

## Electronic Regulatory Systems

### Introduction

Many industries are regulated by governments and governmental agencies with a mandate to maintain the public's best interests. The regulatory process usually involves industry organizations making applications and providing reports to the regulatory body in order to receive or maintain certification, eligibility or some other form of status or approval in the industry. These applications often require the submission and evaluation of large amounts of complex information, mostly documents and forms. This information is central to the regulatory process. The quality and utility of this information has a direct impact on how the regulated industry affects the public, the environment and society as a whole.

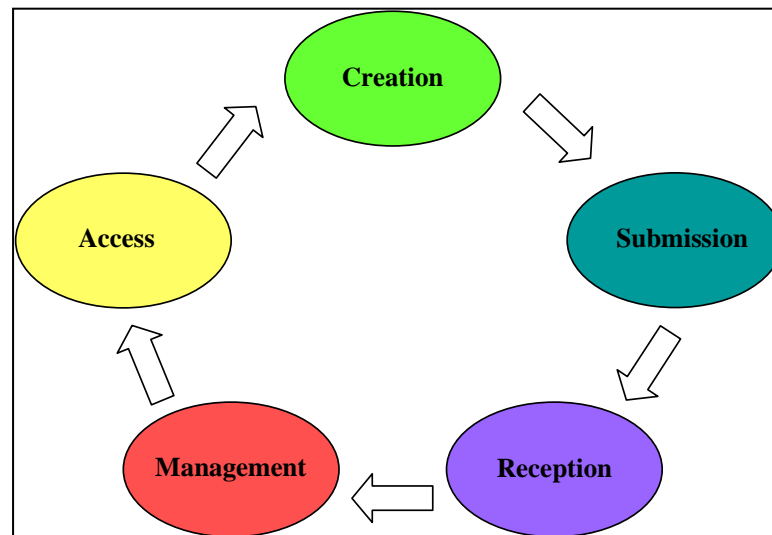
Creating and submitting regulatory applications can be very time consuming and costly for organizations. The process of receiving and processing submissions is also an expensive and resource intensive activity for the regulatory body. As a result, many regulatory bodies are evaluating their regulatory processes in order to improve efficiency and effectiveness, to comply with "government online" initiatives and to streamline the methods of interaction with the industries that they regulate.

This paper presents an overview of electronic regulatory systems, describing the key features and benefits that they can provide.

### The Regulatory Filing Life-Cycle

From the perspective of the data that is involved in a filing, the regulatory process consists of five stages (Figure 1).

Figure 1. The Regulatory Filing Life-Cycle



**Creation** involves the processes related to preparing all the necessary information that is required for a regulatory submission. A variety of documents and forms are usually involved.

**Submission** involves assembling all the information into a package that can be transmitted to the regulatory body. This preparation usually involves a step where an authorized agent signs the data package to attest to its accuracy and completeness.

**Reception** is a task for the regulatory body and usually involves a screening of the submission to ensure completeness and compliance with the requirements.

**Management** addresses issues related to storing and cataloguing the submission data in order to support the evaluation process and meet the legal and policy requirements of the regulator.

Finally, **Access** allows the information to be viewed and used in a timely manner in support of a variety of tasks including evaluation, analysis, reporting and responding to requests for information from the public.

Each of these stages has their own requirements for handling and processing the information that is at the core of the regulatory process.

## Key Challenges

There are a number of requirements that regulatory bodies must consider and address when developing regulatory filing systems that take advantage of information technology. These requirements come from the industry stakeholders that are being regulated, from legislation and regulations and from the internal needs of the regulatory body.

Electronic regulatory systems must be able to

- Accommodate a wide range of information technology capabilities, including hardware, software and networking platforms
- Provide benefits to the industry participants who must use the system, not just to the regulator
- Ensure confidentiality of information during transmission and processing of the submission
- Reduce the number of incomplete submissions that are received by the regulator
- Ensure no corruption or loss occurs when data is electronically submitted
- Reduce the need to re-key data by automatically loading submitted data into operational systems
- Support the regulator's evaluation process by allowing the data to be easily accessed and used
- Ensure the legal and evidential status of electronically submitted data and meet archival requirements
- Support the report generation and data analysis requirements of the regulator, such as producing performance metrics, or summaries of the status of submissions
- Improve the transparency of the regulatory process by providing enhanced access to public information
- Reduce the overall cost and effort to receive and process submissions

Each of these requirements is related to one of the five stages of the regulatory life cycle.

