

## A Message from the IRIS Program January 2018

Many of you who follow the IRIS Program know that for the last several years we have continued to evolve our assessment practices to increase transparency and efficiency in the IRIS Program, its processes, and its products. Many of these practices have centered around the implementation and operationalization of systematic review methods.

As the IRIS Program continues to evolve, we understand how important it is to communicate and engage with our stakeholders and the public early in the development of an assessment, and we are committed to ensuring that the IRIS process incorporates constructive scientific discussion that facilitates assessment development. Key to fulfilling this commitment is for the IRIS Program to build flexibility and efficiency into its processes. IRIS Assessment Plans (IAPs) and Systematic Review Protocols, which explain what will be assessed, and how the assessment will be accomplished, respectively, are important components of this strategy and will provide greater transparency in the development of assessments.

Today, the IRIS Program is releasing the *IRIS Assessment Plan for Uranium* and the *Systematic Review Protocol for the IRIS Chloroform Assessment (Inhalation Reference Concentration)*. The IRIS Program is providing stakeholders and the public an opportunity to review these documents.

### **IRIS Assessment Plans and Systematic Review Protocols**

The IRIS Program continues to implement systematic review in its assessment practices, with the goal to increase transparency and efficiency in its assessment processes and products. As part of scoping and initial problem formulation activities prior to the development of a draft assessment, the IRIS Program carries out a broad, preliminary literature survey to assist in identifying the extent of the evidence and health effects that have been studied in relation to the chemical or substance of interest.

The **IRIS assessment plan** contains a summary of the IRIS Program's scoping and problem formulation conclusions including the Agency need for the assessment; the objectives and specific aims of the assessment; draft Populations, Exposures, Comparators, and Outcomes (PECO) criteria; and identification of key areas of scientific complexity. The IRIS Assessment Plan describes *what* will be assessed.

The **systematic review protocol** presents detailed methods for conducting the full systematic review and dose-response analysis, including any adjustments made to the specific aims and PECO in response to public input into the assessment plan. While the IRIS Assessment Plan describes *what* will be assessed, the chemical-specific protocols describe *how* the assessment will be conducted (see Figure 1).

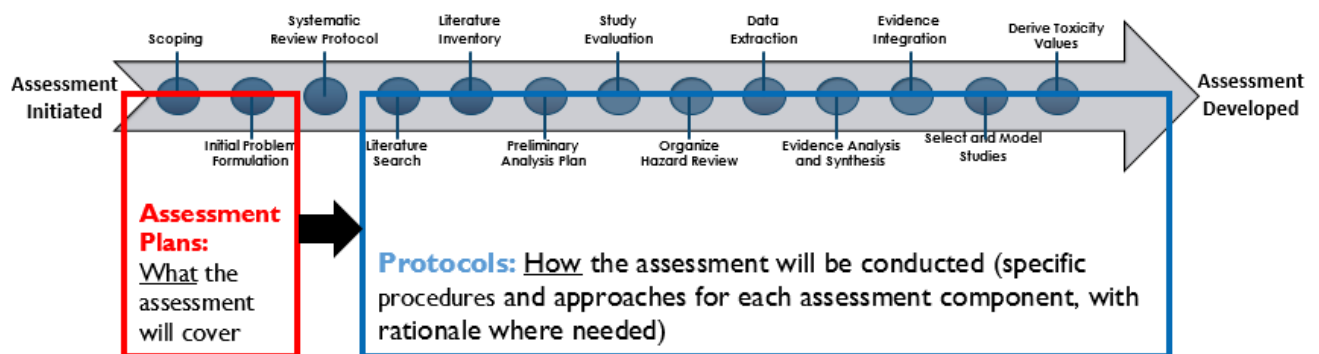


Figure 1. IRIS systematic review problem formulation and method documents.

## **A Message from the IRIS Program**

**January 2018**

### ***Portfolio Approach***

NCEA assessments support policy and regulatory decisions for EPA's programs and regions, and states, tribes, and for other Federal Agencies. To ensure this support is timely and responsive, NCEA is developing a portfolio of chemical evaluation products employing the principles and state-of-the-art practices of systematic review. The portfolio approach will increase public health protection by:

- moving away from a 'one-size-fits-all' approach to chemical risk assessment towards a spectrum of assessment products to meet specific decision contexts;
- facilitating the incorporation of new science into risk assessment and decision-making;
- tailoring assessments to meet the many needs of decision makers; and,
- increasing the number of chemicals that can be evaluated for their effects on human health by utilizing constrained resources in the most efficient manner.

### ***Operationalizing Systematic Review***

A key to the success of this portfolio approach will be operationalizing systematic review. In general, the systematic review strategy is informed by criteria that are defined in scoping and problem formulation enabling assessments to be tailored to meet the needs of decision makers. As such, systematic review in assessments promotes transparency in the choice and application of the assessment type to a particular decision context.

NCEA is collaborating with international organizations to accelerate the initial steps and reduce the burden of systematic reviews through use of automation and machine-learning tools. This will promote and facilitate incorporation of systematic review – pragmatically and effectively. As the portfolio approach unfolds, adhering to the methods and principles of systematic review allows the users and risk managers to apply the assessment products with improved understanding of the strengths and weaknesses of the underlying scientific evidence.