

CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

CORRECTIVE ACTION REQUEST

CAR No. 93-1

Associated AR, SR, NCR NO. Audit 93-1

PART 1: DESCRIPTION OF CONDITION ADVERSE TO QUALITY

During a survey of the Geochemistry Laboratory in Building 57 to verify labeling in accordance with Section 8, Paragraph 8.3.4, several chemicals were noted to have exceeded their shelf-life dates.

T.C. Trbovich

Initiated by: Thomas C. Trbovich

Date: May 7, 1993

PART 2: PROPOSED ACTION

Responsible Element Manager: L. McKague

a) Root Cause:

See attached

b) Corrective Action to Preclude Recurrence:

See attached

Target Date for Completion: 8/31/93

Response provided by:

A. Lawrence McKague Date: 6/4/93

PART 3: APPROVAL

Comments/Instructions:

Director of QA:

Samuel Malin

Date: 6/4/93

PART 4: VERIFICATION OF CORRECTIVE ACTION IMPLEMENTATION

6/4/93. Verified all out of date materials were discarded, Geochemistry & WPE (no other labs use reagents/store reagents). 12/92 was the earliest expired date that was identified after the audit finding. All of the expired solutions were used for Atomic Absorption Analysis, none of which had been performed since 11/92 according to J. Peitay. No remedial action is, therefore, necessary.

Surveillance performed 12/30/93 indicates general compliance with requirement.

Verified by:

Samuel Malin

Date: 12/30/93

Background

It should be noted that CQAM Section 8, Paragraph 8.3.4 does not actually specify to throw out chemicals which have exceeded their shelf-life dates.

For a variety of reasons, chemicals are at times purposefully retained in the laboratory beyond their shelf-life dates: (1) An investigator may elect to keep a chemical for archival purposes. For example, the investigator may suspect contamination of the chemical, a condition which could be important at a later date. (2) An investigator may have a use for the chemical which is independent of the relatively small uncertainty in its composition introduced by passage of its shelf-life date. For example, in testing a procedure for detecting an element, it may be irrelevant whether a solution contains 0.1 or 0.01 ppm of the element. In such a situation, use of the chemical past its shelf-life date may be a cost effective alternative to purchase of a new chemical. (3) An investigator may have reason to believe that the manufacturer was unreasonably cautious in assigning the expiration date. For example, some chemicals are known to be extremely stable under laboratory conditions, the difference in its composition and/or properties at 2 years of age may be the same as at 3 years age, regardless of the manufacturer's suggestions. Investigators routinely use their independent knowledge and training to decide when solutions and compounds they have made are too old to use with confidence.

Remedial Action

Shelf-life dates of chemicals presently in the laboratory will be reviewed in accordance with the procedures described below. Scientific notebooks will be reviewed by QA back to the earliest expiration date of the expired chemicals discovered in the laboratory. If it is found that an expired chemical was used, the Principal Investigator will write a non-conformance report. The usage of the expired chemical will be reviewed to evaluate any adverse effects on quality. If necessary, the experiments or measurements for which the expired chemical was used will be repeated or other corrective actions taken.

a) Root Cause:

Current procedures do not call for a specific review and/or removal of chemicals which have exceeded their shelf-life date.

b) Corrective Action to Preclude Recurrence:

As a general principal, the Principal Investigator shall continue to have discretion in retaining or disposing of chemicals which have exceeded their shelf-life dates. This discretion shall be exercised within the following guidelines:

(A) TOP-012 shall be revised as follows:

3.6.3 Reagents and standards with expiration dates shall be discarded upon expiration, unless:

(a) the expiration date is extended by the Principal Investigator, as evidenced by revision of the date on the container, or

(b) limited use is permitted by the Principal Investigator, as evidenced by striking out the original expiration date and identifying the container "EXPIRED" and including appropriate limitations to its usage.

Revisions to expiration dates by (a) or (b) shall be validated by the Principal Investigator's initials and date of change on the affected container.

(B) Laboratory personnel shall be instructed to notify the Principal Investigator of expired chemicals.

(C) Laboratory supplies shall be surveyed quarterly by QA to identify the presence of any expired chemicals.