## Approaches to Electronic Regulatory Systems

The approaches that can be taken to implement an electronic regulatory system range from an "electronic paper" approach to a more data focused approach that uses the concept of a "regulatory data exchange" format. Each one addresses the key challenges to different extents.

### “Electronic Paper”

In the “electronic paper” scenario, all the forms and documents that comprise a submission are delivered as essentially images of pages that can be viewed on a computer screen or printed out to re-produce a copy of the original document.

Advantages of this approach include:

- Minimal impact to industry stakeholders, since they can just scan their paper documents and submit them on a CD-ROM
- Minimal impact to the regulatory body since once the pages are printed, the evaluation process remains the same
- Significant cost savings can be achieved by simply not having to ship, receive and store large amounts of paper.

Disadvantages include:

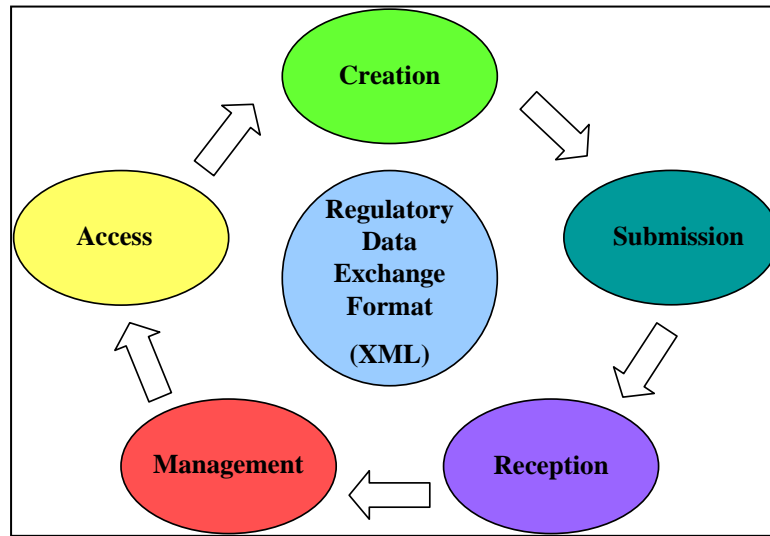
- Data is provided in inconsistent formats from organizations
- The need to manually key data into internal databases remains; no ability to automatically load data from forms and documents into databases
- Little support for analyzing or generating reports on the data from forms and documents

While an electronic paper approach seems to be the easiest to set up and to have the least impact on the organizations involved, the benefits that are achieved through this solution often do not justify implementing it. In many cases, existing paper processes have been highly optimized to the extent that simply replacing paper with a computer monitor doesn’t provide any significant value. When business requirements demand new capabilities, performance standards or services, then a more sophisticated, data-centered solution is required.

### “Regulatory Data Exchange”

Another approach to electronic submission is to define a regulatory submission data exchange format. This data format allows submission data to be created in familiar ways using forms and structured documents, while also enabling the contents of the submission to be accessed and processed in an automated manner. A key requirement of the data exchange format is that it be an open, neutral format. The Extensible Markup Language (XML) provides such a format. A regulatory data exchange format provides a framework for supporting the regulatory life cycle (Figure 2).

**Figure 2. Regulatory Data Exchange and the Regulatory Life-Cycle**



XML allows data to be captured in a well-defined and structured manner so that the data can be automatically validated, read and accessed on any computer platform, in any language. Because XML is a “plain text” format, it is also human readable. The ability to validate a set of data enables an automated screening process to be included in an electronic submission system that only accepts complete submissions. The screening process can reject incomplete submissions and provide a list of missing or incomplete items to the submitter, all without the need for human intervention.

XML provides a means for automatically loading data into databases, since the XML structures can easily be mapped to fields in database table structures. This removes the need for re-keying of submitted data into regulatory evaluation and tracking systems, a time-consuming and error-prone activity.

