eCTD Next Major Release Business Requirements Collation (9-JUN-10)			
ICH Req No.	TOPIC	Requirement	Comment
ICH001	APPLICATION LIFECYCLE	A regulated product application may have one or more regulatory activities associated with it	
ICH002	APPLICATION LIFECYCLE	It must be possible to define a 'Regulatory Activity' to which a group of sequences will belong	
ICH003	APPLICATION LIFECYCLE	A regulatory activity may have one or more sequences associated with it	
ICH004	APPLICATION LIFECYCLE	The message should support the ability to provide one sequence to multiple regulatory activities which may span more than one application.	sequence number values would need to be unique to each application
ICH005	APPLICATION LIFECYCLE	Each sequence should have a unique identifier	
ICH006	APPLICATION LIFECYCLE	Capability to identify which eCTD sequences were used at which step of agency review.	
ICH007	APPLICATION LIFECYCLE	The message should not restrict adoption/implementation of the standard at any point in a product's lifecycle.	principle
ICH008	APPLICATION LIFECYCLE	Compatible both to US/EU product-wise lifecycle and to Japan application-wise lifecycle.	principle
ICH009	ARCHIVE	It must be possible to review and to archive the sequence without need for transformation	principle
ICH010	AUTHOR-REVIEW	It should be possible to review the eCTD	principle
ICH011	AUTHOR-REVIEW	The specification should not restrict the types of file formats which can be submitted for use with the standard (allowed file formats are defined by each implementation and are not defined by the exchange specification).	principle
ICH012	AUTHOR-REVIEW	It should be possible for the reviewer to have access to the entire application from any part of the application.	principle
ICH013	AUTHOR-REVIEW	Clear definition of views across multiple sequences (cumulative, current)	viewer/implementation requirement

ICH014	BACKWARD COMPATIBLE	Elements and attributes defined by V3.x should be able to be mapped to v4.0 constructs (and not the reverse)	
ICH016	BACKWARD COMPATIBLE	The message should support continued use of the information and documentation provided with previous regional implementations, e.g., Module 1, STF.	principle
ICH017	DATASETS	It should be possible to provide data definitions for data sets.	principle
ICH018	DOCUMENT FORMATTING	It should be possible to support the inclusion of scanned documents, primarily for legacy documents	principle
ICH019	DOCUMENT METADATA	It must be possible to describe, in free text, the titles of the files being submitted	Title can be different per usage (e.g., context)
ICH020	DOCUMENT METADATA	Every submitted file will have a unique identifier	
ICH021	DOCUMENT METADATA	It must be possible for a Submitter to provide user defined information or identifier for a file	
ICH022	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance within an application.	
ICH023	DOCUMENT REUSE	The message should support the reuse of electronic files from a previously submitted instance across applications.	
ICH024	DOCUMENT REUSE	It must be possible to include by reference, a file that physically resides in another sequence / regulatory activity / application (e.g.. cross-product submission support)	cross-application and cross-sequence
ICH025	DOCUMENT REUSE	It must be possible to include, by reference, a file that has been submitted in a previous sequence and to be able to identify that this is not new but is being used in a different context	implementation-Reviewer Capability

ICH026	ENVELOPE	It must be possible to assign an identifier to a sequence	to imply an order, to enable sorting (e.g., chronology or review order) or just to assign uniqueness within an application [unique identifier for the sequence within the application and a friendly identifier]
ICH027	ENVELOPE	It must be possible to identify the regulatory agency for which a specific sequence is intended	
ICH028	ENVELOPE	It must be possible to identify the applicant submitting a sequence	
ICH029	ENVELOPE	It must be possible to unambiguously associate a sequence to the application(s) to which it belongs	
ICH030	ENVELOPE	It must be possible to assign a submission type being used for the sequence	
ICH031	ENVELOPE	It must be possible to describe, in free text, the sequence (include a short description of the sequence in the administrative section)	
ICH032	ENVELOPE	It must be possible to identify the Procedure type being used for the application	
ICH033	ENVELOPE	It must be possible to assign an invented name (trade name) for the product covered by the application	Not just EU Regional
ICH034	ENVELOPE	It must be possible to assign an international non-proprietory name(s) (inn) for the drug substance(s) covered by the application	Not just EU Regional
ICH035	EU REGIONAL	It must be possible to identify to which specific country a file is relevant	
ICH036	EU REGIONAL	It must be possible to identify that a file is relevant to all countries	

