DEPARTMENT OF DEFENSE
MERIT
Materials of Evolving Regulatory Interest Team

Emerging Contaminants Directorate

DoD Interests in Emerging Contaminants

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Office of Deputy Under Secretary of Defense
(Installations & Environment)

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Imagine

if the largest industrial complex in the nation could...

- **Predict** which chemicals it used were most likely to pose human health and environmental challenges and be regulated in the future.
- **Develop** a consensus evaluation of risks posed to the sustainability of its mission.
- **Disseminate** rapidly new useful information on scientific and technical implications and options.
- **Leverage and strategically focus** intellectual capital and other resources on highest priority issues.

DoD Strategic Vision for ECs

- **Protect People & Enhance Readiness**
  - Ensure application of sound, thorough science in risk assessments
  - Make processes transparent and inclusive
  - Make sound risk management decisions on emerging contaminants

Three Part Strategy

- Nat'l improvement in risk assessment
- DoD Integrated Risk Management
- Increase transparency and science engagement

- Improve agency involvement to increase understanding and resolve issues

- Early warning & screening process
- Impact assessment
- Informed risk management actions

Materials/EC Tracking Process

Over-the-Horizon Scanning

Review literature, periodicals, regulatory communications, etc.

May be of interest

Watch List

Monitor events; conduct rough impact analysis

Probable mission or budget impacts

Action List

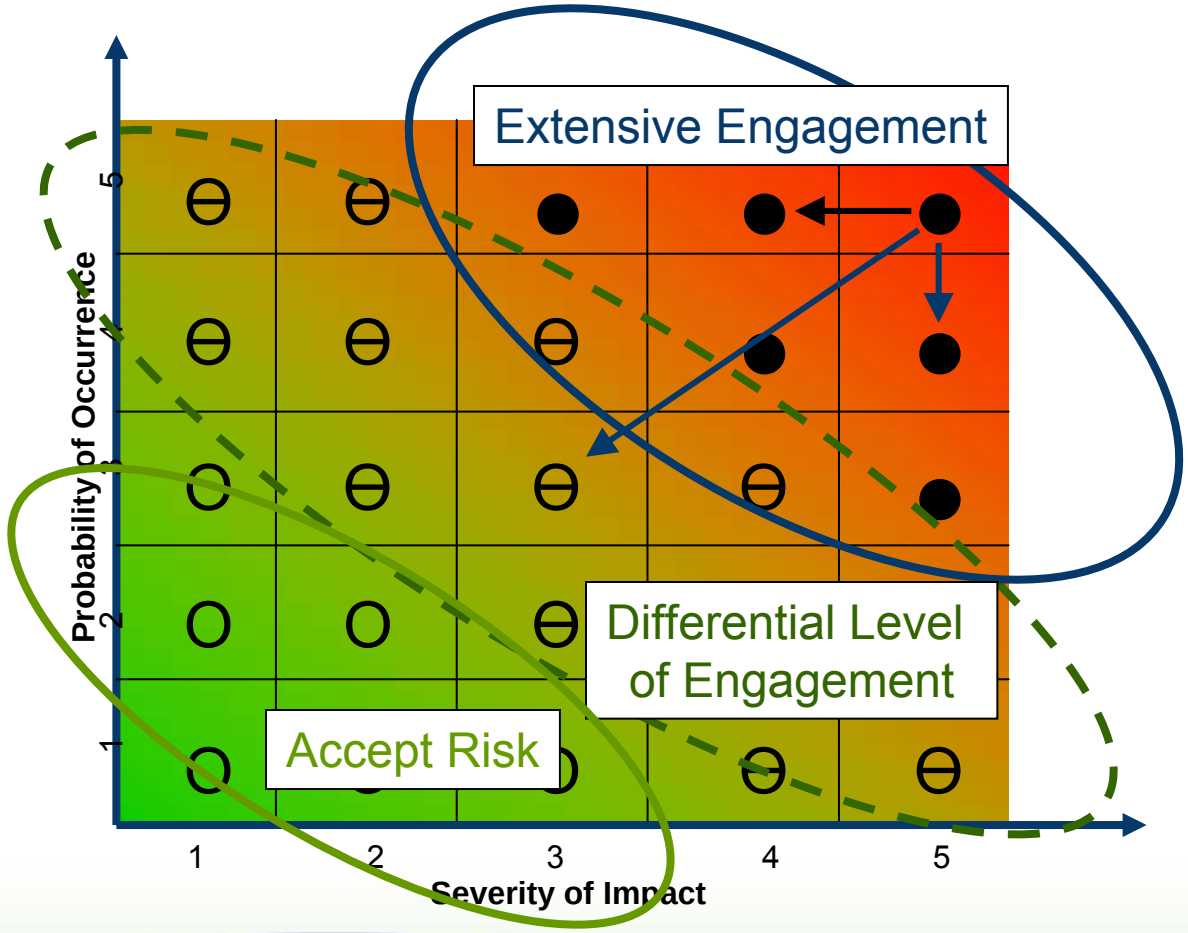
Detailed impact analysis; launch risk management actions, including pollution prevention

Phase I EC Impact Assessment

Probability of Regulation/Re-regulation				
Impact on DoD Functional Categories				
Environment Safety & Health	**Readiness & Training**	**Acquisition**	**O&M of DoD Assets**	**Cleanup**
H	H	H	H	H
M	M	M	M	M
L	L	L	L	L

Material and process decisions span functional areas 3 and 4

Integrated Risk Management Actions



- Risk Assessment
  - Fill science gaps
  - Exposure assessment
  - Benchmark with Industry
- Risk Management
  - Material substitution
  - Process changes
  - RDT&E
  - Acquisition changes
  - Benchmark with industry
  - Stockpile material
  - Increase compliance monitoring
  - Additional training
- Risk communication

