

From IRIS PROGRAM MGT 12/19/07
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Overall Comments to the Statement of Facts for GAO's Review of EPA's IRIS Program:

We thank the GAO for allowing us to review the Statements of Facts, and offer here a few general comments. In addition we are providing a 'marked-up-text' that includes many more detailed comments.

In general, we appreciate the effort that GAO has made to understand the IRIS Program, including its shortcomings and accomplishments. We share with the GAO the goal of making continual improvements, having the IRIS database be credible, scientifically excellent, timely and up-to-date. Our comments follow:

1. In general, a very negative picture is painted of the IRIS Program that is largely based on past history, and gives insufficient attention to the many positive changes that have occurred over the past four years.
 - a. Many of the recent changes are viewed negatively rather than seeing them in light of the positive things that are occurring as a result.
 - b. Trivial examples are commingled with major issues, so that the important issues really do not stand out. For example, changing the peer reviews from letter reviews to face-to-face reviews delays the IRIS process slightly, but has very large benefits in terms of open discussion and consideration of other viewpoints. The delays are minor, but there is an extended discussion in the document, nevertheless, that paints this as an important source of delays and hence more of a problem than a benefit. This misconstrues this change, as an example of a negative influence rather than an improvement.
 - c. Many of the "sins of the past" are due to having an IRIS Program that was based on volunteer efforts by staff in the Program and Regional Offices, who undertook IRIS assessments as "other duties as assigned", and often did not have time to work on the assessments. Recent changes will prevent such situations from occurring in the future.
2. One major recent development of considering IRIS assessments as guidance documents that must be reviewed by OMB, and approved by OMB, is given too little attention. Also missing is a discussion of the implications of this conclusion by OMB, which is extremely important i.e., that the IRIS program cannot release the draft for public comment prior to external peer review, and again cannot release the final draft following peer review, until OMB agrees with EPA's revisions in response to OMB comments, comments which can be very extensive and troubling to address. The addition of this interagency review process, and approval steps, has added tremendously to the time it takes to release drafts at each of these two stages. It seems GAO could determine the additional time this total process addition imposed by OMB on IRIS has taken, in addition to the troubling policy issue it raises e.g., that science is being commented on by an

OMB analyst and that such comments are not in the public arena.

3. Resources are mentioned only in passing. IRIS needs to complete more than 50 assessments a year in order to ensure that no assessment is more than 10 years old, and in order to accommodate the EPA's need for new assessments. This is critical for an IRIS database to be useful and up-to-date. Significant additional resources (FTE and dollars) would be needed to reach this level.

4. IRIS productivity has increased exponentially for the parts of the process that EPA has control over. In FY 2006 and in FY 2007, 16 IRIS assessments per year were sent for interagency review. This level of productivity and accomplishment is a quantum change from previous accomplishments. Consequently, we suggest that graphs in the statement of facts be changed to include these recent accomplishments and indicate the level of productivity and accomplishment planned for the next few years until the program arrives at "steady state".