2.0 ICCVAM TEST METHOD NOMINATION AND SUBMISSION PROCESS

This section describes the process by which "test method nominations[6]" and "test method submissions[7]" to ICCVAM are considered and prioritized for review and evaluation (**Figure 3**). Submissions should be accompanied by all requested information. Although there is no mandatory minimum requirement for information to provide with nominations, ICCVAM consideration of the proposed test method will be expedited by providing as much information as possible. The minimum information required for submissions and recommended to accompany nominations is summarized in **Section 4**. Areas where the requested information is not available or is incomplete should be indicated, along with the scientific approach(es) planned to generate those data.

The Director of NICEATM solicits and tracks the status of proposed test method submissions and nominations, provides updates to ICCVAM, and arranges for a preliminary evaluation of submissions and nominations by NICEATM, as resources permit. Preliminary evaluations summarize the extent to which proposed test method submissions or nominations address the following ICCVAM prioritization criteria:

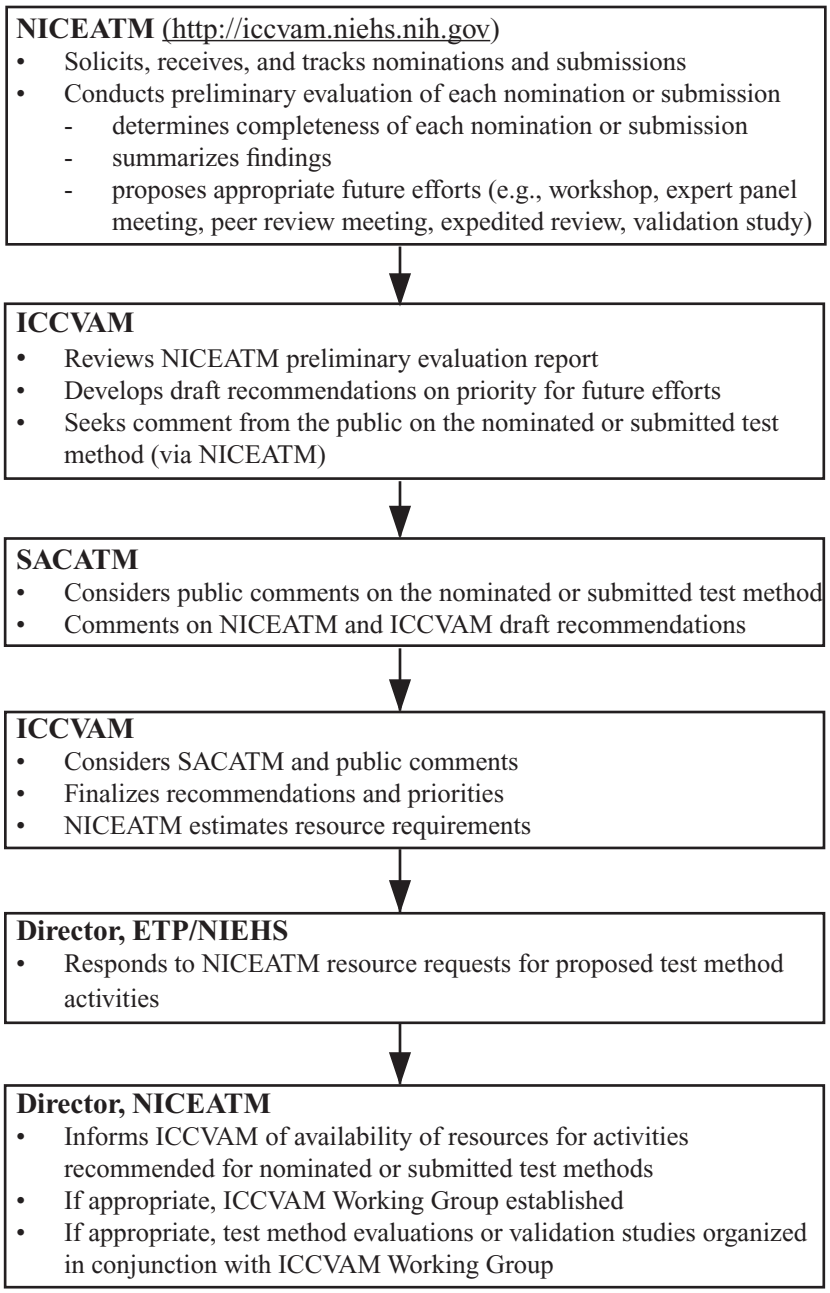
- The extent to which the proposed test method is:
  - Applicable to regulatory testing needs
  - Applicable to multiple agencies/programs
- Warranted, based on the extent of expected use or application and impact on human, animal, or ecological health
- The potential for the proposed test method, compared to current test methods accepted by regulatory agencies, to:
  - Refine animal use (decreases or eliminates pain and distress)
  - Reduce animal use
  - Replace animal use
- The potential for the proposed test method to provide improved prediction of adverse health or environmental effects, compared to current test methods accepted by regulatory agencies
- The extent to which the test method provides other advantages (e.g., reduced cost and time to perform) compared to current methods