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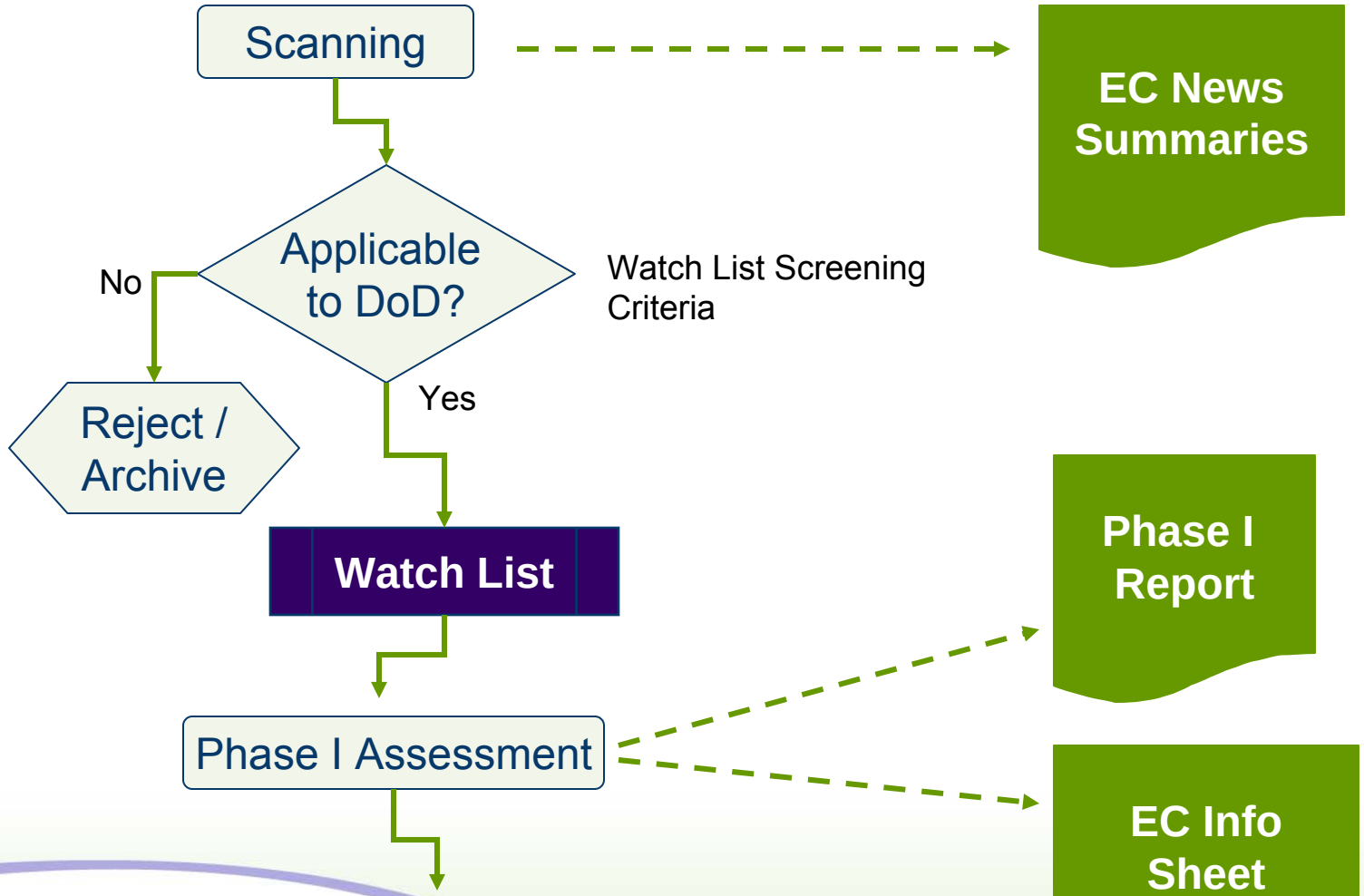
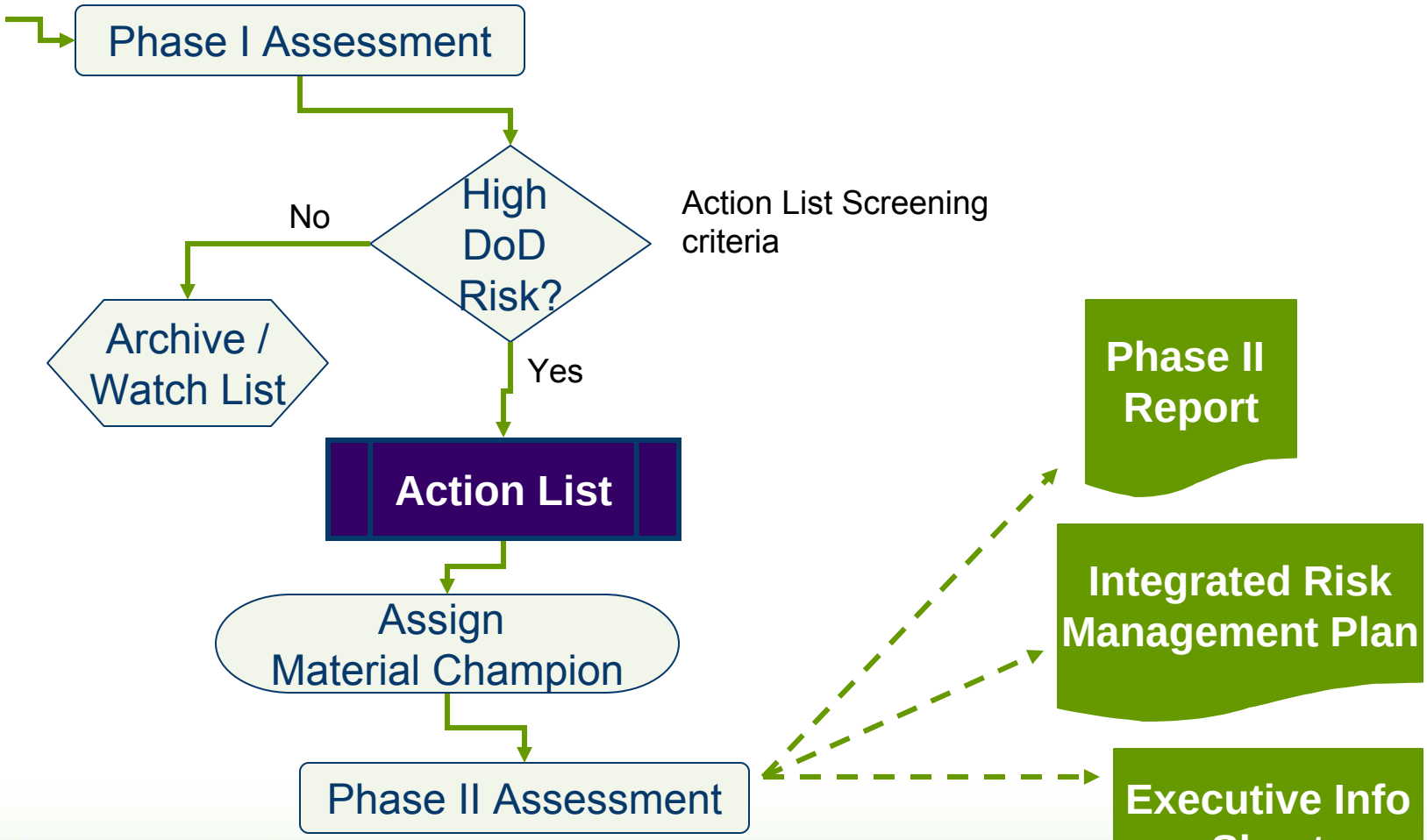
EC Assessment Process - Part 1