ICH037	EU REGIONAL	It must be possible to identify for which country(ies) a specific sequence is intended	
ICH038	HARMONISATION	The message should support ICH-harmonized content (documentation and metadata) and ICH-regional content	
ICH039	HARMONISATION	Need to provide a structure that supports all terminologies for dossier (all regulatory activity related to a product) and regulatory activity (collection of sequences that lead to a decision by the regulatory agency (NDS, SNDS)) which can be mapped to individual ICH-regional regulatory processes	controlled vocabularies / Implementation Guide
ICH040	HARMONISATION	Files should only need to be submitted once to a Health Authority and can be included by reference in multiple sequences to support multiple regulatory actions even across applications	Clarify meaning of application
ICH041	HARMONISATION	Ability to reuse of eCTD submitted in other regions. e.g. reuse of leaf files, XML instance by module, eCSR. To achieve this, it is critical to distinguish global part and regional part even in Module2-5, not only in Module1.	Industry building tool need
ICH042	HARMONISATION	When the same documentation is provided, it should be submitted in the same way across HAs. For example, when a study report is submitted in US it is submitted using the STF which is not acceptable in other HAs. This minimizes reuse capabilities and adds to Industry costs to prepare globally harmonized dossiers.	principle
ICH043	HYPERLINKING	It should be possible for the applicant to include hyperlinks between information	
ICH044	HYPERLINKING	It should be possible to utilise relative addressing for all links.	
ICH045	HYPERLINKING	When a file is replaced, hyperlinks referencing that file can be redirected to the 'replacement' file or retired.	reviewer requirement
ICH046	HYPERLINKING	Need to support relative links across the product lifecycle	

ICH047	ICH PROCEDURE	For validation purposes,
		  - It should be able to uniquely identify:
		    - where in CTD a leaf belongs
		    - the relationship between leafs
		    - the lifecycle relationship (append, delete, or replace) between files
		    - the relationship between sequences
		   - the relationship of a sequence to a regulatory activity
		    - the relationship between applications
		    - the type of relationship (parent-child, reference, etc)
			Principle

ICH048	JP-REGIONAL	Message should support the ability to provide second and subsequent sequences which contain only additional information in XML Instance	Implementation Guide
ICH049	LANGUAGE	It must be possible to assign a language to a document	
ICH050	LANGUAGE	It must be possible to (incorporate unicode character sets) to deal with languages such as Bulgarian and Greek	Deal with greek and cyrillic
ICH051	LANGUAGE	It must be possible to include files with 1 or 2 byte characters, or a mixture of both	
ICH052	LANGUAGE	eCTD viewer should recognize section titles defined in CTD, e.g. "2.5 Clinical Overview". It should have an interface capable to show CTD section titles in any languages by switching standard dictionary provided by regional agencies.	viewer requirement / controlled vocabulary
ICH053	LIFECYCLE	The message should provide the ability to assign new metadata to update information previously submitted e.g., related sequences, submission type, operation attribute, manufacturer name, etc.	Delete examples
ICH054	LIFECYCLE	The message should provide the ability to unassign metadata previously submitted, e.g., related sequences, submission type, operation attribute, manufacturer name, etc.	
ICH055	LIFECYCLE	The message should provide the ability to revise metadata previously submitted, e.g., related sequences, submission type, operation attribute, manufacturer name, etc.	

