



TERA

**Toxicology Excellence
for Risk Assessment**

*a nonprofit corporation
dedicated to the best use
of toxicity data for risk values*

Toxicology Excellence for Risk Assessment

- Non-profit, 501(c)(3) corporation; mission to protect public health
- Founded in 1995; current technical staff of 16 plus several visiting scientists.
- Completes roughly 50 technical projects per year for government and industry
- Focus on – solving risk issues by
 - technology leadership,
 - building bridges and using collaborative processes

<http://www.tera.org>



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TERA Program Areas

- Risk Assessment Research, Development and Training
- Peer Review and Peer Consultation
- International Toxicity Estimates for Risk (*ITER*)
– comparative database of risk information
- StateHELP – pro bono risk support for State and local risk assessors.

Genesis of the Alliance of Risk Assessment Concept

- Concept was born out of recognition that we as a risk science community need to enhance timeliness of guidance to risk managers.
- *TERA's* pro bono StateHELP program is well received and used, but with only 10 free hours per year per state the program is too small for a major impact.
- We built an approach building from concepts learned in our interactions in collaboration building with states and industry stakeholders.

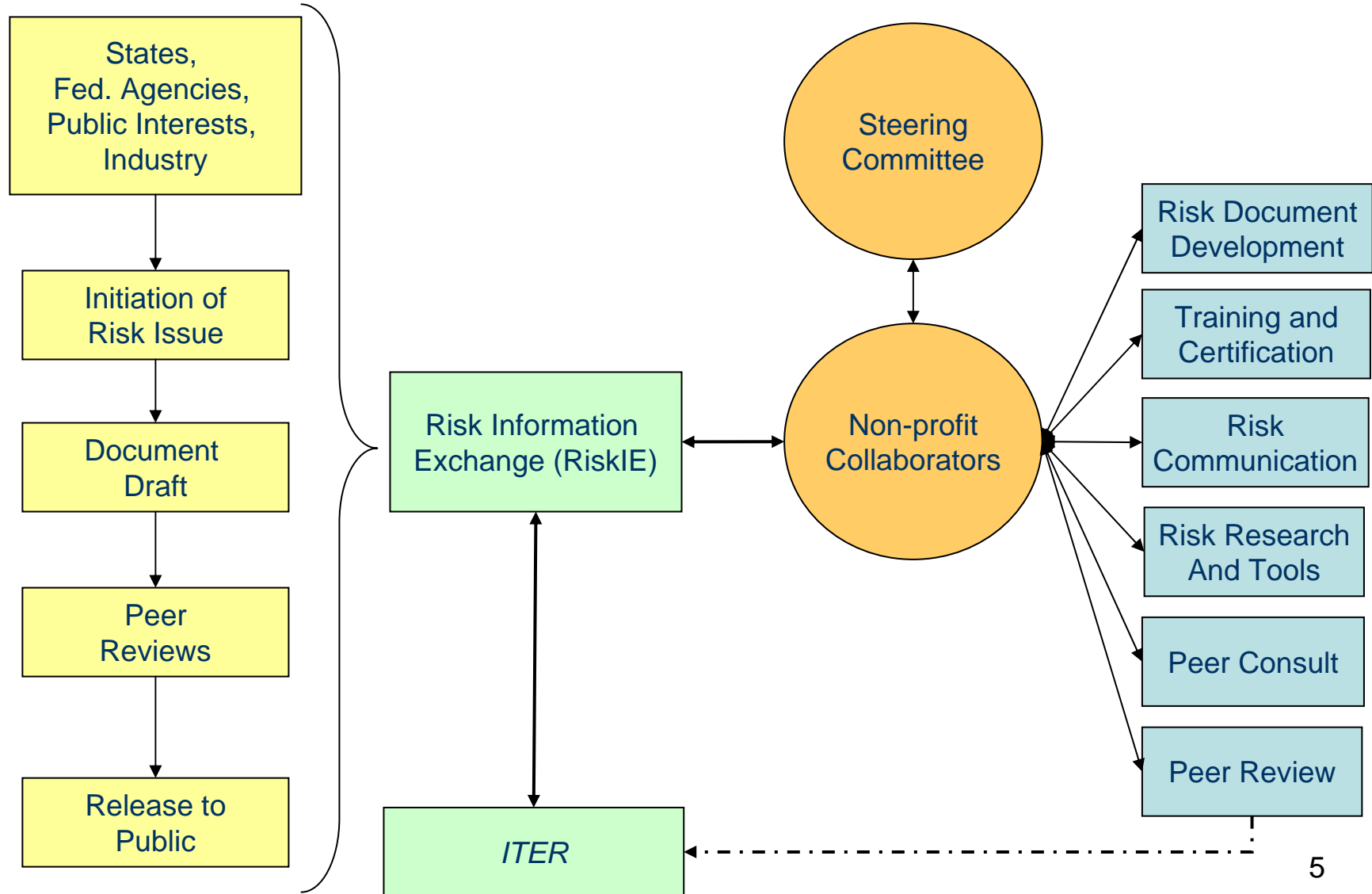


A process to facilitate communication and collaboration toward development of useful and timely risk science products.

Alliance for Risk Assessment (ARA)