What is a Phase I Assessment?

- **An initial assessment of the likelihood that new regulations will be enacted, and the impacts those new regulations will have on DoD.**
- **What's required to conduct a Phase I Assessment**
  - An understanding of the reasons for regulatory change and their probability.
  - An understanding of where, why, how and how much of the materials subject to regulatory change; and the impacts the proposed regulations will have on our operations.
- **Working with the regulatory community to understand the reasons and risk of regulation is often easier than understanding the impacts proposed regulations will have on DOD.**
- **To make sound investment decisions, this situation must change.**
- **We need your help.**

Assessment Process - Part 2



What is a Phase II Assessment?

- **The same as a Phase I assessment, but much more detailed.**
- **Monetary estimates and operational assessments sufficiently detailed to support multi-million to billion+ dollar investment decisions in mitigation efforts.**
- **Mitigation efforts can include RDT&E, material substitution, process changes, protective equipment, new handling procedures, etc**
- **We need your help.**

Current Processes Inadequate

- **Data on material purchase and use scattered across DoD and its suppliers**
- **Databases do not communicate with each other**
  - Formats differ
  - Information collected is not consistent
  - Single point access not possible
- **Manual data calls notoriously inaccurate and incomplete**

Making it Better: EC Industrial Base Working Group

- **Potential Membership**
  - DoD industrial policy
  - Service acquisition commands
    - Systems Engineering
    - ESOH specialists
  - DoD industrial facilities
  - Defense Logistics Agency
  - Other DoD material database resources
  - Cognizant military authorities
  - OEMs
  - Providers of material management services
- **Task**
  - Collect and synthesize comprehensive information about material uses and alternatives to support informed decision making

Differences - Watch & Action List

Watch List

- May impact DoD
- Limited analysis of impact – more qualitative
- Monitor external actions
- Updated regularly
- Short info sheets developed
- Minimal resources expended

Action List

- Likely to impact DoD
- Detailed analysis of impact – more quantitative
- Take RM actions
- Executive info sheets developed
- Significant resources may be expended
- “Material champion” assigned

Integrated Risk Management Plan

- **Engaging with regulators**
  - Agreement on uncertainty factors, toxicity and levels
  - Understanding on efforts needed to achieve mitigation
- **Mitigation Options**
  - Identifying measures available to comply
  - Identifying research needed to develop new materials, processes or handling procedures
  - Estimating time and resources needed to comply
- **Communications**
  - Clear consistent message from DoD
  - May be the same as other users, may differ
- **Decision – best path forward**
  - Invest in science to reduce uncertainty?
  - Invest in mitigation?
  - Combination of the two?