ICH056	LIFECYCLE	Information provided in the message (i.e., metadata) used to categorize documentation (e.g., attributes of drug substance, manufacturer, etc) or supplied in the regional envelope (e.g., Company Name, Sponsor) can be modified (i.e., added, edited, removed) during the life cycle of the application.	
ICH057	LIFECYCLE	Replacement of multiple leafs with single leaf and vice versa should be supported in eCTD.	
ICH058	LIFECYCLE	The process for concatenating individual sequences into a combined sequence view (i.e., the current view and the cumulative view) must be unambiguously defined	viewer requirement / implementation
ICH059	LOGICAL GROUPINGS	Provide ability to group a collection (or set) of files that together represent a document or reviewable grouping (e.g., all files related to a study report, all files related to a labeling document, all files related to a manufacturer or manufacturing component (e.g., container closure))	
ICH060	LOGICAL GROUPINGS	Provide ability to treat a grouping of files as a single entity and to be treated as if it were a single file (complete with all descriptive attributes e.g., title) for all life cycle operations and relationship management and reuse needs	
ICH061	PHYSICAL FILE RULES	Filenames can include underscores	
ICH062	PHYSICAL FILE RULES	It should be possible to constrain the contents to ensure there are no security settings, such as passwords.	Implementation Guide
ICH063	PHYSICAL FILE RULES	The physical file structure. (file/folder structure) should be minimal	
ICH064	PHYSICAL FILE RULES	The technical message should not restrict the types of files that may be transferred. However, implementation guides may restrict the types of files and versions of file formats to be transferred or may specify unique file formats for that region.	principle
ICH065	PHYSICAL FILE RULES	It should be possible to support file systems of different operating systems	principle
ICH066	PHYSICAL FILE RULES	It must be possible to constrain the maximum size of any file (reword to reflect ICH minimum standard)	Implementation issue

ICH067	SCOPE	Allow the capacity to modify the ICH CTD organizational structure (ToC) without modifying or changing the eCTD message structure	
ICH068	SCOPE	It should be possible to compile an eCTD equivalent to the CTD	principle
ICH069	STANDARDS	The message should interoperate with other healthcare standards, e.g. use controlled vocabularies from established standard-based vocabularies	principle
ICH070	STANDARDS	It should be possible to restrict the technology utilized to use open (ISO, W3C, IETF) standards when ever possible.	Principle
ICH071	STRUCTURE	It must be possible to constrain the inclusion of documents at inappropriate locations in the submission structure (e.g.. at highest levels of eCTD)	
ICH072	STRUCTURE	The message should allow for the control/enforcement of document/structural granularity.	
ICH073	STRUCTURE	It must be possible to assign 'attributes' to the contents of specific sections to support the ICH CTD organizational structure (e.g., repeating section 3.2.S)	
ICH074	STRUCTURE	It must be possible to ensure that all files submitted are defined and referenced	
ICH075	STRUCTURE	It must be possible to validate the contents of a sequence against the CTD (e.g., module 6 is invalid)	
ICH076	STRUCTURE	It should be possible to identify all of the files relevant to a specific section of the CTD	
ICH077	STRUCTURE	It should be possible to review the sequence in its entirety or in sections.	Method of transmission should support the consumption
ICH078	TECHNOLOGY	The standard must not be constrained by the need for delivery via a particular medium	principle
ICH079	TECHNOLOGY	It should be possible to include colour and black & white images	principle
ICH080	TECHNOLOGY	It should be possible to support the introduction of new technology to aid in the review process.	principle
ICH081	TERMINOLOGY	The message should support the use of controlled vocabularies for harmonized metadata	

ICH082	TERMINOLOGY	The message should support the use of controlled vocabularies for regional metadata.	
ICH083	TERMINOLOGY	It should be possible to specify date values in an unambiguous manner.	
ICH084	TRANSFER/SECURITY	The message should support a means to enable the validation of the integrity of the electronic files within an instance	
ICH085	TRANSFER/SECURITY	The message standard should not restrict the mechanism for transmitting the message (e.g., media type, network)	principle
ICH086	TRANSFER/SECURITY	The message standard should not restrict or prevent regionally implemented secure electronic message delivery standards	Implementation GuIde
ICH087	TWO-WAY COMMUNICATION	The message should support submission of a sequence from a regulator to a regulated party.	
ICH090	TWO-WAY COMMUNICATION	It should be possible to define the security methods to be used for transmission to the agencies and acknowledgement from the agency.	principle
ICH091	US-REGIONAL	The message should support the identification of the role of the instance within the identified regulatory activity, e.g. presubmision, application, amendment, etc.	
ICH092	US-REGIONAL	The message should support the identification of the regulatory activity associated with the instance, e.g. original-application, labeling-supplement, etc.	
ICH093	VALIDATION	It must be possible to define unambiguously, the validation criteria for a sequence	Principle
ICH094	VALIDATION	Message should contain sufficient information to unambiguously identify which version(s) of the DTD/Schema and controlling vocabularies was used to create the instance	
ICH095	VALIDATION	The message should not require the submission of the DTD/Schema and controlling vocabularies with each instance	
ICH097	COMPATIBILITY	It should be possible for an applicant to build on an eCTD lifecycle started using the eCTD 3.2.x specification and continued using the eCTD NMV specification	