Stakeholder Process

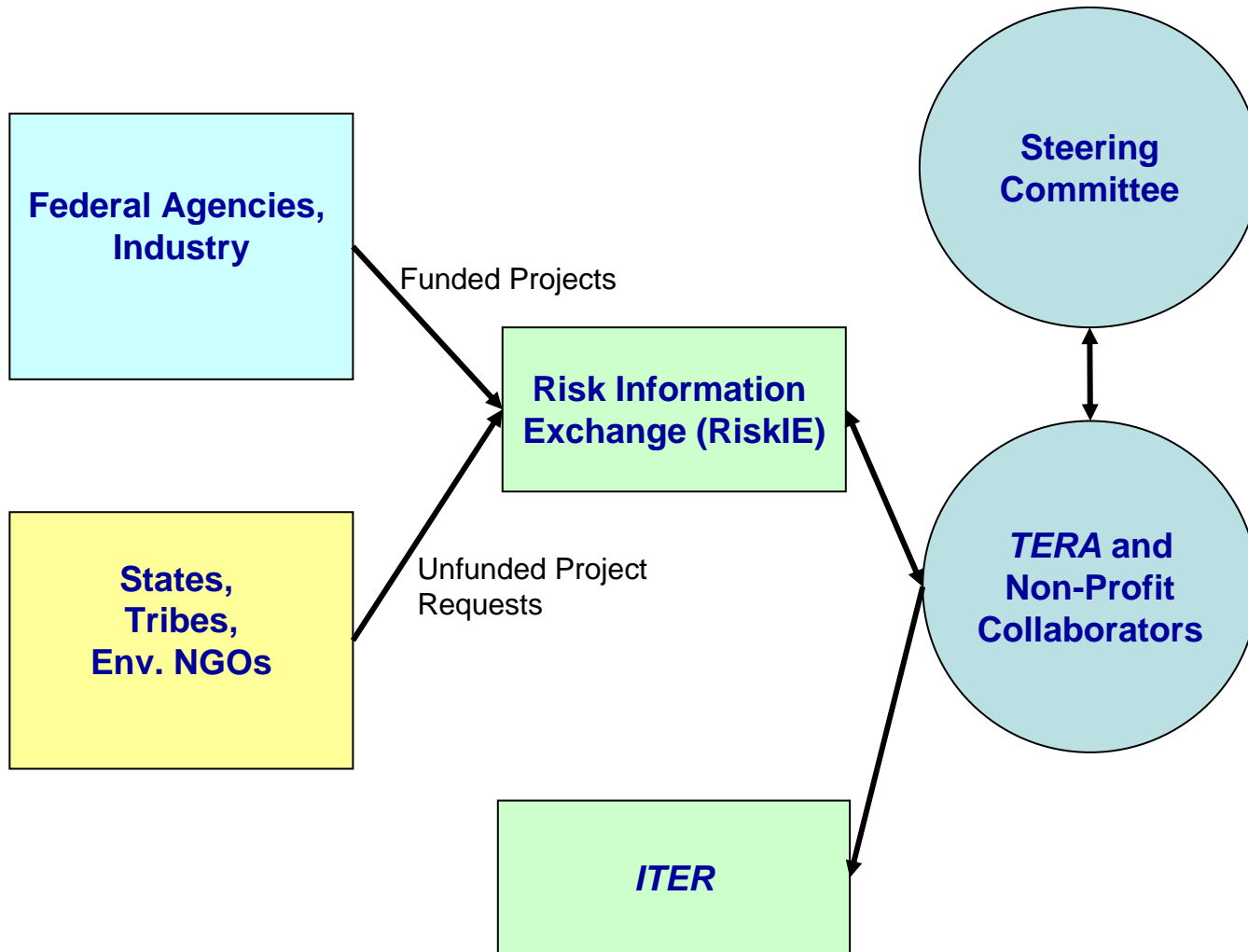
Alliance "Menu" Options



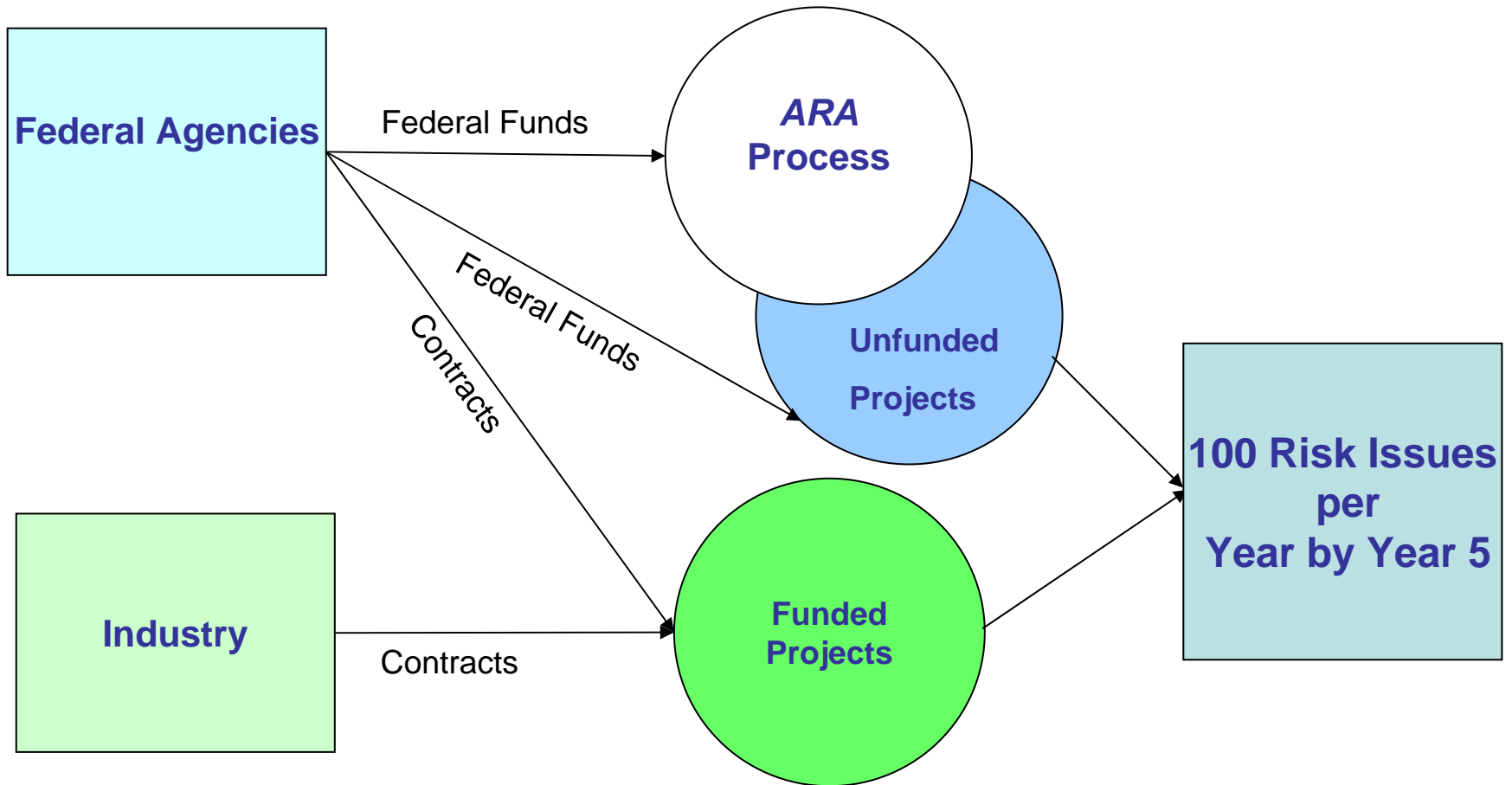
Key Benefits of the Alliance

- Promotes science-based decision making to protect human health
- Enhances harmonization and consistency in risk assessments thru an open, transparent, multi-stakeholder approach
- Provides user control of own process, while providing parallel process for shared help.
- Maintains essential core group of experts that are normally not available within a single agency or state
- Shares costs and human resources among multiple stakeholders to increase output

ARA Work Flow



ARA Funds Flow



ARA Steering Committee

- Provides advice to ARA Partners on mission- relatedness, project prioritization, Conflict of Interest,
- Scientists:
 - 2 States
 - 1 Tribe
 - 1 Env. Group
 - 2 Federal
 - 1 Industry
 - 1 Academic
 - 2 ARA Partners

Why Would Diverse Groups Provide Funding?