EC Watch List

- Tungsten & alloys
- Tetrachloroethylene
- Dioxin
- N-nitrosodimethylamine (NDMA)
- 1,4-dioxane
- 1,2,3-trichloropropane (TCP)
- Nanomaterials
- Dichlorobenzenes
- Beryllium
- Polybrominated biphenyl ethers (PBDEs) and polybrominated biphenyls (PBBs)
- Di-nitrotoluenes (DNT)
- PFOS/PFOAs
- Lead

EC Action List

- **Perchlorate**
- **Royal Demolition eXplosive (RDX)**
  - Cyclotrimethylenetrinitramine
- **Trichloroethylene (TCE)**
- **Chromium VI**
- **Naphthalene**

Imagine: Hexavalent Chromium

- **OSHA PEL reduced by factor of 10 -- At Navy facilities alone, affects 3200 workers**
  - Medical surveillance, Hazard communication, Recordkeeping
  - Protective work clothing and equipment. Respiratory protection
  - Separate hygiene areas and practices
- **If EC Directorate had been in place five years ago:**
  - Earlier engagement with regulators to reconcile dispute over proposed exposure limits
  - Earlier and more accurate assessment of impacts of proposed rule
  - Earlier and better funded R&D projects to improve knowledge of health risks to workers
  - Earlier and better funded R&D on alternative materials and processes

Imagine: Nickel-Cadmium

- **Used by military to plate jet engine compressor propeller blades**
  - Cd leached into wash water during standard maintenance
  - Wash water allowed to flow onto tarmac
  - Once environmental impact realized, wash water captured
  - Long-term solution: replace all coated blades with Al blades over 10 years

- **If EC Directorate had been in place when engine was first designed:**
  - Earlier understanding of Ni-Cd coating issues
  - Earlier and better funded R&D on alternatives to Ni-Cd
  - Environmental implications and costly retrofits could have been avoided

Imagine a future where…

- **Information is shared**
- **Perspectives exchanged**
- **Common definitions and processes exist**
- **Science priorities agreed upon and coordinated research conducted**
- **Environmental and public health liabilities are avoided**

Summary

- **EC management requires new thinking**
  - Proactive vice reactive
  - Investments before regulatory action

- **Potential large payback**
  - Protects people, mission and assets
  - Sustainable

DoD Emerging Contaminant Website!