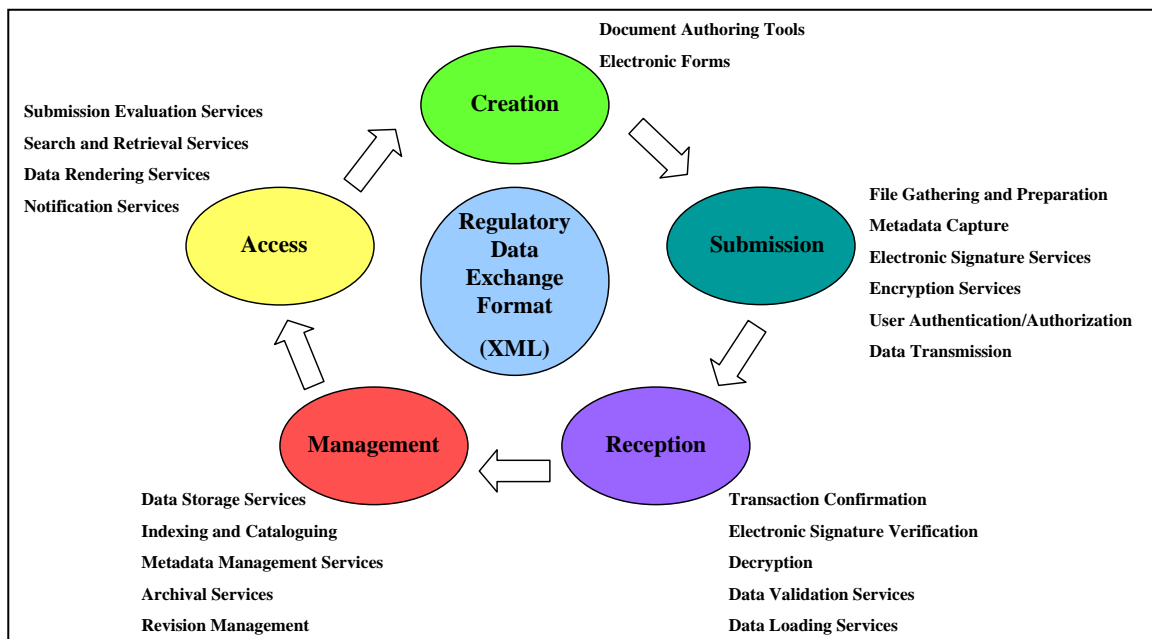
XML is a key aspect of most Internet and computing technologies today. All of the popular relational database products and IT tools have built-in support for XML. It is also compatible with security infrastructures involving digital signatures and encryption. This means that regulatory bodies can take advantage of their existing investments in technology by providing an XML “front end” that extends the functionality and ease of use of applications currently in production use. This “front end” approach can also be used to provide integrated access to multiple systems, enabling the synchronization of data across systems and avoid inconsistencies.

Finally, XML enables access to the submitted information. Because XML data is plain text, data can easily be indexed for searching. It can also be searched based upon the structures in the XML data to provide very granular “field searching”. This also allows for generating reports on almost any aspect of the data. Because XML can be easily processed, data can be re-organized and sorted so that it is presented in a manner that is best suited to how it must be used. It is a simple task to “publish” XML data to multiple output formats such as print, PDF, the Web and others.

Defining a regulatory data exchange format in XML brings together the document centric view of a submission that is required by evaluators and legal authorities, with the data centric view that is needed in order to analyze the data and produce reports using standard IT tools. An electronic regulatory system that is based upon this type of data format (Figure 3) is flexible enough to integrate with existing evaluation and tracking systems, can work with a wide

variety of technology platforms and can be easily extended and modified to evolve with the business processes and policies of the regulatory agency.

Figure 3. An Electronic Regulatory System



## Conclusion

An electronic regulatory system must address the five stages of the regulatory filing life-cycle and meet key requirements that are imposed by industry, legislation and internal processes. Of the two approaches to electronic regulatory systems, “electronic paper” and “regulatory data exchange”, the latter, based upon defining an XML regulatory data exchange format, more effectively enables the creation, processing and management of the data involved in a regulatory submission.

## About Newbook

Founded in 1994, Newbook is a privately owned, full-service consulting company that provides open-source solutions to customers with complex information management requirements.

Newbook believes that technologies should be designed to serve the business. In practice, it means we create systems to the exacting standards of our clients' business – in Aerospace, Health, Standards, and Regulatory Filing. Unlike the one-size-fits-all approach typical in our industry, we do not prescribe applications or systems until the business challenges of our customers are understood. Getting to know the customer’s business environment and the people who create and use the information is essential. After all, truly effective information management solutions are created when consultants and stakeholders have highly collaborative and trusting relationships.

Newbook shares ideas with its peers in international standards committees, leading industry trade associations, and open-source software communities. We believe that knowledge gained from these associations helps our customers make informed decisions about their information.

These simple values are the basis for long-standing relationships with our clients.