- The Alliance for Risk Assessment (*ARA*) mission...
 - Aligns with many public health goals.
 - Provides value; timely; enhanced credibility.
 - Allows Stakeholder input – e.g., via Steering Committee; technical panels.
 - Gives an opportunity for harmonizing risk values.
- Over the years nonprofit corporations have demonstrated the concept can work.
- NLM & *TERA* have success in building *ITER*; ~200,000 hits per month demonstrates likely value of *ARA*

Success Stories

In Collaboration Building

- Peer Reviews of ESLs developed by State of Texas use the *ARA* approach.
- Implementing a Peer Consultation approach with State of Michigan for and DOW related to dioxin.
- Used peer review for industry resorcinol RfD; used by State of Pennsylvania for clean-up activities.
- Worked with State of West Virginia and DuPont to develop provisional clean-up levels for air and water for PFOA, while awaiting Federal EPA response.

NLM's Toxnet

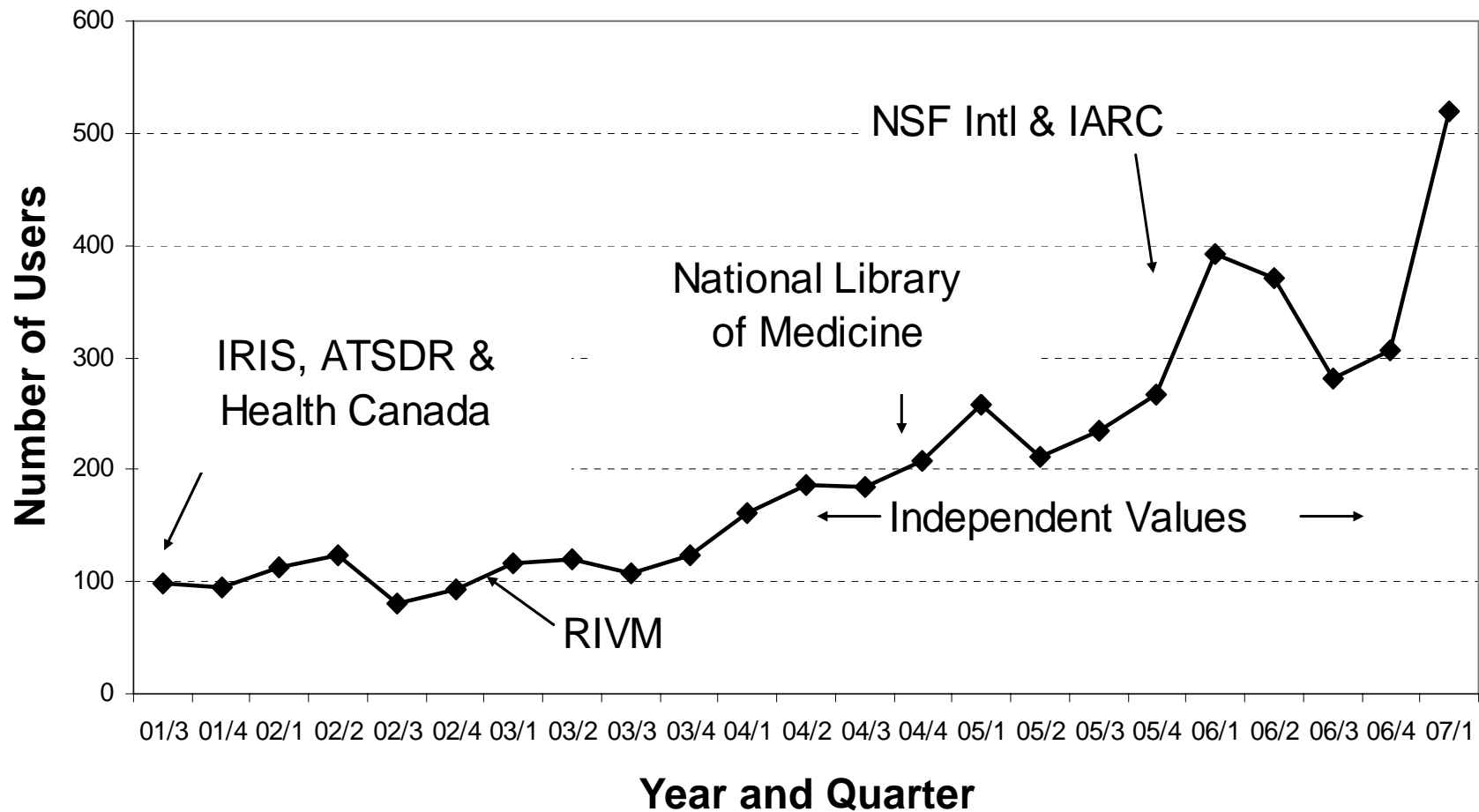
The screenshot shows the NLM's Toxnet website in a Microsoft Internet Explorer browser window. The browser's address bar displays <http://toxnet.nlm.nih.gov/>. The website header features the NLM logo and the text "United States National Library of Medicine" and "TOXNET Toxicology Data Network". Navigation links include "TOXNET PDA Access", "SIS Home", "About Us", "Site Map & Search", and "Contact Us". A secondary navigation bar includes "Env. Health & Toxicology" and "TOXNET".