www.DODMeritinfo.net

www.DENIX.osd.mil

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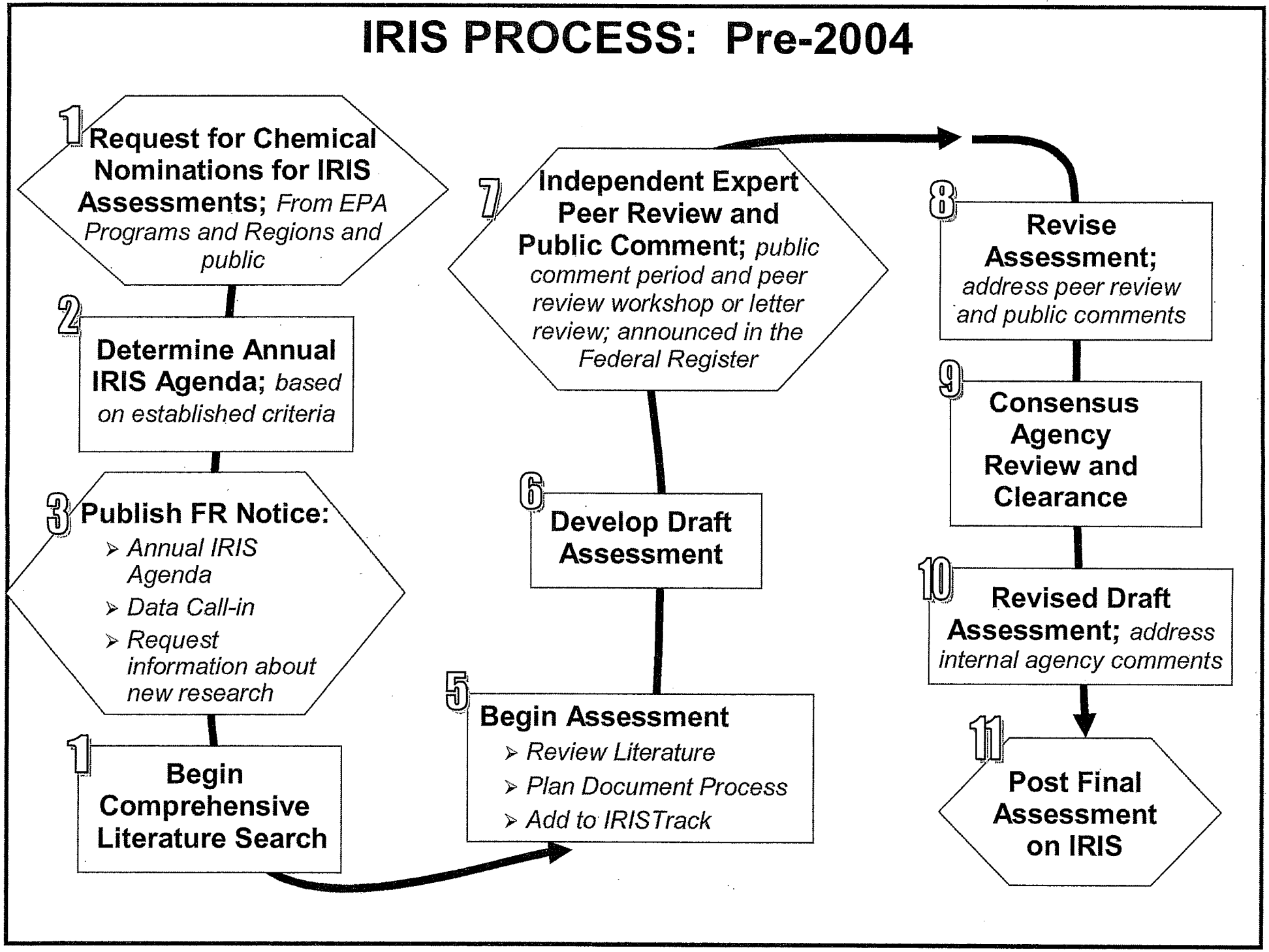
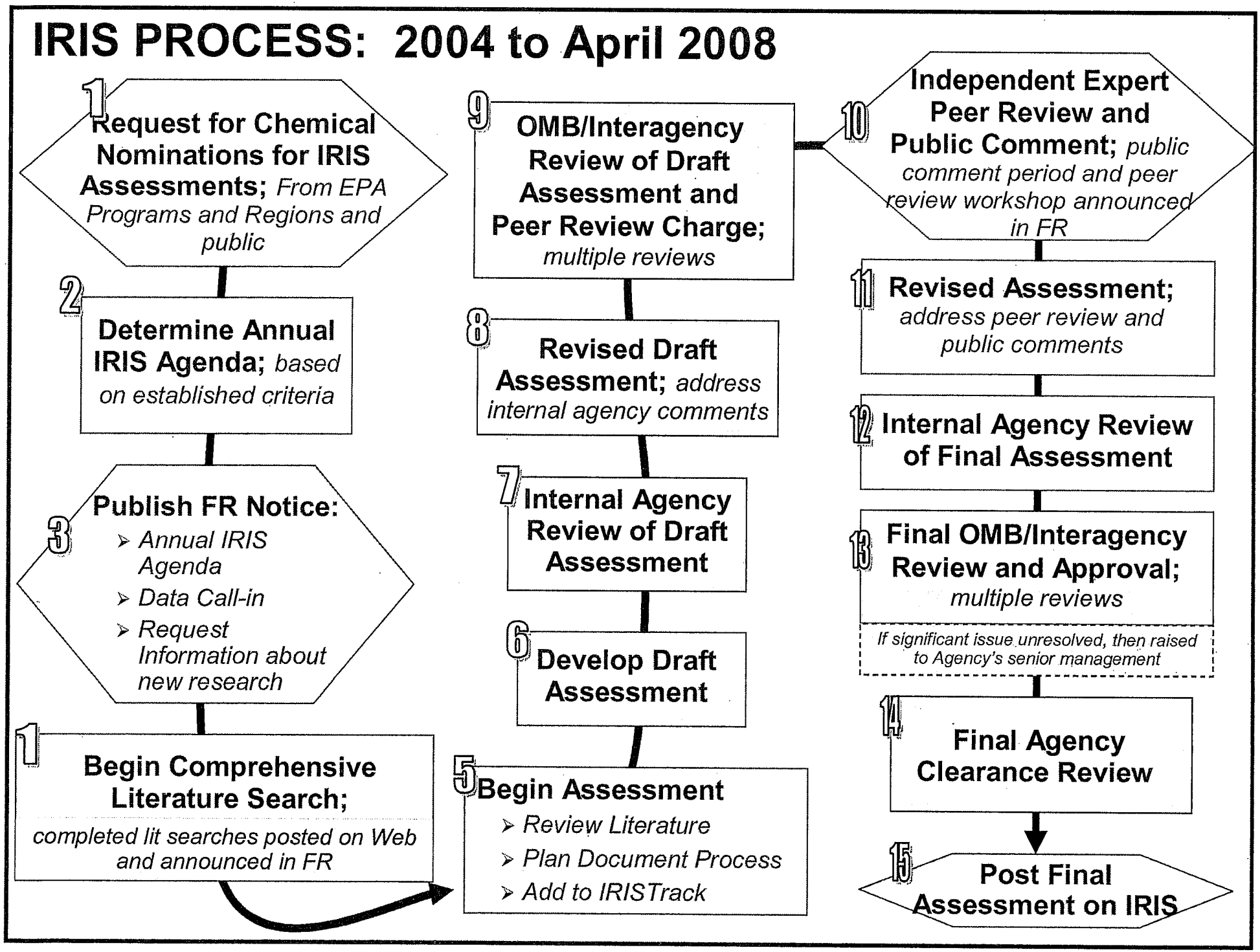
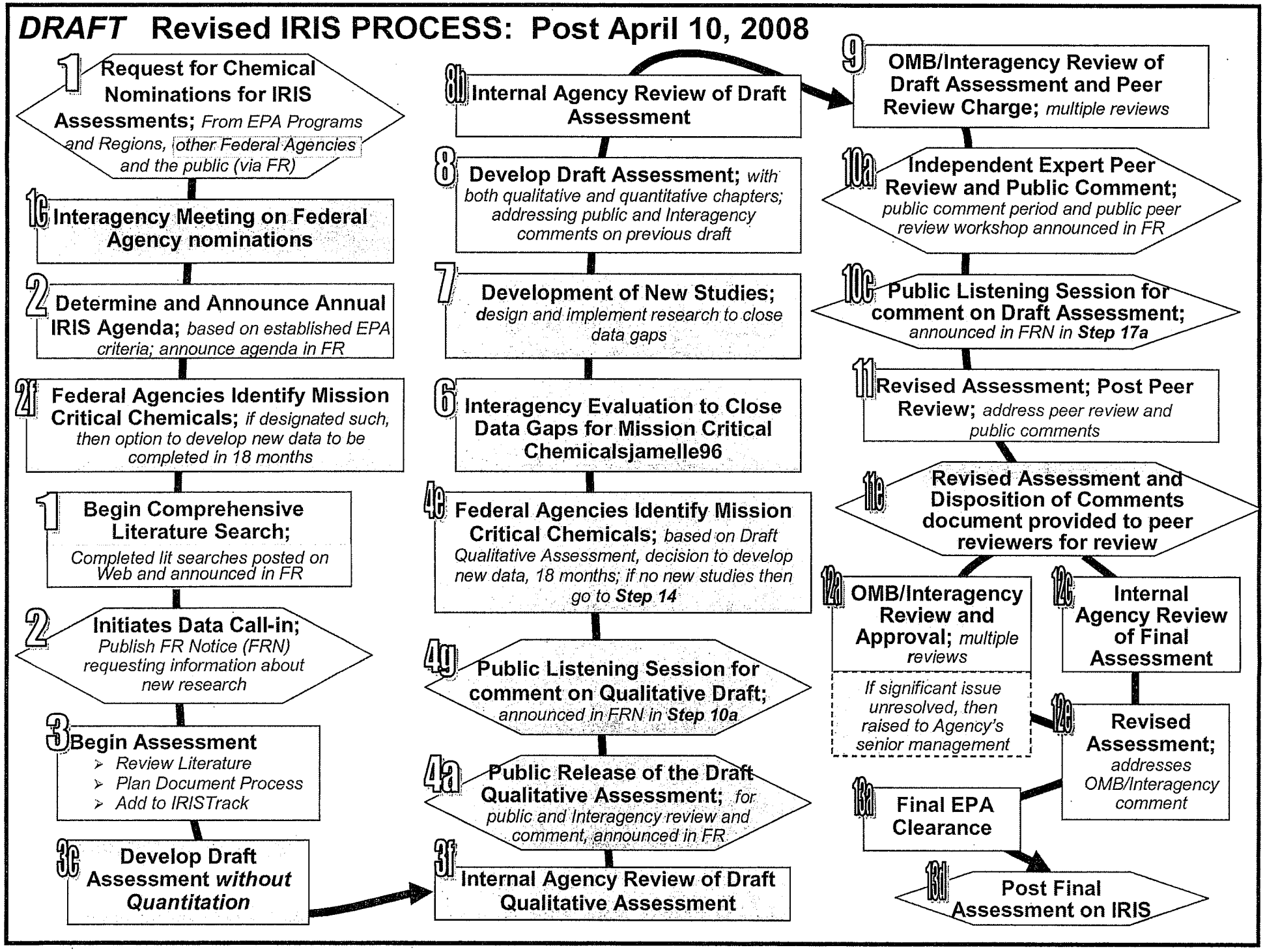
IRIS PROCESS: Pre-2004



