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American Chemistry Council Good Chemistry Makes It Possible

February 27, 2002

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And Information Center
U.S. Environment Protection Agency
Mail Code 2201A
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Cross-Media Electronic Reporting and Records Rule (CROMERRR), Docket Number EC-20000-007

Dear Sir or Madam:

I have enclosed an original and 3 copies of the comments of the American Chemistry Council (ACC) on the above-referenced proposed rule.

If I can provide any additional information on ACC's comments, please feel free to contact me at 703 741 5167.

Sincerely,

Michael P. Walls
Senior Counsel

Enclosures

BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Establishment of Electronic Reporting;	)
Electronic Records	) 66 Fed.Reg. 46162,
Docket No. EC-2000-007	) August 31, 2001

COMMENTS OF THE
AMERICAN CHEMISTRY COUNCIL

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February 27, 2002

COMMENTS OF THE AMERICAN CHEMISTRY COUNCIL

Executive Summary

The American Chemistry Council (the Council) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed cross-media electronic reporting and records rule. 66 Fed.Reg. 46162, August 31, 2001. The Council strongly recommends that EPA withdraw the proposed rule, and reassess the need for and potential impact of the rule. At a minimum, EPA should withdraw the record keeping provisions of the proposal.

The proposed rule is intended to extend the burden reduction goals of the Government Paperwork Elimination Act (GPEA) to environmental reporting and record keeping. However, the proposal would increase the compliance burden faced by the business community tremendously – and would have the illogical effect of making electronic reporting and record keeping more burdensome than paper reporting. The significant concerns raised by the proposed rule demonstrate that there is no simple set of modifications that can be made to the proposed rule, and that withdrawal is the only practical approach at this point.

The Council appreciates that EPA is also trying to address perceived problems with the falsification of information and the submission of fraudulent reports. However, EPA has neither demonstrated nor clearly articulated any specific concerns related to electronic record keeping and preventing fraud, and the Agency has not properly assessed whether the rule will address those concerns. A proposal intended to address possible problems with fraud and false information needs to be based on experience, a complete understanding of the effect of electronic record keeping on accuracy and fraud, and a cost/benefit analysis.

Of particular concern to the Council and its members is that the proposed rule purports to "authorize" electronic reporting and record keeping. There are two unfortunate results of this perception: Some EPA program offices may believe that electronic record keeping and reporting are not permitted unless specifically authorized, and there may be inconsistent application or interpretation of the requirements by program offices.

Even if EPA believes a rulemaking is necessary, the Council believes it is possible to proceed with a very simple rule that implements the Agency's GPEA obligations while affording time to consider what other requirements, if any, are necessary to address the Agency's concerns about fraud and false information.

The Council believes that withdrawal of the proposed rule is warranted for the following reasons.

- Despite EPA's stated intent, the rule is not voluntary. The rule would apply whenever a facility opts to maintain electronic records; would apply to any electronic record; would be triggered by the use of any electronic instrument to generate, maintain, store or distribute records; and would apply irrespective of whether the data is printed out in a hard-copy form.

- The rule is costly. EPA has vastly underestimated the extent to which the rule would require systems and software upgrades, modifications, or replacements, the cost of such changes, and the number of facilities affected. A more accurate estimate of the rule's cost would be upfront implementation costs of some $48 billion, with annual maintenance costs of $20 billion – a far cry from the $1.2 million in costs estimated by the Agency. The economic analysis supporting the proposed rule is deficient in several respects and should be revisited.

- The rule is impractical. The considerable modifications that the rule would require to existing electronic records generation and maintenance systems are impractical. The data archiving, migration and audit requirements alone will require a substantial investment, particularly for customized records management systems, for which there are no off-the-shelf upgrade packages.

- The GPEA does not mandate the rule as proposed. In fact, the rule may exceed the GPEA requirement that electronic records requirements be "no less favorable" than those afforded paper records. The Council is unaware of any current barrier to electronic reporting and record keeping at EPA that warrants the rule. Electronic reporting and record keeping are already widely practiced, and we are not aware of any case in which an electronic record has been considered invalid by the Agency. EPA has until October 2003 to meet its GPEA obligation of "providing the option" for electronic reporting and record keeping, so there is no immediate statutory deadline pressing the Agency to issue a final rule.

- The proposed rule raises several significant legal and policy questions. The Council is concerned about the legal adequacy of the notice provided the public by the proposed rule. The proposed rule also raises important questions about the degree to which it comports with regulatory law and policy regarding economically significant regulations.

- The reporting requirements proposed in the rule raise important concerns in and of themselves. The proposal suggests that electronic reporting is not permitted unless first approved by the Agency, yet some of the Agency's existing regulations mandate electronic reporting. The rule establishes impractical requirements for obtaining, delegating, and revoking electronic signature authority that do not address the realities of doing business in an electronic age.

BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Establishment of Electronic Reporting;	)	
Electronic Records	)	66 Fed.Reg. 46162,
Docket No. EC-2000-007	)	August 31, 2001

COMMENTS OF THE
AMERICAN CHEMISTRY COUNCIL

Introduction

The American Chemistry Council (ACC or the Council) is pleased to submit the following comments on the Environmental Protection Agency's proposed Cross-Media Electronic Reporting and Records rule (CROMERRR).

The Council is the national trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. ACC members represent an industry on the cutting-edge of technological innovation and progress, whose products provide significant benefits to every sector of the global economy. The industry has been in the forefront of the electronic revolution, and has helped pioneer electronic record keeping and reporting for a vast array of production, sales, marketing, distribution, and pollution control purposes, among others.

ACC members are subject to a host of federal, State and local environmental regulations, and maintain the vast majority of the records subject to environmental reporting and record keeping in one electronic format or another. Council members understand the administrative and economic benefits that can flow from electronic record keeping and reporting, and ACC member companies have a significant interest in expanding the number of opportunities to use electronic reporting to satisfy regulatory requirements.

Unfortunately, EPA's proposed CROMERRR will promote neither efficient electronic record keeping nor effective electronic reporting. In light of the significant deficiencies described in these comments, ACC strongly recommends that the Agency withdraw the proposal in its entirety.[1] The Council's primary focus in these comments is on the record keeping elements of the proposed rule, but we believe that additional work on the proposed reporting requirements would aid the Agency in crafting an integrated electronic reporting and record keeping rule that meet its statutory and regulatory policy goals and the needs of the regulated community.

