Item No. DS-2007-11
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Joint Committee Issue Document

NOTE: An issue document may be submitted at any time – it comprises two parts: the cover sheet (this page) and a description of the issue to be submitted to the Joint Committee (following page). A separate issue form is required for each issue submitted. Issue papers include proposals for modification of a standard, information reports (of current research, etc.) and reports of Task Forces. An issue paper shall be categorized as being for ACTION or for INFORMATION. Submitters should limit the Issue Paper to 1 or 2 pages – attachments detailing full recommendations or background information may be attached with supplementary information. The Chairperson of the appropriate Joint Committee will respond within 30 days of receipt of the issue document advising what steps will be taken. Any issue document intended for discussion at a Joint Committee meeting must be received at least 21 days prior to the meeting to ensure inclusion in the agenda.

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Signature of Submitter * Kerri L. Levanseler Date 12-03-07

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Please insert a check (4) in the appropriate place to indicate if you wish the item to be considered as an action item or as an information item.

Action ____X_____ Information ____ _____

NSF Standard(s) Impacted**: 173**

Issue Statement:
Provide a concise statement of the issue, which reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

To revise 6.2.5 "Quality assurance for quantitative test methods" in Standard 173 to address findings in a Nov. '07 American National Standard Institute (ANSI) audit.

Background:
Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee.

Originally, a QC section was added to the standard to provide information regarding the typical practices and quality checks involved for the analysis of supplements as performed by the NSF International Chemistry Laboratories. The section was not written to provide the flexibility needed based on the range of techniques that may be employed. Also, it is important that the language of this section is consistent with the method specific standard operating procedures. Finally, the ANSI auditor referenced ISO 17025 requirements, therefore viewing this section and incorporating revisions from this perspective would be beneficial in terms of future ANSI audits.

Recommendation:
If action by the Joint Committee is being requested, clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by highlighting or underlining; e.g., reference of the issue to a Task Force for detailed consideration; etc. If recommended text changes are more than a half page, please attach a separate document.

Edit 6.2.5 as described herein…

Supplementary Materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

NA

Submitter _Kerri L. Levanseler Date __12-04-07

6.2.5 Quality assurance for quantitative test methods

Many of the quantitative test methods for dietary supplement samples are performed utilizing chromatographic procedures. The typical quality assurance criteria that are applied are described in the following sections, however, some methods may have unique criteria which would be defined within the laboratory standard operating procedures or other reference method. For example, non-chromatographic test methods (such as titration and potentiometric techniques, uv-visible and gravimetric procedures, micro-assays, etc.) would employ quality assurance steps as applicable to the situation.

6.2.5.1 Calibration

Quantification test methods shall be performed using certified reference standards as calibration standards. The standards are typically purchased as single chemicals with greater than 95% purity. If a high-purity standard is not available, a lower-purity material shall be used if there is a means by which the actual purity can be measured (e. g., uv absorbance).

6.2.5.1.1 Multi-level calibration curves

Multi-level calibration curves shall be prepared with a minimum of three concentration levels such that any sample preparations under evaluation would be bracketed by a calibration standard. Curves shall give a correlation ~~coefficient~~ coefficient (r) of 0.995 or higher.

6.2.5.1.2 Single-level calibrations ~~curves~~

If a single level calibration is employed, the standard shall be run in triplicate and the relative standard deviation between these runs shall not exceed 2%. The detector response of the prepared sample shall be within 90% -%110 of that of the standard.

6.2.5.1.3 Blanks

A method/reagent blank shall be included in each analytical run. The blank response for the analyte of interest shall not be greater than one half the response of the lowest calibration standard for multi-level calibration curves. For single-level calibrations, the blank response for the analyte of interest shall not exceed 5% of the sample response.

6.2.5.1.4 Reproducibility/accuracy

All unfamiliar matrices shall be prepared in triplicate.

Whenever possible, two additional preparations shall be spiked with the reference standard(s) to assess recovery/accuracy. The recovery in the range of 70-130% of the theoretical spike value is considered acceptable.

The reproducibility between the two spiked samples as measured by ~~percent~~ relative percent difference (RPD) shall be no greater than 20%. The reproducibility of the method is also evaluated by the percent relative standard deviation (%RSD) of the triplicate sample preparations which should not exceed 25%,

> NOTE – When spiking with the reference standard is price prohibitive, a control sample with a known result shall be tested as part of the analysis run; this shall include a certified reference material or a sample that has been analyzed in the past.

6.2.5.1.5 Continuing Calibration Verification (CCV)

In order to assess instrument stability, a Continuing Calibration Verification (CCV) or bracketing standard~~s~~ shall be run after every 10 sample preparations and/or at the end of the run. The recovery for the CCV shall be between ~~within the uncertainty of the method for the data to be acceptable~~80-120% of the theoretical standard value. CCV standards, which are run to confirm an existing calibration, must show recovery of 90-110%. If the result falls outside this range, a new calibration shall be run.