IRIS PROCESS: 2004 to April 2008



DRAFT Revised IRIS PROCESS: Post April 10, 2008



AA ORD's Revised Comments to GAO subsequent to our OMB exit mtg 1-25-08

Overall Comments to the Statement of Facts On GAO's Review of EPA's IRIS Program

Thank you for allowing us to review the Statement of Facts. The Agency's general comments are written below. The handwritten "mark-up" of the Statement of Facts and the draft of these comments that we sent earlier were provided as a follow-up to the exit interview but had not yet been reviewed by the Agency's senior management.

We appreciate the effort that GAO has made to understand the IRIS Program, including its shortcomings and accomplishments. We share with GAO the goal of continually improving the IRIS database to be credible, scientifically excellent, timely and up-to-date.

1. In general, there should be more emphasis on the positive changes that have occurred in the past four years and less emphasis on older history. Many of the recent changes are characterized negatively rather than described in the context of the positive activities that are occurring.
    a. Major and minor issues are commingled, so that the important issues are not emphasized. For example, changing the peer reviews from letter reviews to face-to-face reviews delays the IRIS process slightly, but has enormous 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.
    b. Many "sins of the past" were due to an IRIS Program that relied 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 similar situations from occurring in the future.
2. More attention should be given to the increased complexity of assessments, which requires more staff effort and a greater level of peer review. This is the largest source of time delays. | new
3. One recent development that should be highlighted is the importance and impact of revising the process for collecting and responding to external feedback on the IRIS assessments. The addition of an interagency review process (which includes OMB) has added additional time to the release of assessments. The role of other Federal Agencies in the IRIS process is promoting communication, sharing information, and teaming with EPA at key points throughout the nomination and assessment activities. The enhanced transparency brought about by teaming Agencies with EPA will help identify scientific issues early and unify scientific thought, which will ultimately help streamline the IRIS process. EPA is working diligently with OMB on the content of the new process, and expects that it will speed the release of future assessments. It would be helpful for GAO to assess the | Totally Revised

benefits and impacts of these changes on the process, including potential impacts on both the timeliness and quality of the final assessments.

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 including additional graphs in the statement of facts to reflect these recent accomplishments and indicate the level of productivity and accomplishment planned for the next few years until the program arrives at "steady state".
5. The "IRIS process document" that is cited in the report is actually incomplete and a work in progress document. This fact should be acknowledged by the report.
6. Interagency deliberations always are considered "deliberative" to allow for free and frank discussions among Federal Agencies. The GAO report should better characterize and describe this practice.

FROM IRIS PROGRAM MGT 12/19/07 (Director, NCEA; Deputy Dir, NCEA; and IRIS Program manager

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".

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

APR 10

DEPUTY ADMINISTRATOR

MEMORANDUM

FROM: Marcus Peacock

TO: George Gray
Assistant Administrator, ORD

SUBJECT: Implementation of Revised IRIS Process

I understand that the Agency has completed its review of the IRIS process. The revised process is described in the document entitled "*EPA's Integrated Risk Information System: Assessment Development Procedures*" (attached). As you are aware, reforming the IRIS process has been an important goal of the Administrator, as reflected in his Action Plan.

I believe that the revised IRIS process will provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. For example, the revised process creates a new step that allows the public to bring forth additional scientific information and to comment on the scope of an assessment early in the IRIS process. New opportunities are also provided for EPA to host a "listening session" during public review and comment periods to allow for broader participation and engagement of interested parties. Additionally, the revised process creates a limited opportunity for other agencies to collect data to fill significant data gaps for "mission critical" chemicals. Although interagency comments on IRIS assessments are considered deliberative in nature (as is the case for all EPA assessments), all conclusions reached by the Agency, including justifications for making science or science policy decisions, are made available to interested parties and the public in the assessment and all IRIS assessments undergo a thorough peer review. Final decisions on the content of IRIS assessments clearly remain with EPA.