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[1] At a minimum EPA should withdraw the record keeping provisions of the proposed rule. Sections I.C and II of these comments outline ACC's view that in light of the significant relationship between the record keeping and reporting requirements, and in light of significant amount of time remaining before the October, 2003 deadline imposed by the Government Paperwork Elimination Act, EPA should consider withdrawing the entire proposal.

The Council appreciates EPA's efforts to understand the full impact of the proposed rule. The Agency has held a number of outreach meetings, public workshops, and stakeholder consultations. Those meetings have confirmed the substantial concern that exists in the general business community about the cost, burden and effect of the rule. The overwhelming majority of the public comment contained in the docket as of February 20, 2002 (including the comments from State environment departments) is negative. EPA has not established that electronic records and reports raise the kinds of reliability and authenticity problems that would merit the drastic requirements contained in the proposal. Indeed, the proposed rule has systemic problems that are not amenable to "quick" fixes. Withdrawal of the proposal rule is the only reasonable response to these problems.[2]

Discussion

I. The Electronic Record Keeping Requirements of the Proposed Rule are Expensive, Unnecessary, and do not Address the Statutory and Compliance Concerns that Prompted the Agency's Proposal.

The Council is particularly troubled by the erroneous assumption that underlies the proposed rule: That the majority of environmental records are generated, maintained, stored and/or distributed in a non-electronic format. Both computer technology and government policy have advanced considerably in the five years since EPA first published its general policy applicable to electronic data interchange,[3] but the proposed rule appears to assume that the business community's use of electronic technology is very much in its infancy. The fact, of course, is that electronic record keeping and reporting are the norm, rather than the exception.[4]

It is difficult to understand how EPA's existing reporting and record keeping requirements could be read not to presume the use of electronic means of generating, storing, maintaining or distributing information.[5] Many EPA regulations reference or

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[2] As described in Section I.C, if a rulemaking is even necessary we believe it is possible for EPA to proceed with a very simple rule that would implement its GPEA obligations while affording time to consider what other requirements, if any, are necessary to address the Agency's concern about fraud and false information.

[3] Notice of Agency's General Policy for Accepting Filing of Environmental Reports via Electronic Data Interchange, 61 Fed.Reg. 46684, September 4, 1996.

[4] In an October, 2001 presentation, Howard Phillips, the Managing Director of Enterprise and Internet Software at Morgan Stanley estimated that technology spending constituted 53% of all capital spending by the end of 2000 – an indication of just how important – and pervasive – technology has become to American industry. See http://www.ksg.harvard.edu/iip/seminars/PhillipsPresentation102901_files/frame.htm.

[5] For example, the Council has compiled an incomplete list of over 125 EPA reporting and/or record keeping requirements in Attachment 1, annexed to these comments. The breadth and scope of reporting and record keeping in environmental compliance programs such as those listed virtually mandate the use of electronic technology. More to the point: each data element generated, maintained, stored or distributed in response to the requirements would be subject to the CROMERRR requirements.

assume the possibility of electronic record keeping.[6] The records used by business to demonstrate compliance with environmental regulations are tied to or maintained in, or are the output of, electronic systems. Many of the records subject to the rule are not simply compilations (or copies) of data organized for business purposes; the records are the data themselves. Any EPA regulation on electronic reporting and record keeping must necessarily account for the integration of electronic technology in the U.S. economy, yet the proposed rule and its supporting analysis fail to do that.

A. The Proposed Rule is Not "Voluntary" and Imposes Significant Costs

Despite its view that CROMERRR establishes voluntary standards[7], EPA has received considerable comment that the proposed rule would be mandatory for all electronic systems that generate or store data for record keeping or reporting purposes. The proposed rule defines the term "electronic record" very broadly[8] and includes records generated, maintained or stored in a computer system. Under that broad definition, it is highly likely that any document (whether generated electronically or not) will qualify at some point as an "electronic record" subject to the CROMERRR requirements. For many businesses subject to EPA regulations, choosing not to use computers would be tantamount to a decision not to comply.

EPA's estimate of the cost of compliance is based on the faulty premise that the rule is indeed voluntary. Using EPA's own figures for the number of affected facilities, initial implementation costs and annual maintenance costs, the proposed rule would cost some $48 billion upfront, and some $20 billion annually.[9] Experience with the Food and Drug Administration's comparable regulation on electronic reporting[10] has demonstrated that verifying compliance with the regulation is a significant and costly undertaking. For example, under the FDA rules, any change in software, whether significant or not, requires a verification audit. The CROMERRR proposal is likely to require similar audits of changes.[11]

The proposed rule would greatly increase the cost of maintaining, modifying and replacing existing record keeping systems. For electronic systems that rely heavily on custom software, there will be significant cost implications for modifying systems to conform to the CROMERRR requirements (including any mandatory file formats). Modifications may not always be possible in some applications. The costs of the rule are likely to be compounded because, contrary to EPA's assumption that most facilities have a single computer system, most facilities in fact have multiple data management systems.

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[6] A number of Clean Air Act regulations explicitly reference electronic reporting (e.g., 40 CFR §§ 60.58c(f), 60.59b(k) 60.2180, and the Continuous Emission Monitoring quarterly reports, 40 CFR § 75.73(f), among many others). Other regulations are media-neutral on record-keeping requirements (e.g., Good Laboratory Practices regulations at 40 CFR §§ 160.195(i) and 792.195(i)).

[7] See 66 Fed.Reg. at 46162, 46167, 46186.

[8] Id. at 46189, proposed section 3.3.

[9] The Council fully supports the comments filed by the American Petroleum Institute, and in particular supports their detailed technical review of the economic analysis conducted to support the proposed rule.

[10] 21 CFR Part 11.

[11] 66 Fed.Reg. at 46170.

Costs will also increase if users cannot easily access the system from multiple locations or computers, or have to seek separate certification to permit filing from separate locations. In addition to the economic costs, however, the proposed rule has some significant practical implications.

