



United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
120 Pennsylvania Avenue, N.W.
4th Floor, Room 4033
Washington, D.C. 2004

Subject: EPA's Proposed Rule to Establish Electronic Reporting; Electronic Records
(CROMERRR). Federal Register: 8/31/01

Dear Sir or Madam,

Quantum Compliance Systems appreciates the opportunity to submit comments in response to the proposed rule on the Establishment of Electronic Reporting; Electronic Record and to address the questions raised in the January 2, 2002 Federal Register notice.

For more than 15 years, Quantum Compliance Systems, Inc. has been a developer of environmental, health and safety information management systems. Our products and systems are specifically designed to provide tools to effectively manage data electronically. Our clients then use these data to achieve and maintain compliance with the multitude of regulatory reporting requirements. The system we offer has been deployed and implemented worldwide by Fortune 1000 companies and small businesses alike.

Historically, our clients and the market have viewed environmental reporting as a necessary cost. What Quantum Compliance Systems, Inc. and other software systems suppliers have strived to do is to move this from a compliance-cost issue to an opportunity for process improvement.

The major incentive for businesses that have deployed an environmental information management system is that it allows them to seamlessly integrate the electronic record keeping and reporting requirements into daily business practices. This, in turn, gives management the tools necessary to set goals and objectives to reduce waste, improve manufacturing processes and streamline operations. The new terms of Sustainability, Ecological and Corporate Responsibility and Best Business Practices are the result. This is the Return on Investment that drives electronic data record keeping for environmental information.

We have reviewed the responses/comments from DuPont, Dow Chemical, ExxonMobil, Procter & Gamble and others. We strongly concur with their assessments that the Proposed Rule as written is not voluntary, would place an undue financial and resource burden on the regulated community, and would impede the ability of the regulated businesses to economically conduct their work for the improvement of the environment. We therefore are recommending that:

- 1) the EPA remove the record keeping provisions (40 CFR §3.30 subpart C) from the rest of the CROMERRR; and
- 2) the EPA should not move forward on CROMERRR until a more through analysis and evaluation of the costs versus the benefits are completed on the balance of the Rule.

Enclosed with this letter, Quantum Compliance Systems, Inc. respectfully submits responses to the questions outlined in the EPA's Extension of Comment Period dated January 3, 2002.

Sincerely,

Patricia Brooks
President and Founder
Quantum Compliance Systems Inc.

What kinds of records do companies currently keep electronically to satisfy EPA regulatory requirements?

The variety and type of records that companies now maintain electronically have grown exponentially over the past five years. This is in part because new technologies have made the process of loading data easier and more cost-effective. In the past, the Environmental Information Management Systems (EMIS) were often used to merely maintain the data records used for preparing major regulatory filings, such as Tier II and TRI reports. Today, companies both large and small are electronically capturing and maintaining data that previously was being maintained manually. With the introduction of the Windows[®] operating system and web technology, electronic collection and processing of data are being pushed down to the operators and field staff, allowing companies to electronically capture data such as daily operating logs, “point-of-use” material transactions, visual inspection records, monitoring data for equipment operation, laboratory data, and operational data (tank level, temperature and flow readings, etc). Previously, these were most commonly retained as hard copy printouts.

How prevalent is this electronic record keeping, and what kinds of system are used?

It has been our experience that the vast majority of businesses now are maintaining information in electronic format because this format is required in order to satisfy regulatory requirements. The PC (Windows operating system) is by far the most common type of system used to store this electronic information. An overwhelming percentage of information is stored in spreadsheets, followed by word processing documents and scanned-document images. A limited number of companies (usually very large ones) maintain the data on corporate computers using commercially available databases or information management systems. Very few, if any, of these systems have been designed with the criteria of maintaining an audit trail and of being capable of transferring records electronically across multiple generations of hardware; both of these criteria have been outlined in the proposed regulations as mandatory features for any electronic record keeping system.

While a limited number of systems do offer robust auditing features, there is little to no market acceptance because of performance impairment and penalties and because they make the software very cumbersome to use.

How are automatically captured data and other raw data maintained electronically?

Our customer base typically uses a feature that loads the electronically captured and raw data automatically. Although raw data can be manually loaded, clients generally seek a more cost-effective means. Typically, the data-loading routines and data entry functions include validation procedures to confirm that valid and verifiable data have been and are being captured.

How will the proposed rules affect companies' electronic recordkeeping practices, and do some of the proposed revisions raise more issues than others?

