

**GAO**

United States General Accounting Office

Report to the Chairman, Subcommittee  
on Oversight and Investigations,  
Committee on Energy and Commerce,  
House of Representatives

February 1984

## PEER REVIEW

# EPA Needs Implementation Procedures and Additional Controls



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**Resources, Community, and  
Economic Development Division**

B-253525

February 22, 1994

The Honorable John D. Dingell  
Chairman, Subcommittee on  
Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives

Dear Mr. Chairman:

In May 1991, the Administrator, Environmental Protection Agency (EPA), established a panel of outside academicians to review the role of science at EPA and evaluate how the agency can meet the goal of using sound science as the foundation for the agency's decision-making. In March 1992, the expert panel reported that science at EPA is of uneven quality, and as a result, the agency's policies and regulations are frequently perceived as lacking strong scientific support. The panel recommended that EPA establish a uniform peer review process for all scientific and technical products used to support EPA guidance and regulations. For this review, we interpreted peer review as the final critical evaluation of scientific and technical program products by independent experts.

In 1993, we reported on the premature release, by an external reviewer, of a draft compendium to an EPA report on environmental tobacco smoke.<sup>1</sup> In that report, we cited weaknesses in internal controls over EPA's peer review process as contributing to the premature release. You then asked us to review EPA's policies and practices regarding the peer review of scientific and technical materials published or issued by the agency. Specifically, we examined (1) EPA's efforts to implement a uniform policy on peer reviews and (2) its controls over documents sent to outside reviewers.

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**Results in Brief**

In response to the panel's recommendations, in January 1993, the EPA Administrator issued a peer review policy statement requiring that technically based products undergo peer reviews. However, the policy statement does not define technically based products and does not specify the implementation procedures or steps needed to perform peer reviews. Ongoing efforts to define technically based products and develop implementation procedures have been delayed due to concerns raised by the various EPA offices that will have to implement the policy. These

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<sup>1</sup>Environmental Tobacco Smoke (GAO/RCED-93-77R, Feb. 8, 1993).

concerns are about, among other things, identifying which products to review, as well as the scope, timing, and cost of the reviews. To resolve these issues, EPA established a work group—consisting of representatives from its program and regional offices and the Council of Science Advisors<sup>2</sup>—to develop specific implementation procedures. However, EPA has not established milestones or deadlines for this group. Plans are to address, in phases over an unspecified period of time, concerns that are hampering agencywide implementation of the policy statement.

EPA does not have consistent agencywide controls over products being sent to external peer reviewers to help reduce the possibility that the products will be prematurely released and perceived as agency policy. EPA has no procedures to ensure that documents sent to external peer reviewers are stamped as drafts and/or include a disclaimer stating that the documents are drafts and do not necessarily represent the views of the agency. Also, EPA does not always have a written agreement with outside peer reviewers that they will not release draft documents without the agency's approval. EPA work groups developing peer review implementation procedures have no plans to address these problems. Therefore, the potential continues to exist that documents may be prematurely released by reviewers and perceived as EPA's position.

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## Background

Nearly a decade ago, EPA learned that the author of seven of the eight key studies it used to support proposed revisions to the carbon monoxide standard was being investigated by the Food and Drug Administration and the Veterans Administration for the falsification of research. Although peer reviews were conducted for these studies, they did not adequately address all relevant concerns. For example, the peer reviews had not looked closely at the author's data or methodology because of his high esteem within the scientific community. When the investigators questioned the scientific validity of the studies, EPA delayed the standards, audited the research data, and concluded that the studies were unreliable for its purposes.

In response to concerns that some of EPA's decisions could be based on unreliable data, the Administrator wanted to institute a uniform peer review policy that would ensure that all of the agency's decisions would be based on objective, credible, unbiased scientific and technological data.

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<sup>2</sup>The Council consists of science advisors from each of EPA's program and regional offices.

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EPA's 5 program offices<sup>3</sup> and 10 regional offices generate scientific and technical data and analyses to support the agency's regulatory, enforcement, and standard-setting decisions. Such data and analyses are also developed by external organizations under contract to various EPA offices.

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## Peer Review Policy Implementation Delayed

The EPA Administrator wanted to issue a uniform policy that included implementation procedures. However, continuing concerns by various EPA office managers over the diversity of products (ranging from basic health research to permits to operate a facility at a specific site) developed by the offices and the availability of time and resources to do the increased number of reviews delayed the implementation of a uniform peer review policy statement.