---

[6]*Test method nomination:* A test method proposed to ICCVAM for review and evaluation for which a complete test method submission is not available. Examples include: (1) test methods for which adequate validation studies presumably have been completed but lack a complete submission package; (2) test methods that appear promising based on limited prevalidation or validation data and are proposed for additional validation studies; (3) test methods that have been developed and are proposed for prevalidation or validation studies; and (4) test methods that are recommended for a workshop or other activity.

[7]*Test method submission:* A test method proposed to ICCVAM for review and evaluation for which adequate validation studies have been completed to characterize the usefulness and limitations of the test method for a specific proposed regulatory testing requirement or application, and adequate documentation of the scientific validity has been prepared in accordance with ICCVAM test method submission guidelines.

Figure 3. ICCVAM Test Method Submission and Nomination Process



- The completeness of the nomination or submission with regard to ICCVAM test method submission guidelines

The Director of NICEATM provides the results of NICEATM preliminary evaluations to ICCVAM, including recommendations and relative priority for further evaluations (e.g., workshop, expert panel meeting, peer review meeting, expedited review process) or validation studies. ICCVAM then:

- Reviews the NICEATM preliminary evaluation report
- Determines whether the test method is of sufficient interest and applicability to one or more agencies to warrant further evaluation
- Develops draft recommendations regarding priority for evaluation, the conduct of validation studies, or other activities

The Director of NICEATM provides the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) with a status report on test method submissions and nominations, the results of NICEATM and ICCVAM preliminary evaluations, and any draft recommendations. The SACATM comments on the draft test method evaluations and recommendations in terms of future ICCVAM efforts. ICCVAM also seeks comment from the public, using electronic methods (ICCVAM listserve groups, the ICCVAM/NICEATM web site) and printed materials and publications (*Federal Register*). ICCVAM considers comments from the SACATM and the public, develops final recommendations, and prioritizes future evaluation and validation efforts.

The Director of NICEATM estimates resource requirements for proposed evaluations and/or validation studies and forwards these, along with ICCVAM, NICEATM, and SACATM recommendations, to the Director of the Environmental Toxicology Program (ETP)/NIEHS with a request for funding, when necessary. The ETP Director responds with information on the availability of the requested resources for the recommended activity.

The Director of NICEATM informs ICCVAM of the availability of funding to conduct the recommended activities. When resources are available to support a recommended activity (workshop, expert panel meeting, independent peer review, expedited review, validation study), ICCVAM establishes an interagency working group of knowledgeable scientists to work with NICEATM in organizing the appropriate evaluation or validation study. In collaboration with ICCVAM and the appropriate working group, NICEATM organizes workshops, expert panel meetings, independent peer reviews, validation studies, or expedited reviews, as appropriate, to evaluate the validation status of the proposed test method.