B. The Proposed Rule Imposes Requirements that are Impractical and in some Cases, Impossible

CROMERRR's provisions are impractical and, in some cases, impossible to implement. Many facilities employ multiple systems in order to track, compile, and report environmental performance. Complying with CROMERRR would require modifications to each and every one of those multiple systems, and will require significant investments of time, financial and human resources. Moreover, for those systems that cannot be modified, new custom systems and software will have to be developed, also at a high cost.

It is also abundantly clear that CROMERRR would apply to a large number of companies not otherwise regulated by EPA but whose business it is to generate or manage records for EPA-regulated entities. These companies – labs, consultants, engineering firms – would also have to reengineer their electronic data gathering and management systems to comply with CROMERRR. These entities employ controls to assure data quality, yet the rule may force their customers to validate those data management systems if the records are expected to qualify as valid under CROMERRR.

EPA has provided no assessment of the possible impact of the CROMERRR requirements on the performance of a typical business system, including any consideration on memory requirements, software functionality, and overall system performance. Moreover, it is not clear that it is technically possible to fully comply with CROMERRR's requirements. For example, CROMERRR would impose detailed data archiving and migration requirements. The Council's experience in implementing several enterprise software packages has been that some functionality and data loss are inevitable in any data migration effort. In our view, it would have been nearly impossible (and not cost-effective, in any event) to create the type of audit trail that could track data migrations from one system to another. The Council's enterprise software is relatively simple compared to the multiple systems and multiple functions served by such software in a modern manufacturing complex, and as a result we believe the CROMERRR requirements are not practical on a broad scale.

It is apparent that EPA had two primary goals in proposing the CROMERRR: implementing the Government Paperwork Elimination Act, and addressing concerns about fraud and false information in environmental reporting. These are distinct goals, however, and in the Council's view EPA and the regulated community would benefit if they were addressed as separate issues.

C. The Government Paperwork Elimination Act (GPEA) does not Require CROMERRR as Proposed

The GPEA is very specific in its approach to forcing reductions in government paperwork. It simply requires federal agencies to allow the option of electronic reporting when practicable.[12] Electronic records may also be submitted or maintained in accordance with procedures developed by the agencies, but such procedures must not deny the electronic record any "legal effect, validity or enforceability" simply because of the electronic form of the record.[13] Admittedly, with little reference to electronic records in the GPEA, it does not provide explicit guidance to EPA in implementing the Act's requirements.

The Council believes there is one essential interpretation of the GPEA that everyone can agree on. The purpose of the GPEA is to ensure that electronic records and reports are treated no less favorably than paper records and reports.[14] Any reasonable interpretation of the term "no less favorable" requires an assessment of the treatment currently afforded paper records, as the basis for determining whether electronic records are treated any differently under CROMERRR.

The Council is aware of no EPA requirements for paper records that dictate how the records are to be stored, maintained, or distributed, or what security measures should be applied. For example, no EPA regulation requires paper records to be stored in a fireproof cabinet, secured in a locked room, generated by and accessible to a limited number of persons only upon proof of identity, under access procedures approved by the Agency and requiring advance approval for changes in those procedures. Yet those are exactly the type of measures that CROMERRR would require for electronic records, and the proposed rule is patently "less favorable" to electronic records as a result.

Further, the GPEA contains no language suggesting that electronic records <u>cannot</u> be maintained absent explicit authorization from an agency. The Council is aware that some EPA program offices may be under the impression that electronic record keeping requires specific authorization from the Agency. The Council believes that EPA should correct these erroneous impressions as soon as possible, perhaps by issuing an Agency-wide policy statement. It is important that all programs offices realize that as a practical and legal matter the Agency must currently recognize the legal effect of electronic records.

As we have noted, electronic methods are the predominant mechanism by which the regulated community generates and maintains environmental records. As no current obstacles to electronic record keeping have been identified, EPA may not need to take any action in order to meet its GPEA obligation. Assuming, however, that the Agency

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[12] GPEA Section 1704(1)

[13] Id. Section 1707.

[14] See S. Rep. 105-355, at __ ("GPEA seeks to 'preclude agencies or courts from systematically treating electronic documents and signatures less favorably than their paper counterparts'", cited in OMB's Procedures and Guidance for Implementation of the GPEA, 65 Fed.Reg. 25508, 25509 (May 2, 2000)).

believes specific action is necessary to comply with the GPEA, it need consider only a simple statement that recognizes electronic records by adopting the GPEA language.[15] Such an approach would permit EPA to put other electronic record keeping concerns and policies on a separate regulatory timeline unaffected by the GPEA deadlines, and would allow EPA to focus on any specific concerns raised by fraud and false information in the context of electronic records.

D. EPA has not Demonstrated that Concerns about Fraud and False Information Warrant such an Onerous Rule.

EPA has indicated that the point of the proposed CROMERRR requirements "is primarily to ensure that the authenticity and integrity of these documents and records are preserved as they are created, submitted, and/or maintained electronically, so that they continue to provide strong evidence of what was intended by the individuals who created and/or signed and certified them."[16] ACC does not dismiss the concerns over the falsification of data and fraudulent statements, but we are very concerned that EPA's proposal is not based on any experience or analysis of the impact of electronic systems on data quality, accuracy, and fraud.

The GPEA does not, of course, address the fraud issue. The Office of Management and Budget's (OMB) guidance on implementation of the GPEA has addressed fraud, however, in suggesting that agencies conduct a risk assessment and cost/benefit analysis. Notably, OMB cautions against a "one size fits all" approach to electronic transactions[17] and specifically cited examples (such as long term relationships between the agency and the regulated entity) where the risks of fraud are lowest.[18] Yet EPA has ignored the OMB guidance. It is abundantly clear that EPA has taken a "one size fits all" approach, and that it has failed to conduct any relevant risk/benefit analysis that would target the rule on real problems of fraud and false information.[19]

In ACC's view, the use of electronic records – particularly in pervasively regulated industries – is more likely to increase data quality and accuracy, and thereby diminish any opportunities for fraud. EPA cannot point to any greater risk for fraud for electronic systems versus paper systems, yet CROMERRR would establish an artificially high bar to reliance on electronic documents or data.

