

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
General Recommendation – ESTRI Gateway 10NOV2005

Title: ESTRI Gateway

Background:

Electronic transfer of regulatory information offers the potential for significant time and resource savings for both Industry and Regulatory Authorities. However, the lack of internationally accepted (and implemented) standards for both the content and transport of this information poses significant obstacles to achieving this objective. Differences exist in the technical environments of Industry and Regulatory Authorities. In addition, there is not agreement concerning the information to be collected and reported nor the terminology to be used in describing this information.

A complete "solution" to electronic regulatory communications consists of several different, but complementary components. These different components are being addressed by the various ICH Expert Working Groups (EWG).

The result of the combined effort of these different EWGs will be the definition of standards that will enable the electronic transfer of regulatory information.

Standards for the transport, format, and security are within the remit of the M2 Expert Working Group while content definition is the responsibility of other ICH EWGs. Due to the rapidly changing nature of technology, it is anticipated that the standards will evolve. To accommodate change, the M2 EWG developed the concept of a core set of standards which represents the current complement of recommended and approved standards.

ESTRI Gateway: The M2 EWG has considered a number of alternatives and has concluded that an appropriately configured gateway provides the only viable solution for the electronic transfer of regulatory information at this time. This gateway concept for communication between parties exchanging information is essential to the success of this effort.

As illustrated in Figure 1, this concept (referred to as the ESTRI Gateway) will enable Regulatory Authorities to electronically exchange and share regulatory information, beginning with safety information. Based on the internationally accepted standards, all communication partners can extract information from internal databases, create the regulatory communication, and send to the receiver with confidence that it will be received intact, protected, regardless of the technology of their internal systems.

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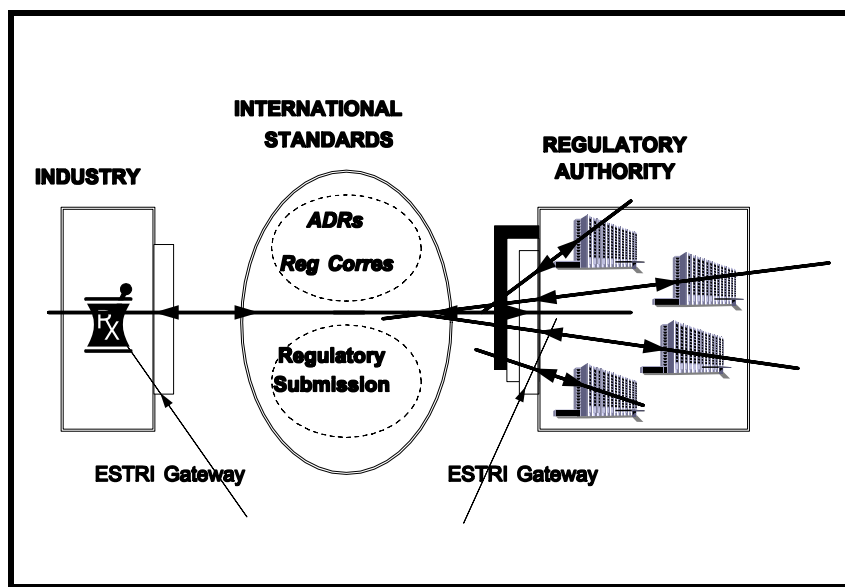


Figure 1

The ESTRI Gateway is a data exchange service that will support regulatory communication based upon any of the recommended standards.

Definition: An ESTRI Gateway is compliant with the recommended core standards. Regulatory Authorities will implement the multiple standards and will be able to transmit to and receive information from all other parties who have implemented such an

ESTRI Gateway, regardless of their technical infrastructure. Where multiple standards have been recommended, Industry must implement at least one of the recommended standards in order to communicate with any Regulatory Authority.

This ESTRI Gateway will be based on individual standards addressing different aspects of the regulatory communication. The following is a list of areas that are currently being addressed by the M2 EWG. Other standards areas will be addressed by the M2 EWG in developing a total solution for regulatory communication.

- Physical Media
- File Format
- Information Transfer

It is the intention of the M2 EWG to keep the number of recommendations to a minimum, i.e. a single standard should be recommended where possible.

The on-going identification and recommendation of standards will allow the ESTRI Gateway to be implemented and to evolve in a systematic manner to accommodate other aspects of regulatory communication - through a single point of implementation and maintenance.

Recommendation:

The M2 EWG recommends the ESTRI Gateway concept with the following definition:

- In each Region the Regulatory Authorities (i.e., EU, FDA, and MHLW) will implement at least one ESTRI Gateway for communication with Industry and with other Authorities that consists of all core standards and functionality required to support the standards. In those instances where multiple standards are recommended, the Regulatory Authority will

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implement all recommended standards.

- Industry desiring to communicate regulatory information electronically with Authorities must implement at least one of the multiple standards.

The M2 EWG recommends the following policy for accepting the current Core Standard Set:

- The current set of recommended, approved, and implemented standards will be accepted by the Regulatory Authorities for the categories of Regulatory Communications to which they apply
- Industry will be able to use any of the Core Standard Set with the assurance that they will be acceptable by Authorities

Conditions:

- In those cases where multiple standards have been adopted for the same functionality (e.g. Floppy Disks, CD-R and DVD-RAM for media), the Regulatory Authorities will provide the necessary infrastructure within their ESTRI Gateway to accommodate all of the multiple standards. This will allow each Authority to receive regulatory communications from any Industry ESTRI Gateway, and it will also allow the Authority to implement a single standard within their organization or member organizations. However, the aim should be to restrict the standards adopted to a minimum.
- This approach will accommodate instances in which a Regulatory Authority may choose to support a specific language implementation of a standard (e.g., Japanese and English) if their regulations require submission in that language.
- These recommendations will be validated via appropriate ESTRI Gateway testing in the three Regions
- Industry and Authorities may use any mutually agreeable mechanism for electronic communication in the case of information categories for which standards have not yet been adopted.

Remarks:

- There may be instances in which Industry and Regulatory Authorities agree that it is mutually advantageous to use an approach for a particular regulatory communication which differs from the Core Standard Set. However, in all instances the Core Standard Set will define an approach which will always be accepted by the Regulatory Authorities and may always be used by Industry.
- It is expected that the Regulatory Authorities will share information about technologies being used and those being considered.