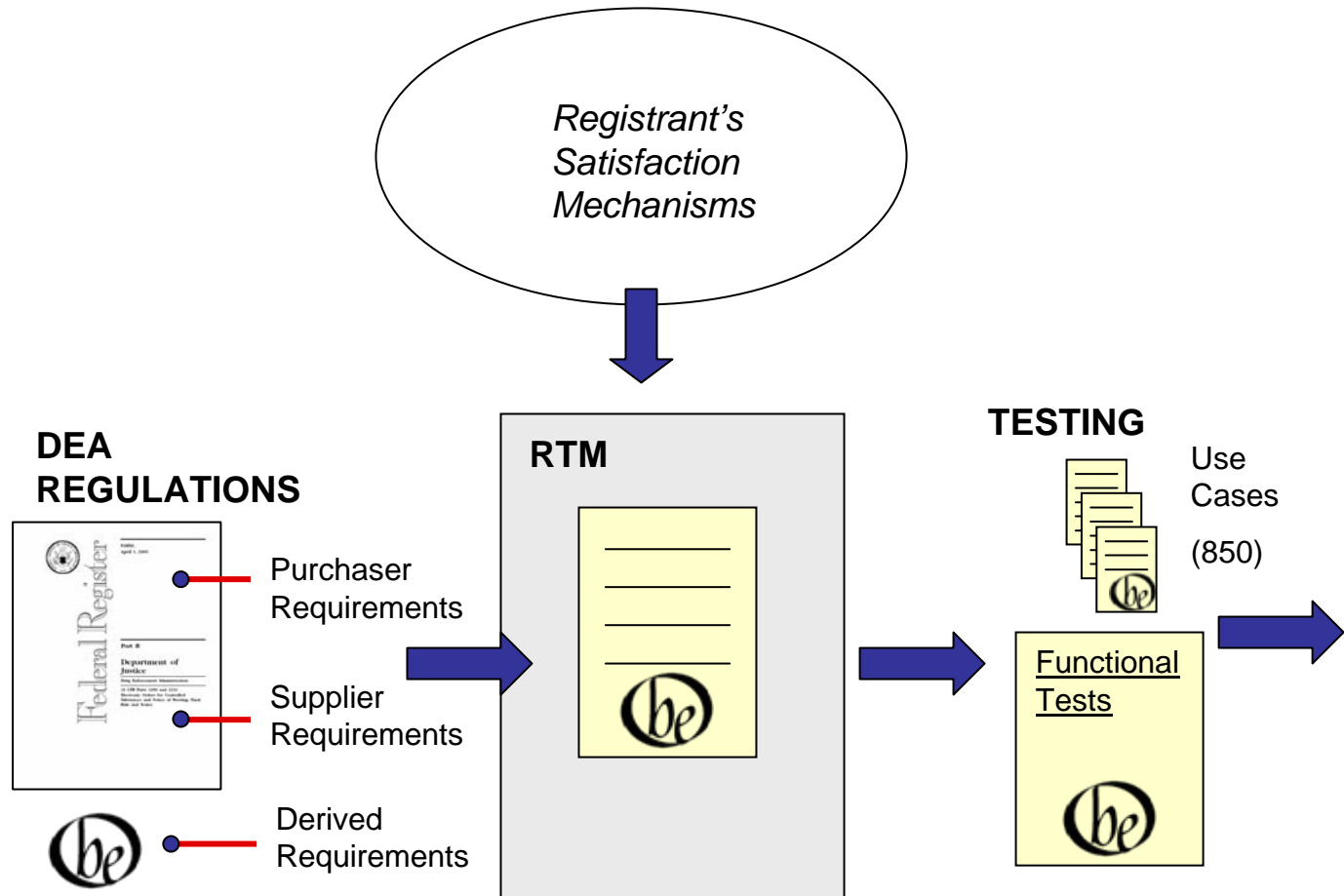




**BruckEdwards, Inc.**

Secure, Compliant,  
Process Improvement

# CSOS Requirements Traceability Matrix





**BruckEdwards, Inc.**

*Secure, Compliant,  
Process Improvement*

# Contact Information

## **Internet**

[Steve.Bruck@BruckEdwards.com](mailto:Steve.Bruck@BruckEdwards.com)

[www.BruckEdwards.com](http://www.BruckEdwards.com)

## **Office**

505 Huntmar Park Drive  
Suite 325Q

Herndon, Virginia 20170

Tel: 703-286-5311

Fax: 703-286-5312

Copyright 2005, BruckEdwards, Inc. No portion of this document may be reproduced, used or distributed in any form without written authorization. All trademarks assumed.