An internal work group met in April 1993 to begin developing specific procedures for managers to use in their peer review decisions. The group was to consider the concerns raised by the various offices and determine what effect the extra time needed to do peer reviews would have on EPA's ability to meet statutory and court-ordered deadlines. EPA officials said that the issue of meeting deadlines was raised because EPA has had difficulty meeting deadlines even without the requirement to conduct peer reviews supporting scientific and technical products.

The availability of resources and independent reviewers to perform the increased number of reviews is another issue that EPA needs to consider in developing a peer review implementation plan. EPA officials said that doing more reviews will increase costs as the agency usually pays external peer reviewers between \$150 and \$300 a day. Some work group members were concerned that EPA would not have the funds for the increased costs, particularly in austere budget periods. Also, some EPA officials were concerned that selecting peer reviewers and handling their comments might take additional staff. Furthermore, the availability of independent reviewers was a concern because some products address highly technical subjects for which there are very few experts available. Some of these experts may not be independent since they may have done work on products for companies that could be affected by decisions EPA makes on the basis of these products.

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<sup>3</sup>The Offices of Air and Radiation, Pesticides and Toxic Substances, Water, Solid Waste and Emergency Response, and Research and Development.

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The broad range of EPA products is another issue that needs to be considered. Some work group members believe that it is difficult to develop one set of procedures that will satisfy the many different types of products developed by EPA's various offices. For example, the Office of Research and Development (ORD) usually develops more traditional research products that may be used by many different researchers outside of EPA as well as within the agency. However, the Office of Air Quality Planning and Standards (OAQPS), within the Office of Air and Radiation, develops technical products that may be designed to meet specific information needs and thus limited in scope and use by others. In addition, regional offices usually develop products that are even more limited in scope. For example, regional offices may develop data and analyses to allow a specific facility an operating permit. These data and analyses are site-specific and would have limited use and be of concern only to those living near the facility.

The work group has made some preliminary conclusions regarding peer review procedures. For example, the group has endorsed a flexible peer review policy. Under this policy, if a product has national ramifications (e.g., standards for radon levels in homes) or is controversial (e.g., a report concerning health effects from environmental tobacco smoke), it should receive a peer review; if it is more site-specific (e.g., data to support noncontroversial permit applications), it may need only a limited peer review or none at all.

The work group has also established four committees to address some of the offices' concerns. For example, committees have been established to develop (1) guidelines for peer reviews of regional offices' work, (2) helpful hints of what to do and what not to do on program-office-level peer reviews, (3) a mechanism to include peer review as part of the regulatory negotiation<sup>4</sup> process instead of after it, and (4) a model procurement instrument to help individual offices obtain external peer review services.

The work group has also identified other concerns. For example, flexibility was identified as a very important component of the implementation plan. However, as of December 1993, the work group had not addressed how it plans to deal with flexibility issues such as determining which products should receive peer reviews, determining the extent of the reviews, and developing a conceptual framework to prevent

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<sup>4</sup>Regulatory negotiation brings interested parties, such as industry, environmental groups, and government agencies, together to agree on how a regulation should be worded to meet all of their concerns, thereby expediting the issuance of regulations and avoiding costly litigation.

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flexibility from generating unjustifiable inconsistency. As of December 1993, EPA officials did not know when uniform peer review procedures would be available—no deadline has been set for completing them.

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## EPA Needs to Strengthen Its Peer Review Policy

Because EPA lacks uniform implementing procedures for its new peer review policy, some of its offices still do not consistently employ such reviews on products developed by their own staffs or by contractors. For example, OAQPS does not require that all of the products it uses to support decisions receive peer reviews. In addition, ORD often uses EPA personnel to review products it develops rather than using independent reviewers, the generally accepted way to do peer reviews. Specifically, we found that:

- OAQPS uses many scientific and technical documents, which may be developed by various sources, including its own staff, ORD, and contractors, to support air quality standards and regulations. However, OAQPS officials said that the office does not require these documents to undergo peer review. In examining products developed by one of its contractors, we found that neither the contractor nor OAQPS had subjected them to peer review. Yet at least one of these products, the “Economic Impact of Air Pollutant Emission Standards for New Municipal Waste Combustors” report, was used to support standards and guidance for municipal waste combustors. According to the EPA officials involved in overseeing the contractor, the agency does not require a peer review of such products.
- ORD officials said that before the January 1993 policy statement, they had a policy that all research and technical documents undergo peer reviews. However, the objectivity of some reviews could be challenged. For instance, one product, “Mutagenicity of Emissions from the Simulated Burning of Scrap Rubber Tires,” which was developed by ORD’s Air and Energy Engineering Research Laboratory, had been reviewed by two other EPA employees—one from the branch that developed the product and the other from OAQPS. According to ORD officials, this report received a peer review at the same level as most other ORD products. The officials said that EPA employees may be used when not enough independent reviewers are available. However, according to officials from the Robert Wood Johnson Foundation and the National Institute of Environmental Health Sciences, such a review by EPA’s staff is not credible since the review was not performed by independent parties.



Another weakness in EPA's peer review process is that authors of some scientific and technical documents help select reviewers. For example, in some cases, the Atmospheric Research and Exposure Assessment Laboratory uses a contractor to recommend individuals who are qualified to review products. An EPA project officer said that a list of potential reviewers is given to the product's author, who can eliminate any reviewer he or she considers unsuitable. The revised list is then returned to the contractor, who makes the final selection.

### Concerns of EPA Science Advisor Over the Peer Review Process

The expert panel also recommended that the EPA Administrator appoint a science advisor to ensure that credible scientific information for the agency's guidance and decisions is available from both EPA scientists and the scientific community. In November 1992, a position was created and filled by an experienced scientific administrator from outside EPA. The EPA Science Advisor is the focal point for science in the agency as well as for the work groups developing peer review implementation procedures. In discussing the delays and difficulties the agency is having in implementing the January peer review policy, the Science Advisor had the following concerns:

- The need to find a way to ensure that the peer review policy is consistently applied throughout EPA's various program and regional offices and laboratories. The Science Advisor identified, for example, 14 different ways unit managers could obtain a peer review, ranging from one by an independent expert within EPA to an extensive review by the National Academy of Sciences. The Advisor said that without criteria, unit managers would inevitably differ to too great an extent when considering the complexity and importance of products and the type and degree of peer review a product would receive.
- The need for a mechanism to ensure accountability. To help devise such a mechanism, the Science Advisor has asked a work group in the Office of Program Planning and Evaluation to consider this issue as part of its efforts to evaluate EPA's entire regulatory development process. The Advisor said that members of this group are aware that EPA's structure is inefficient and sometimes incapable of dealing with issues, such as peer reviews, that cut across division lines. This group's work, which started in June 1993, is expected to impact the peer review implementation procedures—the group is trying to identify a way to hold managers accountable for ensuring that their products meet all the applicable requirements, including the peer review policy. However, the group has



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not yet identified an acceptable accountability mechanism. According to the Science Advisor, possibly the only means to ensure accountability under EPA's current structure would be for the EPA Administrator to require evidence of peer review before products go to printing. Inserting accountability into the implementation procedures may further delay the release of products. As with the work group addressing overall peer review, the group addressing peer review accountability has just begun its efforts and has not set a date for recommending a solution.

- Effectively communicating the policy throughout EPA so that managers know that all products should be considered for peer review. The Science Advisor said that while the January policy was not specific as to which products to review, contractor-provided products are also subject to the policy. The Advisor was concerned when he learned that some of the project managers we interviewed were either not aware of the policy or did not believe it applied to contractor-provided products. He further explained that without some method to hold managers accountable for doing peer reviews that some may ignore the policy.
- Confusion between peer involvement and peer review. The Science Advisor said that some offices within EPA routinely use employees from the same office as the author to conduct peer reviews. He explained, however, that this is not peer review but is more closely associated with peer involvement. He believes that for EPA to avoid later criticism, project managers should use independent reviewers from outside their own office to conduct peer reviews. The Advisor said that while peer involvement is a valuable tool, it is no substitute for peer review.

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## Controls Needed Over EPA Products That Are Independently Reviewed

EPA does not have procedures to ensure that products sent to external individuals for peer review are clearly identified as draft products and are not prematurely released. As we previously reported, a draft report on environmental tobacco smoke was prematurely released by a reviewer. In that instance, the reviewer released a copy of the technical compendium to the draft report. This document had not received a final review by EPA managers to determine if its contents met agency policy. Also, the document had not been marked as a draft to ensure that anyone receiving it would know that it might not represent agency policy. The compendium, which later proved to be controversial, also contained a chapter that was written by the reviewer. As of this date, EPA has not developed procedures to preclude the premature release of documents.