The main content area is titled "TOXNET - Databases on toxicology, hazardous chemicals, environmental health, and toxic releases." and is organized into three columns:

- Select Database:** A list of databases with links to their descriptions:
 - ChemIDplus
 - HSDB
 - TOXLINE
 - CCRIS
 - DART
 - GENETOX
 - IRIS
 - ITER
 - Multi-Database
 - TRI
 - Haz-Map
 - Household Products
 - TOXMAP
- Search All Databases:** A search interface with the text "Enter term(s) to search all databases.", a search input field, and "Search", "Clear", and "Help" buttons. Below this is a "TOXNET Search Options" section with instructions:
 - Search all databases: Enter term(s) in box above
 - Search a specific database: Click database at left
 - Database description: Click on the [?]
- Env. Health & Toxicology:** A section titled "Portal to environmental health and toxicology resources." with a "VISIT SITE" button.
- Support Pages:** A list of links:
 - ▶ Help
 - ▶ TOXNET FAQ
 - ▶ TOXNET Update Status
 - ▶ Fact Sheet
 - ▶ Database Description
 - ▶ Training Manuals
 - ▶ News

At the bottom of the page, there is a footer with copyright information: "Copyright, Privacy, Accessibility U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894 National Institutes of Health, Health & Human Services". The browser's status bar at the bottom shows the address <http://www.nlm.nih.gov/> and the "Internet" icon.