These and other improvements to the IRIS process help to define critical and appropriate roles for public and interagency comments and interactions, and promote and foster greater communication and sharing of information between interested parties and EPA. I believe that the outcome of these improvements will be a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor. The revised process is also expected to result in a much more timely completion of IRIS assessments than has occurred in the past.

The Administrator gave us this task three years ago. Given this and the many advantages the revised process holds relative to past or current practices, the Agency should begin following the steps outlined here as soon as possible. Consequently, I request that you implement the new

EPA's Integrated Risk Information System

Assessment Development Procedures

Introduction: The Integrated Risk Information System (IRIS) is a U. S. Environmental Protection Agency (EPA) database that contains the Agency's science and science policy positions on chronic human health effects that may result from exposure to environment contaminants. Through IRIS, EPA provides the highest quality science-based human health assessments to support Agency policymaking activities.

Since the 1980s when IRIS began, EPA has taken many steps to improve the IRIS process that make it more accessible and transparent. In addition, the Agency has worked to enhance the independent expert peer review process to assure high quality human health assessments. In its continuing efforts to improve risk assessment practices, EPA has reviewed its development processes for human health assessments that, once completed, are included on IRIS.

The role of other Federal agencies and the public in the IRIS process is to promote communication, sharing of information, and teaming with EPA at key points throughout the nomination and assessment activities. Agencies may identify chemical substances that are critical to their mission and operation, therefore initiating targeted discussions with EPA in the development of risk assessments for these mission critical chemicals. The public is also offered opportunities to bring forth data and expertise to inform the IRIS process. The enhanced transparency brought about by teaming of other Federal agencies and the public with EPA will help identify scientific issues early, which will ultimately help streamline the IRIS process.

I. Annual Chemical Nomination Process

1. EPA Initiates Annual Nomination Process for IRIS Assessments (75 days)

A. EPA's Office of Research and Development (ORD) issues a *Federal Register* (FR) notice inviting public nominations of chemical substances for ORD to consider for inclusion on the IRIS Program annual agenda (Agenda). Nominations could include chemical substances to consider for the development of new assessments as well as the revision of assessments already on IRIS for which critical new information is available. Nominations must be submitted within 60 days of the solicitation.

B. Simultaneously, ORD asks the EPA Program and Regional Offices and other agencies to nominate chemical substance(s) for inclusion on the Agenda.

   a. Agencies include, but are not limited to, HHS, NASA, DOA, DOE, DOT, DOD, OMB, CEQ, and OSTP.

   b. Each interested agency appoints one point of contact (POC) at the organizational level it deems appropriate. Each agency POC is responsible for keeping their management appropriately informed and for coordinating reviews of draft IRIS documents by that agency.

   c. ORD appoints the POC in the IRIS program.

   d. ORD notifies EPA Program and Regional Offices via memorandum to the EPA Deputy Assistant Administrators and Deputy Regional Administrators, with a copy to the intra-Agency IRIS Review Committee (via email); about the request for assessment nominations.

F. The other agencies identify to ORD an initial list of the chemical(s) on the IRIS Program Annual Agenda that they have determined meet the definition of mission critical [1].

II. The Assessment Process

1. EPA Conducts Scientific Literature Search (60 – 90 days)

A. ORD appoints a chemical manager(s) for each chemical on the IRIS Program Annual Agenda.

B. The chemical manager(s) direct an EPA contractor to conduct and complete a comprehensive search of the scientific literature for the chemical.

2. EPA Initiates Data Call-In (45 – 60 days)

A. After the literature search has been completed for each chemical, ORD publishes an FR notice that notifies the public that completed literature searches for a set of chemicals are available on the IRIS Internet site, and invites the public and other agencies to submit additional scientific information (studies, reports, other assessments, etc.) on the chemical.

   a. FR notice requests information on new research that may be planned, underway, or in press.

   b. FR notice includes notification that the initial literature review results for each chemical are available on the Internet for review (eliminates submission of information about which EPA is already aware).

   c. FR notice includes information on how and where to submit scientific information.

   d. A minimum of 45 days is provided for submission of information.

B. ORD ensures that EPA Program and Regional Offices and other agencies are aware of the FR notice:

   a. EPA Program and Regional Offices: via email

   b. Other agencies: via email to agency POCs. Each agency POC is responsible for keeping his/her management appropriately informed.

C. Other agencies confirm to ORD whether the chemical is mission critical. It is expected that only a few chemicals will receive this designation.

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[1] A mission critical chemical is one that is an integral component to the successful and safe conduct of an Agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints.

5. EPA Initiates Review of Public and Agency Comments (30 days)

A. ORD compiles and reviews all public and other agency comments received on the draft Qualitative Assessment, and shares the comments with EPA Program and Regional Offices and other agencies.

B. ORD provides other agencies and EPA Program and Regional Offices with information about any significant changes that might occur in the IRIS assessment as a result of the public or other agency comments and listening session.

C. If another agency or the public wants to discuss with ORD a particular comment or set of comments, they should contact the IRIS POC to arrange a meeting with ORD.

D. If significant alternative science or science policy judgments are raised by the public, EPA Program or Regional Offices, or other agencies, these will be added to the document and brought forward in the charge to the independent external peer review panel.

