Change Control Process for European eCTD Standards
Version 1.1

December 2006

Document Control

Change Record

Version	Date	Author(s)	Comments
0.1	10 September, 2003	Miguel Bley	Draft
0.2	11 September, 2003	Miguel Bley	Draft
0.3	23 September, 2003	Miguel Bley	Draft
0.4	5 November, 2003	Miguel Bley	Draft
0.5	1 July, 2004	Miguel Bley	Draft
1.0	1 July, 2004	Miguel Bley	Adopted by the TIGes for publication on NtA
1.1	8 December 2006	Miguel Bley	Change of submission address to ectd@emea.europa.eu adopted at TIGes meeting on 20 November 2006

Reviewers

Version	Name	Organisation
0.1	All participants in the meeting	TIGes
0.2	Miguel Bley	TIGes
0.3	All	TIGes/NtA-TIGes Interlinking
0.4	All	TIGes/NtA-TIGes Interlinking
0.5	All	TIGes/NtA-TIGes Interlinking/JIGes
1.1	Juan Rueda	EMEA

Distribution

Version	Date	Name	Status
0.1	11 September, 2003	TIGes	Reviewed
0.2	12 September, 2003	Joint TIGes-Industry Group	Reviewed
0.3	23 September, 2003	TIGes/Joint TIGes-Industry Group	Reviewed
0.4	10 November, 2003	TIGes/NtA-TIGes Interlinking	Adopted
0.4	5 December, 2003	JIGes	Adopted
0.5	2 July, 2004	TIGes/NtA-TIGes Interlinking/JIGes	Submitted
1.0	2 July, 2004	NtA Chair for publication on NtA	Submitted
1.1	8 December 2006	NtA Chair for publication on NtA	Submitted

CONTENT:

Introduction

The eCTD Specification was signed by the ICH Steering Committee in September 2002 and adopted by the CPMP in November 2002. The Telematics Implementation Group for Electronic Submission (TIGes) validated the position of the European regulators delegation at the ICH-M2 Expert Working Group (ICH-M2 EWG) that produced the eCTD standard. The TIGes administers European eCTD standards and its task is to facilitate the implementation of eCTD by both applicants and Competent Authorities in the European Economic Area (EEA). Changes to the eCTD Specification are managed by the ICH-M2 Implementation Working Group (ICH-M2 IWG) through the Change Control Process for the eCTD. As with the eCTD Specification, the European eCTD standards are likely to change due to technological progress, new concepts (i.e. for administrative forms and product information) and experience gained with the implementation of eCTD. For successful implementation of eCTD, change control should be in place to effectively communicate and execute changes to the European eCTD standards.

Scope

This document establishes the change control process for European eCTD standards in the EEA. These regional standards are Modules 1, 2.3.R and 3.2.R. With regard to change requests on harmonised aspects of the eCTD Specification in Modules 2 to 5, the ICH-M2 IWG should be consulted.

Purpose

The TIGes is authorised by the Telematics Management Committee (TMC) to administer changes to the European eCTD standards. Change control is established to serve the following purposes:
- Evaluate and approve or disapprove proposed changes to the specification
- Ensure implementation of approved changes
- Represent the interest of all groups who may be affected by the changes

The change control process applies to all aspects of European eCTD standards.

Change Control Process

European eCTD Standards Questions and Change Requests

Questions and change requests may originate from all interested parties, as follows:

1. Questions or change requests submitted to the ICH-M2 IWG requiring regional guidance should be posted in the eCTD IWG Q&A and Tracking document and forwarded to the chairman of the TIGes for European guidance.

2. When changes in the regulation impose modification of the content or the procedures guidance in the Notice to Applicants that affects European eCTD standards the NtAWG should consult with the TIGes through the NtA-TIGes Interlinking Group. All questions and change requests from the NtAWG should be documented and submitted to the TIGes chairman. The TIGes chairman should make Notice to Applicants changes requests a high priority on the European eCTD standards change requests list.

3. Questions and change requests by Industry/Vendors could be submitted to the eCTD contact person in an EEA country. Prior to being submitted, questions and change requests should undergo any necessary testing by the requestor and the Competent Authority in the country sponsoring the request and sufficient practical examples on the issue should be provided. A preference is expressed that questions and change requests from industry should be channeled through either national or international industry associations. Questions and change requests should then be forwarded to the Chairman of the TIGes for tracking, distribution and resolution.

Change Control Form

A Question and Change Request Form is provided in Appendix A.
Each change request should minimally contain the following information:

- Contact information
- Change request information, if applicable
  - Summary of the problem, including rationale
  - Item to be changed
  - Version number and date of the European eCTD standard
  - Detailed description, including results of any testing
  - Recommended solution, if any
- Question information, if applicable
  - Clear formulation of the question including rationale
  - Reference to the European eCTD standard the question is referring to
  - Version number and date of the European eCTD standard the question is referring to.

Change Control Meetings

At each meeting of the Joint TIGes-Industry eCTD Implementation Group appropriate time will be set aside for European eCTD standards change control. Any member of the TIGes or the Joint TIGes-Industry eCTD Implementation Group can request that the chairman of the TIGes schedule an emergency change control meeting.