The proposed rules will remove any incentive companies may have to electronically capture data, and may prohibit the use of many systems. As noted in the answers to the above questions, audit trail features significantly impact performance and cost. Additionally, the complexity of these features means that only advanced and sophisticated users will be able to use such systems confidently. In an inescapable irony, this proposed rule would accomplish just the opposite result from its stated intent; namely, the small and unsophisticated businesses who

would best benefit from the use of electronic data gathering and record keeping will be the very ones who won't be able to afford to do so under this rule. It makes little sense to promulgate and implement a rule that will actually prevent the cost efficiencies that would be gained from electronic methods, and that, in fact, will probably push businesses back to paper methods.

The rationale presented by the EPA for this rule is that it would treat electronic data record keeping similarly to paper record keeping. However, it appears that the rule holds electronic methods to a higher, and essentially impossible-to-achieve, standard.

How do companies currently ensure the integrity and reliability of their electronic records especially where they do not use audit trails and what role do recognized industry standards play?

The EPA's discussion about the supposed "benefit" of audit trails appears to be misplaced. Audit trails, in and of themselves, do not ensure data integrity or validity; audit trails simply track and record changes to data. Environmental Information Management Systems typically include procedures that ensure the integrity of both manually and electronically loaded data. Over the past 5 years, QCS has noted a markedly increased desire within the industry to provide additional integrity and validity checks. This desire is driven by two factors. The first is the opportunity to "mine" the database for previously unanticipated reasons, in order to identify benefits and trends that would improve business efficiencies and productivities. The second is because these data are used to generate regulatory filings. It is in a business' best interest to include robust validation and verification features. If this rule eliminates the growth in the use of databases, future increases in economic productivity may be prevented as a result.

What special issues are raised by the proposed criteria for long term archiving, and how do companies currently address this problem?

The primary issue that companies face with respect to the long term archiving of data is not related to the archiving process but rather to the functions and/or technologies that would be required in order to restore the data at some future time. Although many computer database systems, including the ones supplied by QCS, do offer functions to archive and restore data, the "restore" functions generally work properly only when operated on a limited number of previous versions of the software and operating systems. For example, software functions designed to operate on DOS 3.0 programs seldom will run on Windows[®] 98 or MS2000. Similarly, files that were archived using a very "old" version of a software package or Environmental Information Management system typically cannot be restored to the most current version unless the archived data are "transformed" and "upgraded" through some type of preprocessor. The reason for this "upgrade" process is because newer versions of the software may have different database structures and/or different data types and fields, may perform different manipulations and calculations of the data, and produce different reports than the earlier versions.

In other words, a rule that would require archived data to be transportable across innumerable operating and computer database systems (including to technologies and software about which no one has even dreamed of, let alone designed) would also require that the data be "changed" during that process. This latter step conflicts with the rule's stated purpose of preventing any changes to the data during its regulated, required "shelf life." This internal conflict needs to be resolved, although no easy solution presents itself at this time.

Because software and technologies are changing so rapidly (a computer software system can become “obsolete” within five years of its introduction), many of our clients currently resort to exporting the archived data into “easy-to-transport,” “easy-to-electronically-read” file formats (such as “comma-delimited” or ASCII text formats) or to printing the data output (reports) to electronic “portable-document format” (PDF) files. However, even in these situations, the data are being “changed” from its original format and content and still run the risk of obsolescence or destruction.

Where archiving involves the conversion of electronic records to paper, how do companies ensure data integrity and reliability, and what role do recognized industry standards play?

To our knowledge, none of our customers currently convert the data to paper for archiving purposes. It is not uncommon for clients to save data in a PDF or TIFF (a form of image file) format that historically had been printed onto paper. As noted above, the long-term implications of such electronic “image” storage are still unknown, and it may become necessary at a future time for our customers to resort to using paper as the long-term storage medium.

Are there new products or technologies that will help companies address the proposed standard for electronic record keeping?

The computer software database market is continually evolving and continues to make great strides in providing tools for businesses to better manage and run their operations. It appears to be extremely premature at this time to add regulations in an exponentially increasing manner that will severely impair and inhibit the use and maintenance of every size of database and electronic record keeping process. As noted above, numerous factors need to be considered before a rule such as this one are again contemplated, let alone promulgated: what is meant by “data integrity,” “data usability,” “data longevity,” “purpose of audit trails,” “the differences between paper and electronic processes,” *etc.*