EPA products are sometimes sent to external individuals who perform the reviews for free. Some of the reviewers are not under contractual or other

written agreement to refrain from releasing EPA products without prior approval. In our February 1993 report, we discussed the premature release of documents by a peer reviewer that was doing the review without financial compensation and thus had no contract with EPA. Also, EPA did not have any other written agreement with the reviewer that he would not release the document without EPA's approval. The technical compendium was not stamped "Draft," nor did the cover letter accompanying it contain a disclaimer that would have alerted the reader that the document was a draft. The Director of EPA's Indoor Air Division said that it would have been good practice for the cover letter to have included a disclaimer stating that the document was not a final EPA product.

While no assurance exists that a disclaimer would discourage the premature release of draft documents, EPA would, at least, have a sound basis for clarifying that such documents are subject to revision and do not represent the agency's position. However, none of the work groups have been tasked to address this issue.

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## Conclusions

By developing an agencywide policy requiring that its scientific and technical products undergo peer reviews, EPA moved toward ensuring that its decisions and regulations are based on objective, credible information. However, because this policy is very general, relying on each internal unit to tailor its peer reviews, and because EPA has not yet adopted implementation procedures, peer reviews remain inconsistent and not fully effective. In addition, controls over materials undergoing peer reviews by outside individuals remain weak as EPA does not obtain written agreement from all reviewers that they will not release documents without EPA's approval. Moreover, documents are not always marked as drafts and do not always have an accompanying disclaimer stating that they do not necessarily represent agency policy.

EPA has established a work group to address the implementation problems, but progress has been slow, and the agency has not established a deadline for completing this work. EPA's difficulties in developing implementation procedures to accompany the peer review policy demonstrate the importance of establishing deadlines for the work group. Also, it is not clear when EPA will address such issues as how to hold managers at all levels accountable for their peer review decisions, how to ensure that reviewers' independence is not unduly influenced by the fact that products' authors have the authority to eliminate unwanted reviewers, and how to ensure that products developed by contractors receive appropriate

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peer reviews. Until such implementation procedures are established, the universal peer review policy is not likely to have much effect.

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## Recommendations

In order for the agency's peer review policy to be successful, we recommend that the EPA Administrator set a schedule for developing, completing, and implementing agencywide peer review procedures. Also, the Administrator should develop and implement controls that protect against the premature release of documents by external peer reviewers.

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## Agency Comments

We discussed the information contained in this report with EPA officials, including the Science Advisor and the Director of the Office of Technology Transfer and Regulatory Support, who generally agreed with its facts. Their comments are included where appropriate. However, at your request, we did not obtain written agency comments on a draft of this report.

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## Scope and Methodology

We conducted our review from January through December 1993 in accordance with generally accepted government auditing standards. Our work focused primarily on examining the peer review of research products for EPA's air and radiation programs and obtaining peer review information from EPA Regions I and IV to get an understanding of concerns EPA regional offices may be having with implementing the policy. We interviewed officials and obtained documents from EPA's Offices of Air and Radiation, and Research and Development and the agency's laboratories at the Research Triangle Park in North Carolina. We also interviewed two of the four members of the panel that had reviewed EPA's previous peer review policy and officials at the National Institute of Environmental Health Sciences in Durham, North Carolina; the Department of Energy's Argonne National Laboratory in Argonne, Illinois; the Research Triangle Institute at the Research Triangle Park; and the Robert Wood Johnson Foundation in Princeton, New Jersey.

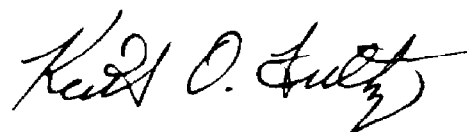
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Unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies to the EPA Administrator and make copies

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available to others upon request. This report was prepared under the direction of Peter F. Guerrero, Director, Environmental Protection Issues, who can be reached at (202) 275-6111 if you have any questions. Major contributors to this report are listed in appendix I.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Keith O. Fultz". The signature is written in a cursive style with a large, sweeping flourish at the end.