Preparing for the Meeting

A list of change requests will be organised and presented by the chairman to the TIGes prior to the meetings.

Questions and Change Requests Review

The questions and change requests will be presented at the Joint TIGes-Industry meeting where they would take one of the following paths:

1. Defined as out of scope include:
- Is not relevant
- Issues related to ICH-M2 eCTD guidance. These should be covered by the ICH-M2 Change Control Process for eCTD.
- Issues related to Modules 2-5, except 2.3.R and 3.2.R. These should be covered by the ICH-M2 Change control process for eCTD.
- Requires regulatory answer. Forwarded to the NtA-TIGes Interlinking Group.

2. Defined as in scope after presentation and discussion of the question or change request so that it can be processed by the Joint TIGes-Industry eCTD Implementation Group include :
- Approval and proposal to the TIGes for :
– Standard change by the TIGes : posted and submitted to NtA-TIGes Interlinking Group.
– Q&A document : posted and submitted to NtA-TIGes Interlinking Group.
- Assignation to a subgroup for further review and testing : posted
- Deferral to next Joint TIGes-Industry eCTD Implementation Group meeting : posted
- Rejected : posted

Additional testing may be called for before a question or change request can be fully evaluated. The question or change request would stay on the European eCTD standard change control agenda and be presented at the next meeting for additional review.
The TIGes will make the final decision on the Q&A and the implementation of a change request.

Approved Q&A and Change Requests

Q&A and change requests approved by the TIGes would either be addressed in Q&A or implemented into the European eCTD standards and presented by the chairman of the TIGes to the NtAWG through the NtA-TIGes Interlinking Group for approval and publication.

The TIGes will implement approved Q&A and change requests in the European eCTD standards at appropriate intervals. The version number and date of the standards will be updated in that case and an indication will be provided on transition periods for implementation. Approved Q&A and changes

will be communicated through the Q&A and Change Request Tracking Document. In urgent cases, the standard will be updated immediately.

Documentation

The following documentation will be posted on the Commission's web site in the relevant location of the Notice to Applicants.

- Updated version of the European eCTD standards adopted by the NtAWG.
- Updated Q&A and Change Request Tracking Document adopted by the NtAWG that includes the status of approved, deferred or rejected.

Working drafts of the above documents adopted by the TIGes will be posted on the EMEA's web site: http://esubmission.eudra.org/tiges . They will become official guidance when posted on the Commission's web site.

European eCTD Standards Release Strategy

Stability of the European eCTD Standards is important to ensure that industry and regulators can develop or procure efficient tools. In order to provide this stability and in line with the release strategy for ICH eCTD specification, the European eCTD Standards will follow a specific release strategy that allows software application developers and managers to plan for the future.

Major Releases

Major new releases of European eCTD Standards will be announced at least two years before they occur. Major releases include changes that significantly impact DTDs, major modifications to architecture, or significantly impact the software applications being used. These major releases will be addressed by the Joint TIGes-Industry eCTD Implementation Group and follow the Change Control Process described in this document.

Major releases will be identified by a new numbering sequence (e.g., 2.0, 3.0).

Minor Releases

In between major releases of European eCTD Standards, the Joint TIGes-Industry eCTD Implementation Group could also propose minor releases of the standards. The scope of these minor releases will be to correct minor issues with the specifications that hinder standards implementation or software application development. For minor modifications to the European eCTD Standards, notification will occur when the minor release is published on the Notice to Applicant.

eCTD should always mirror the CTD structure. Modifications introduced in the European eCTD Standards to comply with CTD guidance will be considered minor releases and proposed by the NtA-TIGes Interlinking Group.

Minor releases will continue the numbering sequence of the last major release (e.g., 2.1, 2.3).

Version Compatibility

Backwards compatibility will be considered for each European eCTD Standards release. Descriptions of the scope of each change will be provided with each new release.

APPENDIX A : European eCTD Standards Q&A and Change Request Form

Contact Information

Organisation Name:	
Organisation Address:	
Contact Name:	
Address:	
Telephone Number:	
Email Address:	

Change Request Information

Summary	*This should be a short summary of the problem including rationale*
Submission Date	*Date you submit the Change Request*
Item To Be Changed	*Indicate the exact item to be changed. For example the EU Module 1 specification, Application Form DTD, etc.*
Version Number and Date	*Indicate the specific version of the item for which you are proposing the change.*
Description	*Provide a detailed explanation of the problem, any known solutions, and steps on how to recreate the error, if applicable. If this is a new requirement or enhancement, please provide the reason for the requirement or enhancement and any known solutions. If you have any sample output, sample code or other examples to help clarify the description, attach the samples to this form. Also provide a detailed description of any testing or research that was done to support the solution(s) being proposed and any advice on backward compatibility issues.*
Recommended solution, if any	

Question Information

Question	*This should be a clear formulation of the question including rationale*
Submission Date	*Date you submit the question*
Referred Item	*Indicate the exact item the question is referring to. For example the EU Module 1 specification, Application Form DTD, etc.*
Version Number and Date	*Indicate the specific version of the item the question is referring to.*

Submit a completed electronic copy of this form to the following address: **ectd@emea.europa.eu**