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[15] For example: "Any requirement in this title [Title 40 of the CFR] that a record be maintained may be satisfied by maintaining an electronic record in lieu of a paper record." This type of approach would not raise any concerns about conformity the requirements of the Administrative Procedure Act (APA), discussed in Section III, below, because it is a subset of what EPA proposed, it is a ministerial action within EPA's discretion, and would impose no new requirements or burdens on any regulated entity. We strongly recommend this approach to EPA.

[16] 66 Fed.Reg. at 46164.

[17] 65 Fed.Reg. at 25510. Indeed, EPA seems to assume that all EPA required data, records and documents merit the highest level of security and sensitivity, and that in turn merits the CROMERRR approach. ACC believes that a cost/risk/benefit analysis would shed considerable doubt on the validity of that assumption.

[18] Id. at 25517.

[19] ACC notes in Section III that EPA's cost-benefit analysis developed to support the rule fails to meet even the minimum standards for such studies.

The Council strongly recommends that EPA withdraw the proposed rule. The Office of Environmental Information should determine what, if any, fraud concerns exist with existing electronic reporting and record keeping programs. That information should allow EPA to tailor a regulation, if a regulation is necessary, to the specific problems identified by program offices. EPA should also conduct a new cost/risk/benefit analysis, following the guidance developed by OMB for implementing GPEA obligations.

E. It is Premature to Consider Alternatives to the Proposed Criteria for Weighing the Validity of Electronic Records.

EPA has specifically requested comment on possible alternatives to the nine criteria for weighing the validity of electronic records set out in CROMERRR.[20] The Council believes it is premature to consider those alternatives.

A narrowing of the definition of "record" would not necessarily address the problems inherent in the CROMERRR proposal. The CROMERRR approach of protecting every electronic data point and document is obviously too expansive, but narrowing the definition of a covered record raises other questions. For example, if an electronic record is only the final output of a system that may maintain data electronically for some time period before the "record" is created, what is the point of requirements to guarantee the validity of the "record?" ACC recommends that EPA consider how a limited definition of "electronic record" could be developed to avoid classifying <u>all</u> computer-generated data or documents as records subject to the regulatory requirements (as is the case with CROMERRR). EPA should not make the proposed rule final and simply "grandfather" existing systems or records. That approach does little to remedy the problems identified with the proposed rule, and could provide a disincentive to develop new data and records management systems.

EPA has also requested comment on replacing the nine CROMERRR criteria with the two criteria generally applied to electronic transactions under the Electronic Signatures in Global and National Commerce Act[21] (the "E-Sign" statute) – accuracy and accessibility – presumably implemented through guidance to be issued by the Agency. ACC believes the E-Sign criteria are a viable benchmark for determining the validity of electronic documents in commerce. Although assessing electronic systems against two criteria for minimal functional capabilities is certainly better than applying nine criteria, there will be no net benefit in such an approach if the result is to reinstate the CROMERRR requirements through guidance. More importantly, it is not possible to determine whether even the two E-Sign criteria are needed until EPA has developed the cost/risk/benefit analysis required under the OMB GPEA implementation guidance.[22]

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[20] 66 Fed.Reg. at 46169-46170, 46171.

[21] P.L. No. 106-229 (2000).

[22] The E-Sign criteria already apply to "documents that are created in a commercial, consumer, or business transaction, even if those documents are also submitted to a government agency or retained by the regulated community for government purposes," as EPA has acknowledged. 66 Fed. Reg. at 46167.

EPA has also suggested the alternative of employing a performance-based, "records management system" approach. Although a performance-based system is conceptually an improvement over the approach taken in the proposed rule, a performance-based system would still require the elaboration of some benchmarks against which performance can be measured and evaluated. Even in this case, however, it is premature to discuss alternatives to the CROMERRR criteria when it is not apparent on the regulatory record developed thus far what is required to enhance confidence in the data and records generated in current systems.

ACC notes a particular concern over proposed Criterion 9, which would require that "computer systems (including hardware and software), controls and attendant documentation [be] readily available for agency review." ACC opposes this criterion, as facilities are already required to produce records in useable form, and facilities would presumably use a combination of paper and electronic records in response to a proper request. This criterion does not provide a useful benchmark for determining the validity of electronic records and could be read to vastly increase EPA's intrusion into electronic record keeping systems.

If anything, the public comment received thus far on the CROMERRR proposal indicate that the overriding need is for EPA to study existing records requirements, including records retention requirements. Many of EPA's records retention requirements were developed when paper systems were the primary method of compliance, and the time may have arrived when EPA can consider shortening record retention schedules.[23]

It is clear that records management problems affect a broad range of public interests, including governments. For example, even the National Archives is not prepared to accept electronic data, and insists on hard copies or microfiche.[24] In ACC's view, the Chief Information Officers (CIO) Council, chaired by the Office of Management and Budget, should address the larger problem of electronic record keeping,[25] which in turn could help develop appropriate guidance as EPA assesses existing record keeping and reporting practices.

II. The Proposed Electronic Reporting Provisions Would Benefit from Additional Public Input and Agency Consideration

As noted earlier, the reporting provisions of CROMERRR are not the primary focus of ACC's comments. However, the reporting provisions of the proposed rule would benefit from additional public input and consideration.[26]

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[23] No Food and Drug Administration record retention period exceeds 5 years, for example.
[24] See www.naragov/records/rmi.html.
[25] See, e.g., http://www.cio.gov/.
[26] The Council notes that if EPA were to pursue a very simple rulemaking (as outlined in Section I.C above), it would address any potential legal concern that current electronic reporting is somehow not authorized or does not meet GPEA requirements.

State governments will obviously have a significant interest in commenting on the proposed reporting provisions. Many states have or will soon adopt mandatory electronic reporting for at least some environmental programs, and it is important the EPA's electronic record keeping and reporting rules promote those efforts.

In addition, the proposed rule adopts general requirements for obtaining, delegating, monitoring and revoking electronic signature authority that does not address the reality of business in the electronic age.[27] At a minimum, the requirements for registration and renewal of electronic signature authority are burdensome and far exceed the requirements imposed on paper reporting. Many facilities will require multiple designated signatories to addressing the various regulatory programs covering the facility. Alternates will probably be required for those designated signatories as they may not always be available. In today's dynamic economy people, positions and titles are constantly changing, and ACC expects that the change would necessitate frequent changes in the designated signatory. A burdensome and intrusive process for identifying and certifying designated signatories will provide a further disincentive for industry to adopt electronic reporting, and instead provide an incentive to retain paper reporting as the preferred mechanism.

