

Quality Assurance for Alternative Assessments

From: Dale Johnson 6/12/11

Quality assurance (QA) of Alternative Assessments (AA) falls into two distinct categories:

- QA of the actual process or procedures used in the AA
- Scientific or technical QA of the outcome of the AA

In order to create a workable process with the greatest chance for success, DTSC should issue a Guidance Document to be used for AA along with recommended tools and procedures. These can be created by a third party under a RFP process. Note that a first phase was already completed and this can be used as the template to complete the Guidance Document. The completed Guidance Document should also indicate the process audit procedures to be used to comply with the guideline.

The Guidance Document should indicate the qualifications required to conduct the two types of AA. Each could require a certification, which can be developed through an on-line educational program run through various universities. This can be initiated via one or two workshops with interested parties. It is anticipated that the on-line and continuing educational aspects will emerge quickly because of the demand for certification. There will also be a third party consulting aspect that will emerge to provide qualified AA individuals.

As the AA begins, a preliminary “work plan” will be submitted to DTSC to establish that the process is now on the docket with a timeframe identified. The “work plan” should include details about the AA itself, and identify the qualified individuals involved in the AA process. The DTSC review should be cursory and primarily focused on verifying the chemical(s) and products involved, and to assure the AA individuals are indeed qualified.

DTSC should establish a voluntary AA Technical and Scientific Review Panel (TSRP) that will be convened no more than four times a year. The final AA will be presented to the TSRP in a public forum and the TSRP will advise DTSC on any action to be taken. This will be the primary “independent third-party” review of the AA. The qualifications and expertise of the TSRP will be spelled out in the AA Guidance Document issued by DTSC. DTSC does not have to follow the recommendations of the TSRP but will spell out in specifics why certain decisions on AAs are being made.

This is a proposal for a simplified process that will allow “manufacturers” to complete AAs internally if qualified or to use qualified third-party contractors. The key to this process is to establish tools and procedures that can be used to satisfy the regulations. Additionally, the Guidance process can take place in two phases (1) Issue the RFP and start a pilot program with 5 initial AAs to test the system and create the Guidance, and (2) issue the final Guidance Document within a specified timeframe.