

ANALYTICAL METHOD TRANSFER

Proposed Agenda:

I. Overview of the Method Transfer Process

- Purpose of Analytical Method Transfer
- Strategies of Method Transfer
- Phases of Method Transfer
- Determine Gap Analysis

II. Preparation Phases of Method Transfer

- Contents of method transfer package
- Training options involving method transfer
- Determine impacts on the transfer process

III. Establishing Method Transfer protocol

- Developing Method Transfer protocol
- Determine acceptance criteria
- Evaluating and documenting transfer data

IV. Key Factors impacting Method Transfer

- Exploring key process steps that are site dependent
- Understanding method capabilities to set acceptance criteria
- Investigating method transfer failures

V. Interactive discussion and exercises will be developed based on group background.