EPA might review what other approaches to reporting are currently implemented by Federal agencies and consider how those models might apply to environmental records. In ACC's view, EPA's systems should not focus on what happens before a report is filed, but rather should provide appropriate incentives to ensure that a correct report is filed.[28]

The Council believes that much of the regulated community's interest in the CROMERRR proposal has been focused on the record keeping provisions and not the reporting provisions. In light of this, ACC recommends that EPA at a minimum hold public workshops to address the reporting provisions prior to any further action on the regulation.

III. The CROMERRR Federal Register Notice is Procedurally Inadequate, does not Conform to Established Administration Policy, and Should be Withdrawn.

In addition to the substantive failings explained above, the notice and comment process regarding the record keeping provisions of CROMERRR is flawed as a matter of administrative law and does not conform to the established policies of the Bush Administration.[29] These legal and administrative concerns provide further support to ACC's recommendation that EPA withdraw the proposed rule.

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[27] See 66 Fed. Reg. at 46173.

[28] For example, the Security and Exchange Commission's (SEC) EDGAR system allows companies to file SEC-mandated reports electronically, and affords a limited opportunity to correct any mistakes.

[29] It should be noted that a procedural issue would also arise in connection with the reporting provisions of Subpart D, if a final CROMERRR mandates significant changes to State reporting systems. That defect might not occur if EPA makes final a CROMERRR that allows state electronic reporting systems to

As noted earlier, EPA's Federal Register notice describes the electronic record keeping provisions as voluntary.[30] EPA's own cost-benefit analysis estimated that only some 428 facilities would voluntarily choose to adopt systems complying with the electronic records provisions. On that basis, EPA determined that it did not have to comply with the Regulatory Flexibility Act (RFA) or the Small Business Regulatory Enforcement and Fairness Act (SBREFA).[31]

In fact, there is ample evidence that at least the electronic records provisions are mandatory, as discussed above. Somewhere between 1.4 and 1.7 million facilities are likely to be affected by the rule, with a consequent economic impact in the billions of dollars.

The Administrative Procedure Act (APA) requires that a notice of proposed rulemaking (NPRM) provide adequate notice of an agency's regulatory intent.[32] Failure to provide adequate notice renders the final rule invalid.[33] In the case of CROMERRR, however, the Federal Register notice and EPA's underlying assumptions mask the true nature of the proposed rule, and as a consequence the proposal fails to pass legal muster under the APA.[34] Moreover, the large number of companies and organizations that are only now becoming aware of the CROMERRR proposal is a good indication that potentially affected interests have not been provided adequate notice.

In addition, the APA requires a final rule to be a "logical outgrowth" of the NPRM. In this case, a final CROMERRR that effectively mandated electronic record keeping provisions as proposed would not be a logical outgrowth of a "voluntary" proposal.

The RFA and SBREFA mandate an appropriate analysis whenever a rule is determined to have a significant economic impact on a substantial number of entities.[35] CROMERRR clearly would have that effect, yet EPA did not comply with RFA or SBREFA because it claimed CROMERRR is voluntary.[36] EPA should withdraw the proposed rule, conduct the required RFA and SBREFA analyses and the OMB-suggested

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continue without significant change. In light of the other significant systemic problems identified with the rule, however, EPA should also resolve the procedural issue with respect to reporting.

[30] 66 Fed.Reg. at 46162, 46167.

[31] Regulatory Flexibility Act, P.L.No. 96-354 (1980)(codified at 5 U.S.C. §§601-612)(hereafter "RFA"); Small Business Regulatory Enforcement and Fairness Act, P.L.No. 104-121 (1996)(codified at 5 U.S.C. § 601 note)(herafter "SBREFA").

[32] Administrative Procedure Act, 5 U.S.C. § 553 et seq.

[33] See, e.g., PPG Indus. Inc. v. Costle, 659 F.2d 1239, 1249-51 (D.C.Cir. 1981)(rulemaking set aside when NPRM determined to be inadequate to afford a meaningful opportunity to comment); MCI Telecommunications Corp. v. FCC, 57 F.3d 1136 (D.C.Cir. 1995)(footnote reference in NPRM to impact of proposed rule on a particular sector was not adequate notice).

[34] ACC does not believe it was EPA's intent to deliberately understate the impact of the proposed rule in order to avoid any potential procedural requirement.

[35] See RFA, 5 U.S.C. §603(a); SBREFA, 5 U.S.C. § 601 note.

[36] 66 Fed.Reg. at 46186.

cost/risk/benefit analysis, and propose a different approach than that contained in CROMERRR, if any regulations are found to be necessary.

ACC believes that the proposed rule also violates the Administration's regulatory policy.[37] These violations are so serious that the Agency should withdraw the proposed rule, re-analyze the anticipated benefits and costs, and reconsider whether any rule is required at all. In particular, EPA has not identified the existing regulations that have created or contributed to the problem that currently preclude electronic record keeping and reporting. Such an analysis is in keeping with the intent of the Executive Branch's regulatory policy, which requires each agency to "examine whether existing regulations have created, or contributed to, the problem the new regulation is intended to correct."[38]

The Agency's economic analysis[39] is also flawed as a matter of Administration policy. The analysis is based on a fundamental misunderstanding of the requirements of the proposed rule as voluntary, which has the effect of inflating the net benefits anticipated under the rule. This interpretation has a major effect on the estimated cost of the proposed rule, and leads to the striking difference between the Council's estimate of $48 billion in initial costs and EPA's estimates.[40] EPA should withdraw the rule and revisit the economic analysis supporting the proposal.

The economic analysis does not identify any alternative to the proposed rule that would address the stated objective. The identification and analysis of alternatives is one of the cornerstones of Executive Order 12866:

> For each significant regulatory action, the issuing agency shall provide to OIRA an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public, and an explanation of why the planned action is preferable to the identified potential alternatives.[41]

OMB recently clarified this point in a memorandum to agencies:

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[37] The Executive Branch policy on regulation can be found in several documents, including Executive Order 12866, "Regulatory Planning and Review"; Office of Management and Budget (OMB), "Economic Analyses of Federal Regulation Under Executive Order 12866" (1996)(the "best practices" document); OMB Memorandum M-00-08, "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements", March 22, 2000; and OMB memorandum, "Presidential Review of Agency Rulemaking by OIRA," September 20, 2001 (memorandum from OIRA Administrator John Graham to the President's Management Council).