Keith O. Fultz  
Assistant Comptroller General



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# Major Contributors to This Report

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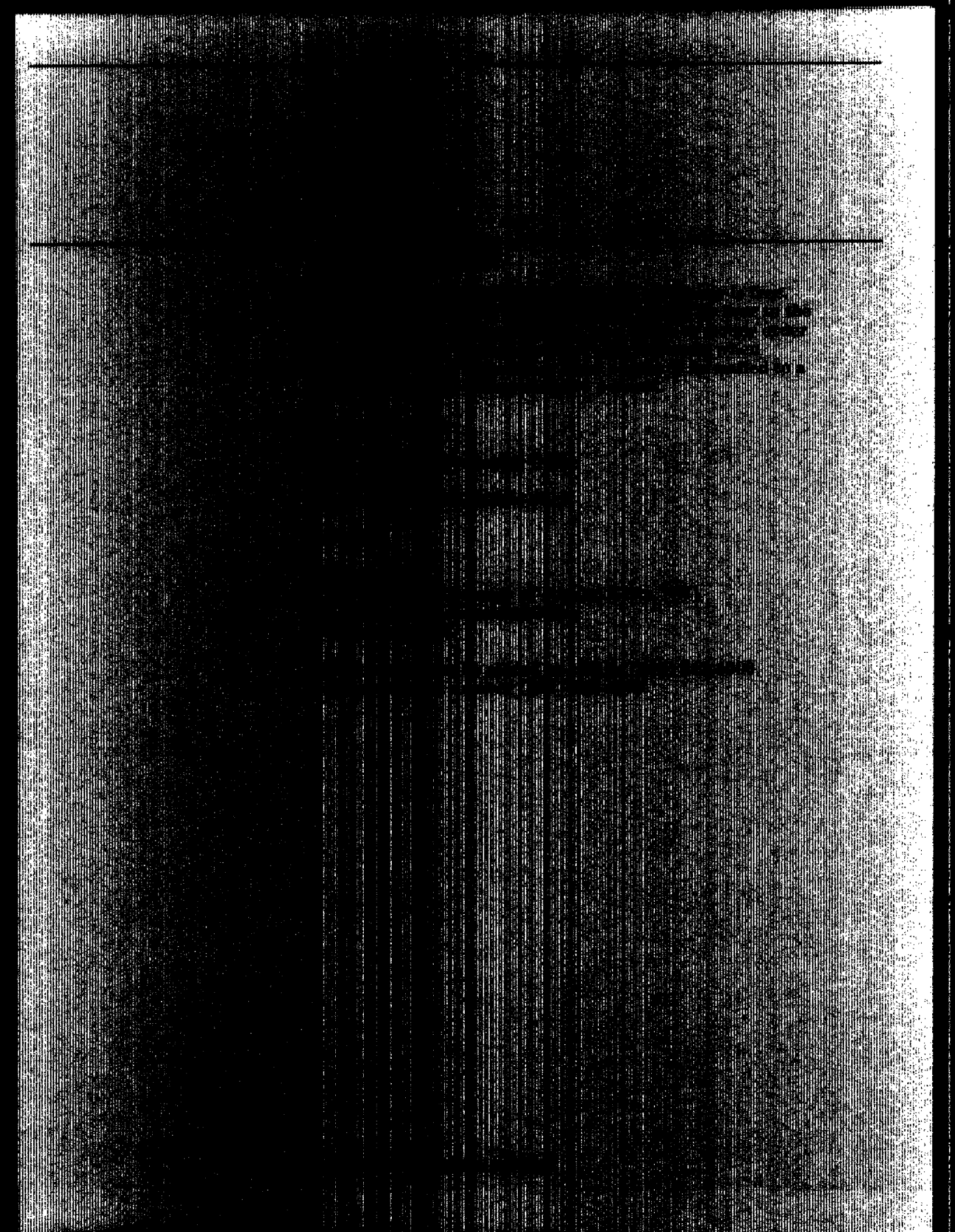
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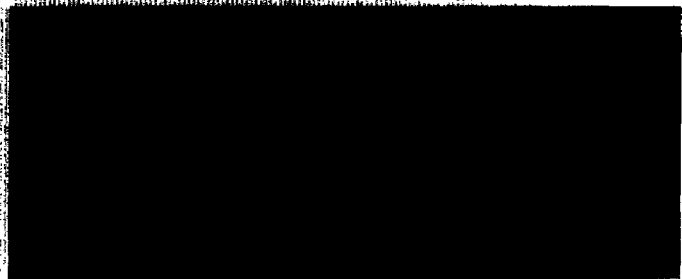
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