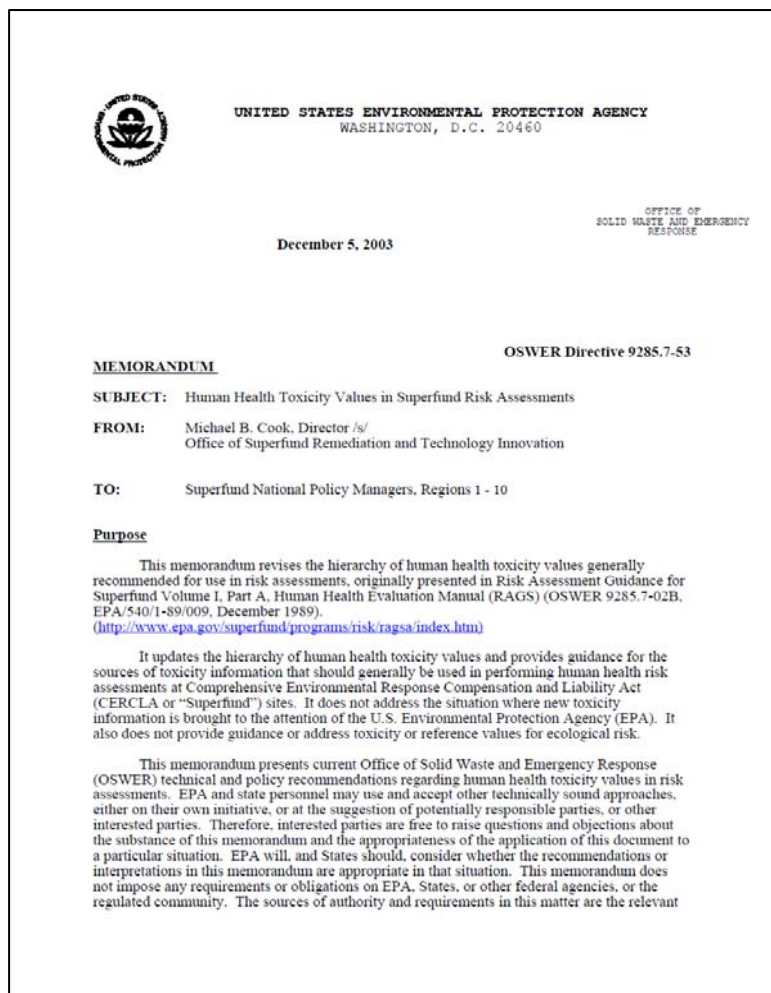
ITER Daily Users



Does This Effort Duplicate Current Federal Efforts?

- This effort does not duplicate ATSDR MRLs, EPA IRIS, FDA ADIs, Health Canada TDIs or RIVM TOCs.
- To the contrary, *ARA* shares resources to avoid duplication because:
 - It does not replace individual regulatory processes; *ARA* users tap in as appropriate.
 - Many risk values/issues will never be worked by federal groups.
 - Current federal approaches have resource limitations; thus, new chemicals addressed without duplicate effort.
 - Update of older values can benefit federal groups as one technical input to internal deliberations.
 - *ARA* goes beyond risk values/issues – it is also a shared resource for training and data communication.

ARA Supports Existing Risk Values



- Provides guidance for sources of toxicity information that may be used in performing human health risk assessments
- *ITER* can supplement existing toxicity data
- *ARA* can provide Tier III values

Why a non-profit?

From a government perspective, non-profit status has four benefits:

- **Independence / Objectivity.** We are chartered to operate and act free of commercial or political bias, so we take an objective stance.
- **Superior Value.** All monies go to supporting our mission, allowing us to devote the greatest resources to our work and delivering the highest value for the government dollar.
- **Usable Results.** We are outcome driven and results oriented; our value is measured by the utility of our work—we help sponsoring organizations make a difference.
- **Kindred Spirit.** We share the spirit of public service; we understand the inner workings and detailed tasks that are the key to achieving progress.



A Collaborative Approach for Solving Public Health Risk Assessment Issues

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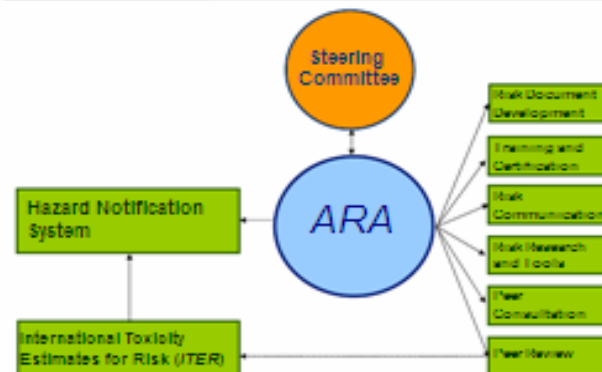
What is the ARA?

The Alliance for Risk Assessment (ARA) is a collaborative effort of organizations dedicated to supporting public health protection by improving the process and efficiency of risk assessment, and increasing the capacity for developing risk information to meet growing demand.

Our bodies interact regularly with chemicals in our food, in our environment, at our work, and in the products we use every day. The ARA provides information and resources to help understand potential human health risks from chemicals.

The ARA provides a unique venue for governmental, industrial, environmental, and non-profit organizations to collaborate to produce the high quality risk assessment science.

The ARA Process



[Click here for a larger view](#)

Guiding Principles of the Alliance for Risk Assessment

- Promote science-based decision making to protect human health
- Enhance harmonization and consistency in risk assessments through an open, transparent, multi-stakeholder approach
- Maintain access to groups of risk assessment experts that are normally not available within a single organization, agency or state
- Share costs, information, and human resources among multiple stakeholders to increase the capacity and quality of risk values

ara (a·ra) [ay-ruh, air-uh] : n. ..., protection, ... (Latin)

Contact Us



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