

storage and transportation procedures. An earlier paper by the U.S., CD/CW/WP.266 discussed this area in some detail and may serve as a base for development of procedures. Standard sample preparation procedures for the instruments selected would be included in this database section. Of critical importance is the development of instrument calibration procedures and the use of known analytical standards for both pre and post analysis calibration and periodic sample blanks during the analytical process.

A third portion of the analytical database comprises the methodology for handling the analytical results arising from inspections, via the chromatograms, spectra, field measurements etc., accumulated at the inspection site. Special concern has been expressed here to protect commercial information. This concern may be dealt with by restricting the compounds included in the database as described earlier or by limiting the analytical methods which may be used to analyze samples or both. The analytical results should be capable of being entered into the database in a variety of formats, i.e., textual, tabular, graphic, structural, etc., or show reaction data. The database should also permit cross reference or analysis of data in a variety of forms and formats.

Sources of Data

The sources of data for the various elements of the analytical database will be varied and numerous as a function of its purpose and intended use. Initial declarations of compounds included in the inventories of parties will identify the primary compounds to be included in the database. From these, precursor and degradation compounds and their derivatives can be determined. Analytical data gained by the inspectors from on-site analyses will be entered to confirm those declarations. Should anomalies arise, additional, more detailed analyses will be performed at off-site laboratories.

Data may be developed during the laboratory certification process which must be retained in the database for future comparison. Likewise, analytical methods development data will be a continuous process since new, more compact, and more accurate instruments are being developed every day. The database must provide comparison information between established methods and any new methods developed to allow correlation of analytical results over time. Additional inter-laboratory comparisons may be necessary to ensure that uniform results are being obtained by the various parties involved in the inspection process. Further, a quality assurance (QA) program for all laboratories involved must be maintained in the database. The QA program can encompass both quality control aspects, i.e., instrument calibration and