QCP8

COUNTING ROOM QUALITY CONTROL

1.0 PURPOSE

To establish a standard procedure for documenting and evaluating Quality Control (QC) parameters related to routine performance of counting room instruments, which may affect analytical results.

2.0 RESPONSIBILITIES

2.1 Laboratory Staff

- Record performance data and compare to established criteria

2.2 Laboratory Manager or designee

- Identify parameters to be routinely measured and initiate tabulation of such information
- Establish acceptable performance criteria or ranges for operating parameters
- Instruct employees in proper recording and evaluation of performance data
- Review performance data (minimum of weekly), document findings, and initiate corrective actions, when appropriate

2.3 Quality Manager

- Perform reviews and audits of performance documentation, document findings, and track corrective actions

3.0 PROCEDURES

3.1 The Laboratory Manager or designee will identify parameters for acceptable operation of counting room instrumentation. Examples include, but are not limited to: detector response/efficiency, background, resolution, and linearity.

3.2 The Laboratory Manager or designee will establish acceptable performance ranges or criteria for the operational parameters to be monitored. Manufacturers'

specifications, contractual requirements, standard procedures, or operational experience may be the basis of the performance criteria. The acceptance criterion is three sigma from a mean established from a minimum of 20 measurement for each parameter.

3.3 The Laboratory Manager or designee will determine the method and frequency of QC checks appropriate for various parameters and the method of documenting the QC results. Operational performance data may be recorded, utilizing software inherent in equipment computer systems, by hand in logbooks, or on specially developed forms.

Data will be tabulated and charted to improve visual presentation of trends and comparison with acceptance criteria.

3.4 The Laboratory Manager or designee will determine the actions to be taken when QC results for each instrument do not satisfy the three sigma acceptance criteria. The actions include rerunning QC checks at least 2 more times with all parameters passing, taking the instrument out of service until the problem is defined and resolved, or having the instrument recalibrated.

3.5 The Laboratory Manager or designee will determine the actions to be taken when QC results for a given instrument parameter, e.g, total counts, are consistently in the warning range between 2 and 3 sigma. The actions include confirming the reliability of the check source, taking the instrument out of service until the problem is defined and resolved, and/or having the instrument recalibrated.

3.5 Operational performance data will be reviewed at least weekly by the Laboratory Manger or his designee for completeness, conformance with acceptance criteria, appropriate resolutions or corrective actions, and to determine if there are trends that could indicate possible deterioration of system performance.

3.6 Requirements for performing QC checks will be incorporated into the appropriate procedure for the instrument or activity, along with the performance criteria, required actions, and any requirements for special statistical evaluations, associated with the review/evaluation process.