CHAPTER 14

Quality Control

Quality control can be one of the biggest challenges for a laboratory that must respond to a mass fatality incident. Careful monitoring is necessary to help avoid problems that can result from the increase in scope and volume of work. This chapter offers suggestions for monitoring quality control.

Laboratory directors understand that quality management—quality assurance and quality control—is critical to reporting data in an accurate and timely manner. Quality assurance is based on policies and procedures that provide confidence in a laboratory's ability to produce accurate DNA profiles. Quality control focuses on gathering and analyzing process data to determine whether the results are as expected.

In order to assure quality, a laboratory responding to a mass fatality incident should make every effort to follow the relevant standards for sample testing and the analysis of DNA profiles. These standards may include the Federal Bureau of Investigation's Quality Assurance Standards for Forensic DNA Testing Laboratories and Convicted Offender DNA Data-Basing Laboratories. A laboratory also may follow the American Association of Blood Banks' Standards for Parentage Testing. However, each mass fatality incident is unique—and, after careful consideration and consultation with experts and others involved in creating standards, a laboratory may decide to modify policies to facilitate more rapid reporting of identifications. Of course, any increase in the speed of reporting must occur without compromising accuracy. And any modifications to an existing standard—whether made on a per-sample or ad hoc basis—should be fully documented and retained in a quality management record created specifically for the mass fatality incident response.

Although every individual involved in the testing process is responsible for maintaining quality, at least one laboratory employee should be given the responsibility and authority to ensure that the laboratory adheres to proper standards in processing the mass fatality incident samples. This quality control manager plays a critical role in ensuring that the entire laboratory meets the criteria of the quality program, particularly because errors left uncorrected become more difficult to resolve as time goes by.

We developed the KADAP kinship data set to test new versions of the software. This quality control of "evolving software" allowed us to find "bugs" and correct them, if we didn't get the results that we expected.

Robert Shaler

Intentional Redundancy

Although unintentional redundancy can diminish productivity, it may be an important quality control measure to use a 5–10 percent redundancy when making DNA identifications of mass fatality victims. Intentional redundancy may take several forms, including the duplicate analysis of samples or using multiple software programs for confirming matches and kinship. Also, a second laboratory might perform a duplicate analysis. To accomplish this, two cuttings are taken—and given separate numbers—when the samples are prepared. Needless to say, care should be taken to ensure that duplicate cuttings are from the same sample, as, depending on the type of disaster incident, the commingling of remains may be a concern. In such cases, it should not be assumed, for example, that tissue samples from the same shoe are from the same victim. (See chapter 9, *Information Technology*, "Sample Accessioning/LIMS Requirements" for more discussion on the commingling of remains.)

Multiple Test and Software Systems

Another useful redundancy is running multiple test systems, either in-house or by vendors. If multiple test systems are used—including different multiplex kits—the profiles from each should be compared. Even though there is a match in one system, there may be a nonmatch in another as a result of a mutation, testing problems, or differences in the power of exclusion. Of course, all discrepancies must be resolved prior to reporting an identification.

Redundancy of software systems, such as multiple matching and kinship programs, may also be considered. In addition, the particular realities of each mass fatality incident may require new software approaches. If a program is written—or significantly modified—for a particular event, it may be advisable to run "control" data through another software system to ensure consistent results. Relying on a new version of software without testing it against a validation data set can lead to errors in identifications, especially in terms of finding and ordering partial profiles. In the World Trade Center identification effort, validation data sets were critical to ensuring that the continually evolving software programs were operating properly.