

Comprehensive Literature Search and Data Call-In

Completed lit searches posted on Web and announced in FRN

FRN requesting information about studies not in lit search and new research

1 Complete Draft IRIS Assessment

2 Internal Agency Review

3 Science Consultation on the Draft Assessment with other Federal Agencies and White House Offices

EPA coordinates Interagency review

6A Internal Agency Review and EPA Clearance of Final Assessment

5 Revise Assessment

Address peer review and public comments; prepare response to comments document

4 Independent Expert Peer Review, Public Review and Comment, and Public Listening Session

Draft assessment and peer review charge posted on Web site

Public comment period and Listening Session announced in FRN

Peer review meeting announced in FRN

6B EPA-led Interagency Science Discussion

Science feedback on final assessments from other Federal Agencies and White House offices

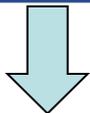
7 Post Final Assessment on IRIS

Includes IRIS summary, Toxicological Review and response to comments

Comprehensive Literature Search and Data Call-In

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Complete Draft IRIS Assessment

Additional Details about Step 1

Before beginning draft development, the IRIS Program:

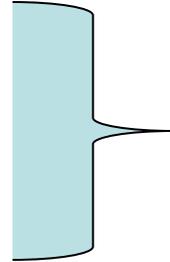
- Conducts internal planning and scoping meeting to identify EPA needs for the assessment; and
- Conducts public meeting on technical problem formulation (planning and scoping summary will be publicly released).

As part of developing the draft assessment, the IRIS Program:

- Conducts literature search and critical study selection;
- Develops evidence tables that succinctly summarize the critical studies to be considered in developing the assessment;
- Publicly releases literature search, literature search strategy, critical study selection criteria, evidence tables for critical studies, and exposure-response figures (which graphically depict responses at different exposure levels for studies in evidence tables);
- Convenes public meeting to discuss literature search, evidence tables, exposure-response figures, and key issues;
- Implements recommendations from the National Research Council related to developing IRIS assessments, including systematic review of scientific information and enhanced evidence integration;
- Identifies hazards;
- Selects studies for dose-response assessment;
- Derives toxicity values;
- Prepares draft assessment and draft external peer review charge.

2

Internal Agency Review



Additional Details about Step 2

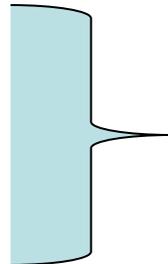
During Internal Agency Review, the IRIS Program:

- Shares draft assessment with EPA's program and regional offices;
- Convenes a meeting to discuss draft assessment;
- Identifies any scientific issues; and
- Determines needed disciplines of peer review panel members and the scope of the external peer review.

3

Science Consultation on the Draft Assessment with other Federal Agencies and White House Offices

EPA coordinates Interagency review



Additional Details about Step 3

During Science Consultation, the IRIS Program:

- Shares draft assessment and draft external peer review charge with other Federal Agencies and the Executive Office of the President (EOP) for a science consultation (which is managed and coordinated by EPA);
- Provides a specific date for receiving written comments (written comments will become part of the public record);
- Convenes a meeting of the other Federal Agencies and EOP to discuss issues raised in the written comments;
- If appropriate, may include science questions raised during this step in the draft external peer review charge; and
- Revises the draft assessment, as appropriate.

4 Independent Expert Peer Review, Public Review and Comment, and Public Listening Session

Draft assessment and peer review charge posted on Web site

Public comment period and Listening Session announced in FRN

Peer review meeting announced in FRN

Additional Details about Step 4

As part of public review, comment and discussion and independent expert peer review, the IRIS Program:

- Publicly releases draft assessment on IRIS website;
- Publicly releases draft peer review charge on IRIS website (concurrent with the public release of the draft assessment);
- Convenes public meeting on draft assessment;
- Discusses draft peer review charge at public meeting;
- May revise the draft assessment or peer review charge prior to peer review to be responsive to public comments;
- Submits draft IRIS assessment and peer review charge questions to external peer review panel (organized by a contractor or by EPA's Science Advisory Board); and
- Participates in public peer review meeting.

5 Revise Assessment

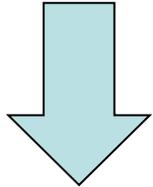
Address peer review and public comments; prepare response to comments document

Additional Details about Step 5

As part of revising the draft assessment, the IRIS Program:

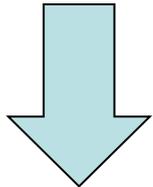
- Evaluates external peer review panel recommendations and all public comments;
- Revises draft assessment, as appropriate;
- Develops a disposition of peer review and public comments and provides these as an appendix to the IRIS assessment.

6A Internal Agency Review and EPA Clearance of Final Assessment



6B EPA-led Interagency Science Discussion

Science feedback on final assessments from other Federal Agencies and White House offices



7 Post Final Assessment on IRIS

Includes IRIS summary, Toxicological Review and response to comments

Additional Details about Steps 6A and 6B

As part of step 6A, internal Agency review and EPA clearance of final assessment, the IRIS Program:

- Sends final draft assessment for final internal review by EPA's program and regional offices.

As part of step 6B, EPA-led interagency science discussion, the IRIS Program:

- Provides other Federal Agencies and EOP with final draft assessment and related materials (e.g., IRIS Summary; appendices);
- Provides a specific date for receiving written comments with a focus on the disposition of peer review and public comments (written comments will become part of the public record); and
- Convenes a meeting with other Federal Agencies and EOP to discuss final comments.

NOTE: Steps 6A and 6B occur simultaneously.

Additional Details about Step 7

As part of posting the final IRIS assessment, the IRIS Program:

- Completes the IRIS assessment (including the Toxicological Review, IRIS Summary, and any appendices);
- Posts final IRIS assessment and related materials to IRIS website.

Assessment Development Timelines

Step	Time Frame: Standard Assessments	Time Frame: Complex Assessments
1 IRIS draft assessment completed	10.5 months	15 months
2 Internal Agency Review	3 months	3 months
3 Interagency science consultation	2 months	3 months
4 Public comment and External peer review	5 months	9.5 months
5 Draft assessment revised	2 months	4 months
6a Internal Agency Review	2 months	3 months
6b Interagency science discussion		
7 Final IRIS assessment	1.5 months	1.5 months
TOTAL	26 months	39 months

The time frames are anticipated to represent an average, with some assessments potentially taking longer depending on the nature of the analytical tasks and the range of issues raised during peer review