[38] See Executive Order 12866, section 1(b)(2).

[39] U.S. EPA, *Cross-Media Electronic Reporting and Recordkeeping Rule: Cost-Benefit Analysis*, EP908T2, March 2001.

[40] Id., Table 3-4.

[41] Executive Order 12866, section 6(a)(3)(C).

> Agencies must prepare a Regulatory Impact Analysis for each regulation that OIRA or the agency designates as "economically significant". . . The RIA must provide an assessment of benefits, costs, and potentially effective and reasonably feasible alternatives to the planned regulatory action.[42]

To comply with this presidential directive, EPA must identify alternatives and analyze their respective costs and benefits. OMB guidance[43] suggests that alternatives include at least one more stringent and one less stringent than the planned action.

The Executive Order requires that agencies consult with state officials before imposing regulatory requirements that might significantly or uniquely affect them.[44] The economic analysis shows that states will incur costs from the proposal, and appendix C lists information sources for the data underpinning the estimate of state costs. This list has one glaring omission: state consultation. Apparently, EPA's estimate of state cost was conducted without input from or consultation with state officials. The Council believes the Agency should have consulted with state officials before conducting the economic analysis. Consultation would reduce the uncertainty inherent in the Agency's cost estimates and lend credibility to some of the critical assumptions underpinning the Agency analysis (e.g., state implementation rate).

Without considering the potential alternatives to the proposed rule, the Agency cannot determine if the proposed rule maximizes the net benefits to the public, a point that is central to the regulatory philosophy of the Bush Administration.

> In choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.[45]

Notably, the GPEA – the only statute that might possibly be construed to mandate "another regulatory approach" – imposes no limitation on the alternatives that EPA could consider (except, of course, to provide that they cannot treat electronic documents less favorably than paper documents). The Council believes that the only way EPA can meet the requirements of the Executive Order is to analyze a sufficient number of alternatives and make a determination with respect to which alternative maximizes net benefits.

Further, the Agency's economic analysis apparently failed to use the "best reasonably obtainable scientific, technical, economic, and other information" concerning the consequences of the intended regulation. This approach is mandated by Executive

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[42] Memorandum from OIRA Administrator John D. Graham to the President's Management Council, September 20, 2001.
[43] See "best practices" document.
[44] Executive Order 12866, section 1(b)((9).
[45] Id., Section 1(a).

Order[46] and, in the case of the proposed rule, pertains to the data and assumptions chosen by the Agency to estimate benefits and costs. Several aspects of the economic analysis demonstrate a failure by EPA to use the best available scientific and technical information:

- The most critical assumptions are not identified, and the analysis does not include a sensitivity analysis to determine the effect of these assumptions on costs and benefits.
- There is a complete lack of support for the claimed benefits in the economic analysis.
- The analysis assumes two people per facility would have to register per with EPA for electronic signature authority. The Council believes that the actual number is much higher. For a typical basic chemical facility, five or more people would have to register, and for larger more complex facilities, the number would be even greater. The Agency could and should obtain a realistic estimate of potential registration costs by surveying potentially affected entities.
- The proposal would prevent any electronic reporting or record keeping until EPA established a notice of acceptability. If EPA doesn't publish a notice of acceptability immediately after the effective date of the rule, environmental monitoring and enforcement will be negatively affected. The analysis must acknowledge this possibility and quantify the impact. The analysis should also acknowledge that EPA already mandates some electronic reporting, and encourages electronic reporting of other routine reports (such as reports to the Toxics Release Inventory), all without CROMERRR.
- The analysis does not acknowledge that standard software packages, widely used for record keeping, would have to be re-written in order to comport with the requirements in the proposed rule. The cost associated with this activity must be quantified, as must the anticipated costs of revising custom software packages.
- The economic analysis should acknowledge that the opportunity cost of the proposed rule is very high because the cost of compliance is likely to draw resources away from planned improvements in information technology (IT). The true cost of the proposed rule is the loss in productivity that will occur due to a drop in future IT investment.

The analysis supporting the proposed rule is seriously flawed; the economic analysis shows a particular lack of analytical rigor and transparency, the two signature components of the Bush regulatory policy.

OMB has indicated that it will return proposed regulations to an agency for reconsideration when the agency has relied on a low quality economic analysis, when regulatory standards are not justified by the analysis, or when there is an inconsistency between the rule and the principles in Executive Order 12866. The Council believes the proposed rule should be withdrawn and reconsidered because <u>each</u> of OMB's withdrawal criteria have been met: the quality of the analysis is low (e.g., assumptions were used in

[46] Id., Section 1(b)(7).

lieu of actual data, the policy scenario was badly characterized, no sensitivity analysis was conducted, no support provided for the claimed benefits), the regulatory standards are not justified by the analysis (e.g., record keeping provisions), and there are several inconsistencies between the rule and the principles in the Executive Order (inadequate justification for the record keeping provisions, no identification or consideration of regulatory alternatives, no attempt to maximize net benefits, no state consultation, failure to use the best reasonably obtainable information).

In summary, EPA should withdraw the proposed rule. The analysis EPA has conducted thus far to support CROMERRR is incomplete at best and flawed at worst. EPA must conduct a careful and comprehensive study of any potential fraud and false information concerns associated with electronic reporting and record keeping. Only after that study should EPA determine whether it should re-propose a rule that is much more limited in scope and effect.