ICH098	COMPATIBILITY	No applicant should be required to resubmit data in the eCTD NMV specification if it has previously been submitted using the eCTD 3.2.x specification. (It is recognised that in the future, further major versions of the eCTD specification may require data migration guidance to ensure the use of data over the life of a drug product).	principle
ICH099	COMPATIBILITY	Tools designed to view eCTD NMV sequences must also be able to view a lifecycle started with the eCTD 3.2.x specification. However, the reverse requirement is not needed (i.e. it is not needed that tools for the eCTD 3.2.x specification should be able to view sequences created using the eCTD NMV specification).	principle
ICH100	COMPATIBILITY	It is expected that once an eCTD lifecycle is transitioned to the eCTD NMV specification, then no further submissions/sequences will be made in the eCTD 3.2.x specification.	principle
ICH101	COMPATIBILITY	The implementation guide must state how lifecycle relationships can be maintained from eCTD 3.2.x to eCTD NMV.	
ICH102	COMPATIBILITY	Ability to reuse content; files submitted in eCTD sequences can be referenced in eCTD NMV submission units	
ICH104	DESIGN CONCEPTS	The file format of the message should be xml-based.	principle
ICH105	DESIGN CONCEPTS	The message standard should not prevent or restrict the ability to e-sign the message.	principle
ICH106	DESIGN CONCEPTS	The message standard should not prevent or restrict the ability to encrypt the message for secure transfer purposes	principle
ICH107	DESIGN CONCEPTS	The message standard must not require encryption	principle
ICH108	INTEGRITY	Integrity checks for all files included in the sequence are required.	
ICH109	DESIGN CONCEPTS	The message should provide the ability to identify further specific usage of the file (e.g., SPL, SDTM, application format, packaging insert, CTN) beyond that defined by the CTD	
ICH110	INTEGRITY	The ability to specify which algorithm is being used for file integrity checks is required.	

ICH112	TWO-WAY COMMUNICATION	It must be possible to relate any message to a particular message, regulated activity and/or application.	
ICH113	TWO-WAY COMMUNICATION	Every eCTD message must be uniquely identifiable.	
ICH114	DESIGN CONCEPTS	In principle, the number of xml files managing content should be kept to a minimum and use a consistent technical design approach even though the content models may differ regionally	principle
ICH115	ENVELOPE	The message standard must provide the ability to include information required for the processing (e.g., message standard version) and integrity (e.g., checksum) of the message	
ICH116	ENVELOPE	The message standard must provide a three-level hierarchy of application, regulatory activity and submission unit.	principle
ICH117	ENVELOPE	The message standard must provide information about the product.	enumerate data points to be required regionally
ICH118	ENVELOPE	The message standard must provide enough information to identify the sender.	enumerate list of all data elements required to effect 2-way communication
ICH119	ENVELOPE	The message standard must provide enough information to identify the recipient.	enumerate list of all data elements required to effect 2-way communication
ICH121	LIFECYCLE	The order/sequence of leaf elements within a CTD section must be able to be controlled	

ICH122		A file can be displayed in multiple sections of the CTD (preserving the leaf - file concept in the current eCTD specification)	
ICH123		Maintain a similar file-leaf model as in the current eCTD in the eCTD NMV, with the following exception/changes: a. The operation attribute value "append" be removed from the list of allowed values (leaving only new, replace and delete) b. Allow a replace or delete leaf to modify more than one leaf in a previous sequence or sequences c. Allow a single leaf to be "modified" by more than one leaf in later sequences (supports changes in granularity)	
ICH124		A file can be replaced in one existing eCTD section or context without impacting the use of the file in other eCTD sections or contexts	
ICH125		Life cycle operations must occur within the same context as the existing (target) leaf	
ICH126		There should be no restrictions on the characters used in controlled vocabularies	principle
ICH127		There should be a basic ICH stylesheet for presentation purposes	
ICH128		STF construct should be integrated into the message standard	
ICH129		Cardinality rules of the current eCTD Specification should be retained plus those cited in approved Change Requests (e.g., CR#1490/1500 - Module 3.2.A.3 will be made a repeating attribute in Version 3.2 of the specification based on excipient).	
ICH130	DESIGN CONCEPTS	The message standard should allow the ability to e-sign the message.	principle