6. Evaluation of Agency Interest in Closing Data Gaps for Mission Critical Chemicals (90 days)

A. If another agency is interested in filling a significant data gap, it must first document that the chemical is mission critical (see Annual Chemical Nomination Process - **Step 2.F** and The Assessment Process - **Step 4.E**).

B. For mission critical chemicals, the agency interested in addressing data gaps will consider the comments provided in **Steps 4 and 5**, and submit to ORD a research plan that documents how the conduct of new research has the potential to reduce uncertainties, clarify the mode-of-action, or inform the estimation of dose-response. The other agency must also show that the proposed research and peer review can be completed in less than 18 months. If desired, a letter of agreement between ORD and the other agency sponsoring the research can be created articulating the relevance of the proposed research to the risk assessment and how the proposed research may inform the risk assessment. Such a letter would indicate the timeframe for expected research to be completed.

C. The sponsoring agency may decide that an independent 3rd party consultation should be done to evaluate the estimated costs of the proposed research, and the expected benefits of additional research for the assessment. This 3rd party consultation must be completed during this 90 day period.

D. If a sponsoring agency wants to partner with an external party or any other agency to conduct a study, that decision is theirs to make, but ORD and other interested agencies should be informed.

E. If no request for developing new short-term research is received, or if no interest in conducting such research is expressed for mission critical chemicals, proceed to **Step 8.**

7. Design and Implementation of New Studies for Mission Critical Chemicals (365 – 540 Days)

A. If in **Step 6** the consequences and interest in closing data gaps are determined to be critical by ORD, in consultation with the intra-Agency IRIS Review Committee and other interested agencies, the agency can sponsor the new research.

a. The draft IRIS Toxicological Review draws upon the previous draft Qualitative Assessment and the comments received in **Steps 4 and 5.**

b. ORD reviews and analyzes any new short-term research completed under **Steps 6 and 7.**

c. The draft IRIS Toxicological Review includes a quantitative assessment, including application of uncertainty factors, mode-of-action information, and dose-response modeling.

B. The draft IRIS Toxicological Review undergoes internal ORD review (30 – 45 days).

C. ORD submits the draft IRIS Toxicological Review for internal review via the intra-Agency IRIS Review Committee and addresses intra-Agency comments (30 – 60 days).

D. Determination of peer review characteristics:

a. For mission critical chemicals, ORD will cooperate with other interested agencies to determine the level of peer review (e.g., National Academy of Science (NAS) review, EPA Science Advisory Board (SAB) review, or contractor-led panel peer review), panel disciplines, and the scope of the review.

b. For other chemicals, ORD determines the level of peer review, panel disciplines, and the scope of the review.

c. ORD develops any contract documentation.

9. EPA Initiates Interagency Review of Draft IRIS Toxicological Review (45 – 105 days)

A. ORD sends the draft IRIS Toxicological Review and draft external peer review charge questions to OMB to initiate interagency review.

B. ORD develops a charge for interagency reviewers. It is anticipated that the interagency review charge will remain similar for each draft IRIS Toxicological Review, with chemical specific text added as appropriate.

C. OMB distributes the draft IRIS Toxicological Review, draft external peer review charge questions, and the interagency review charge to interagency reviewers.

a. Length of review period is 30 – 60 days and depends on complexity of draft assessment documents.

b. OMB facilitates interagency review to help assure timely response within designated review period.

D. OMB compiles and provides all interagency comments to ORD; other agency comments are deliberative.

a. ORD assumes "no comment" from other agencies that do not respond within the designated review period.

b. If another agency requests an extension of the review period, both the IRIS POC and OMB POC should be contacted regarding the request and the justification.

E. ORD addresses the interagency comments and develops a "disposition of comments" document and revises the draft assessment documents, as appropriate, within 15 – 30 days.

D. Within 90 – 120 days, ORD develops a disposition of peer reviewer and public comments and provides the disposition of comments document and the revised IRIS Toxicological Review and IRIS Summary to the external peer review panel members for their comment within 30 days.

E. ORD provides the disposition of peer reviewer and public comments document and any additional peer review panel comments from **Step 11.D** as an appendix to the IRIS Toxicological Review.

12. EPA Initiates Final Agency and Interagency Review of the IRIS Toxicological Review and IRIS Summary (30 – 45 days)

A. ORD sends the final IRIS Toxicological Review and IRIS Summary to OMB for distribution to the other agencies.

B. In general, this distribution is intended as a final check-in to address any remaining issues and ensure that public and peer reviewer comments were adequately considered or addressed by ORD.

C. Concurrently, ORD sends the IRIS Toxicological Review and IRIS Summary to the intra-Agency IRIS Review Committee for comment (30 days).

D. OMB compiles and provides all interagency comments to ORD within 30 days.

   a. ORD assumes "no comment" if the other agencies or EPA Program or Regional Offices do not respond within the designated review period.

   b. If another agency or EPA Program or Regional Office requests an extension of the review period, both the IRIS POC and OMB POC should be contacted regarding the request and the justification.

E. ORD addresses and resolves any remaining issues in consultation with OMB and other agency or EPA Program or Regional Office POCs within 15 days. Should resolution of any issue not be achieved in discussions with the POC, the other agency or EPA Program or Regional Office that raised the issue may decide to elevate the discussion to their senior management level to achieve resolution. The final decision on IRIS content remains with EPA.

13. EPA Completion of IRIS Toxicological Review and IRIS Summary (60 days)

A. ORD completes the IRIS Toxicological Review and IRIS Summary.

B. ORD prepares the final assessment to post on the IRIS Internet site.

C. ORD insures 508 Compliance and EPA web site compliance.

D. ORD posts the assessment to the IRIS Internet site. ORD completes and maintains the public record.