Attachment 1

EPA Reporting and Record Keeping Regulations[1]

Clean Air Act (CAA)

1. GENERAL RECORDKEEPING FOR NSPS
2. EMISSION GUIDELINES AND COMPLIANCE TIMES FOR SULFURIC ACID PRODUCTION UNITS
3. STANDARDS OF PERFORMANCE FOR SYNTHETIC FIBER PRODUCTION FACILITIES
4. STANDARDS OF PERFORMANCE FOR FOSSIL-FUEL FIRED STEAM GENERATORS FOR WHICH CONSTRUCTION COMMENCED AFTER AUGUST 17, 1971
5. STANDARDS OF PERFORMANCE FOR THE PHOSPHATE FERTILIZER INDUSTRY: TRIPLE SUPERPHOSPHATE PLANTS
6. STANDARDS OF PERFORMANCE FOR AMMONIUM SULFATE MANUFACTURE
7. STANDARDS OF PERFORMANCE FOR THE PHOSPHATE FERTILIZER INDUSTRY WET-PROCESS PHOSPHORIC ACID PLANTS
8. STANDARDS OF PERFORMANCE FOR THE PHOSPHATE FERTILIZER INDUSTRY: SUPERPHOSPHERIC ACID PLANTS
9. STANDARDS OF PERFORMANCE FOR PHOSPHATE FERTILIZER INDUSTRY: DIAMMONIUM PHOSPHATE PLANT
10. STANDARDS OF PERFORMANCE FOR INCINERATORS
11. STANDARDS OF PERFORMANCE FOR NITRIC ACID PLANTS
12. STANDARDS OF PERFORMANCE FOR SULFURIC ACID PLANTS
13. STANDARDS OF PERFORMANCE FOR STATIONARY GAS TURBINES
14. STANDARDS OF PERFORMANCE FOR THE PHOSPHATE FERTILIZER INDUSTRY: GRANULAR TRIPLE SUPERPHOSPHATE STORAGE FACILITIES
15. SMALL INDUSTRIAL-COMMERCIAL- INSTITUTIONAL STEAM GENERATING UNITS
16. INDUSTRIAL-COMMERCIAL- INSTITUTIONAL STEAM GENERATING UNITS
17. VOLATILE ORGANIC LIQUID STORAGE VESSELS
18. STEEL PLANTS: ELECTRIC ARC FURNACES CONSTRUCTED
19. VOC EQUIPMENT LEAKS
20. VOC EMISSIONS FROM POLYMER MANUFACTURING
21. VOC EMISSIONS FROM SOCMI AIR OXIDATION PROCESSES
22. VOC EMISSIONS FROM SOCMI DISTILLATION OPERATIONS
23. NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS MONITORING REQUIREMENTS
24. VINYL CHLORIDE

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[1] This list excerpted from American Chemistry Council, The Four "R"s: Regulatory Records Retention Requirements (2001).

25. FUGITIVE EMISSIONS OF BENZENE
26. NATIONAL EMISSION STANDARDS FOR ASBESTOS
27. EQUIPMENT LEAKS FUGITIVE EMISSION SOURCES
28. BENZENE STORAGE VESSELS
29. BENZENE TRANSFER OPERATIONS
30. NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS BENZENE WASTE OPERATIONS
31. NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS COMPLIANCE EXTENSION FOR EARLY REDUCTIONS
32. CHEMICAL ACCIDENT PREVENTION PROVISIONS
33. PROTECTION OF STRATOSPHERIC OZONE SUBPART A – PRODUCTION AND CONSUMPTION CONTROLS RECORDKEEPING AND REPORTING REQUIREMENTS
34. PROTECTION OF STRATOSPHERIC OZONE SERVICING OF MOTOR VEHICLE AIR CONDITIONERS RECORDKEEPING REQUIREMENTS
35. PROTECTION OF STRATOSPHERIC OZONE LABELING OF PRODUCTS USING OZONE-DEPLETING SUBSTANCES RECORDKEEPING REQUIREMENTS
36. PROTECTION OF STRATOSPHERIC OZONE SUBPART F – RECYCLING AND EMISSIONS REDUCTION
37. PROTECTION OF STRATOSPHERIC OZONE – RECYCLING AND EMISSIONS REDUCTION: STANDARDS FOR BECOMING A CERTIFYING PROGRAM FOR TECHNICIANS

Clean Water Act (CWA)

1. GUIDELINES FOR THE PREPARATION AND IMPLEMENTATION OF SPILL PREVENTION CONTROL AND COUNTERMEASURE PLANS
2. NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) OR PRETREATMENT PERMIT APPLICATIONS AND SUPPORTING DATA
3. NPDES CONDITIONS APPLICABLE TO ALL PERMITS
4. SECTION 404 PERMIT CONDITIONS
5. REPORTING REQUIREMENTS FOR POTWs AND INDUSTRIAL USERS
6. MONITORING AND RECORDS REQUIREMENTS FOR SEWAGE SLUDGE PERMITTING
7. NPDES - COMPLIANCE EXTENSION FOR FACILITIES INSTALLING INNOVATIVE TECHNOLOGY

Resource And Recovery Conservation Act (RCRA)

1. IDENTIFICATION AND LISTING OF HAZARDOUS WASTE DEFINITION OF SOLID WASTE
2. IDENTIFICATION AND LISTING OF HAZARDOUS WASTE – EXCLUSIONS: SAMPLES SHIPPED FOR TREATABILITY STUDIES
3. IDENTIFICATION AND LISTING OF HAZARDOUS WASTE – EXCLUSIONS: TREATABILITY STUDY LABORATORIES
4. SMALL QUANTITY WASTE GENERATOR MANIFEST REQUIREMENTS

5. GENERATORS OF HAZARDOUS WASTE RECORDKEEPING REQUIREMENTS
6. GENERATORS OF HAZARDOUS WASTE EXPORT RECORDKEEPING REQUIREMENTS
7. RECORDKEEPING REQUIREMENTS FOR TRANSPORTERS OF HAZARDOUS WASTE
8. TSD FACILITIES INSPECTION REQUIREMENTS
9. TSD FACILITIES PERSONNEL TRAINING RECORDS
10. TSD FACILITIES MANIFEST SYSTEM RECORDKEEPING AND REPORTING
11. TSD FACILITIES OPERATING RECORD
12. TSD FACILITIES GENERAL GROUND-WATER MONITORING REQUIREMENTS
13. TSD FACILITIES DETECTION MONITORING PROGRAM
14. TSD FACILITIES COST ESTIMATES FOR CLOSURE
15. TSD FACILITIES LAND TREATMENT RECORDKEEPING
16. INTERIM STATUS TSD FACILITIES LANDFILL RECORDKEEPING
17. TSD FACILITIES INCINERATOR MONITORING AND INSPECTIONS
18. INTERIM STATUS TSD FACILITIES PERSONNEL TRAINING RECORDS
19. INTERIM STATUS TSD FACILITIES MANIFEST SYSTEM RECORDKEEPING AND REPORTING
20. INTERIM STATUS TSD FACILITIES OPERATING RECORD
21. INTERIM STATUS TSD FACILITIES GROUNDWATER MONITORING RECORDKEEPING
22. INTERIM STATUS TSD FACILITIES CLOSURE PLAN
23. INTERIM STATUS TSD FACILITIES POST-CLOSURE PLAN
24. INTERIM STATUS TSD FACILITIES COST ESTIMATE FOR CLOSURE
25. INTERIM STATUS TSD FACILITIES POST-CLOSURE CARE COST ESTIMATES
26. INTERIM STATUS TSD FACILITIES LAND TREATMENT RECORDKEEPING
27. INTERIM STATUS TSD FACILITIES LANDFILLS RECORDKEEPING
28. PETITION TO ALLOW LAND DISPOSAL OF WASTE PROHIBITED UNDER SUBPART C OF 268
29. TESTING, TRACKING, AND RECORDKEEPING REQUIREMENTS FOR GENERATORS, TREATERS AND DISPOSAL FACILITIES
30. HAZARDOUS WASTE PERMIT APPLICATION
31. HAZARDOUS WASTE PERMIT CONDITIONS – MONITORING AND RECORDS

Toxic Substances Control Act (TSCA)

1. GENERAL RECORDKEEPING FOR SECTION 8 (a) INFORMATION GATHERING
2. CHEMICAL-SPECIFIC RECORDS: ll-AMINOUNDECANOIC ACID (11-AA)
3. CHEMICAL-SPECIFIC RECORDS: P-TERT-BUTYLBENZOIC ACID (P-TBBA), P-TERT-BUTYLTOLUENE (P-TBT), AND P-TERT-BUTYLBENZALDEHYDE (P-TBB)

4. CHEMICAL-SPECIFIC RECORDS: CHLORINATED NAPHTHALENES
5. CHEMICAL-SPECIFIC RECORDS: CHLORINATED TERPHENYL
6. CHEMICAL IMPORTS AND EXPORTS GENERAL IMPORT REQUIREMENTS AND RESTRICTIONS- CHEMICAL SUBSTANCE IMPORT POLICY
7. CHEMICAL IMPORTS AND EXPORTS NOTICES OF EXPORT UNDER SECTION 12(b)
8. INVENTORY REPORTING
9. PREMANUFACTURE NOTIFICATION (PMN): RECORDKEEPING
10. NOTICE OF COMMENCEMENT OF MANUFACTURE OR IMPORT
11. SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES
12. CERTAIN SIGNIFICANT NEW USES HAZARD COMMUNICATION
13. CERTAIN SIGNIFICANT NEW USES RECORDKEEPING REQUIREMENTS
14. CHEMICAL SUBSTANCES MANUFACTURED IN QUANTITIES OF 10,000 kg OR LESS PER YEAR
15. PREMANUFACTURE NOTIFICATION EXEMPTION: CHEMICAL SUBSTANCES USED IN OR FOR THE MANUFACTURE OR PROCESSING OF INSTANT PHOTOGRAPHIC AND PEEL-APART FILM ARTICLES
16. PREMANUFACTURE NOTIFICATION EXEMPTION: NEW POLYMERS
17. WATER TREATMENT CHEMICALS: HEXAVALENT CHROMIUM-BASED WATER TREATMENT CHEMICALS IN COOLING SYSTEMS
18. PCB MANUFACTURING USE IN & SERVICING OF TRANSFORMERS
19. PCB MANUFACTURING: STORAGE AND DISPOSAL
20. PCB DISPOSAL CHEMICAL WASTE LANDFILLS
21. CLEANUP OF LOW CONCENTRATION PCB SPILLS
22. CLEANUP OF HIGH CONCENTRATION PCB SPILLS
23. PCBs AND PCB ITEMS IN SERVICE OR PROJECTED FOR DISPOSAL
24. COMMERCIAL STORERS AND DISPOSERS OF PCB WASTE
25. INCINERATION FACILITIES
26. CHEMICAL WASTE LANDFILL FACILITIES
27. HIGH EFFICIENCY BOILER FACILITIES
28. STORAGE AND DISPOSAL FACILITIES SPECIAL RECORDS
29. IMPORTERS AND PERSONS GENERATING PCBs IN EXCLUDED
30. MANUFACTURING PROCESSES
31. IMPORTERS, MANUFACTURERS, PROCESSORS OR USERS OF CHEMICALS
32. INADVERTENTLY GENERATING PCBs
33. GENERATOR OF PCB WASTE
34. TRANSPORT OF PCB WASTE
35. PCB WASTE COMMERCIAL STORAGE OR DISPOSAL FACILITY
36. GOOD LABORATORY PRACTICE STANDARDS
37. SPECIFIC CHEMICAL SUBSTANCE TESTING REQUIREMENTS

Underground Storage Tank Program (UST)

1. INTERIM PROHIBITION FOR DEFERRED UST SYSTEMS
2. NEW UST SYSTEMS
3. OPERATION AND MAINTENANCE OF CORROSION PROTECTION
4. UST REPAIRS

5. RELEASE DETECTION
6. CLOSURE RECORDS

Underground Injection Control

1. GENERAL REQUIREMENTS
2. REQUIREMENTS FOR CLASS I, II, AND III WELLS
3. APPLICATION FOR A PERMIT; AUTHORIZATION BY PERMIT
4. PERMIT CONDITIONS
5. POST-CLOSURE CARE REGARDING CLASS I HAZARDOUS WASTE INJECTION WELL

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

1. MODEL ADMINISTRATIVE ORDER FOR REMEDIAL
2. INVESTIGATION/FEASIBILITY STUDIES Section XVII
3. MODEL REMEDIAL DESIGN/REMEDIAL ACTION CONSENT DECREE Section XXV
4. CERCLA SECTION 103 NOTIFICATION REQUIREMENTS RESPECTING RELEASED SUBSTANCES

Emergency Planning and Community Right-To-Know Act (EPCRA)

1. TOXIC CHEMICAL RELEASE RECORDKEEPING