

From: Duncan Ellison [duncan.ellison@videotron.ca]
Sent: Tuesday, August 02, 2011 3:01 PM
To: 'Paula Brown'
Cc: Hoffman, Joan
Subject: RE: Comment #03236: Appropriately qualified individual

Thank you Paula for your reply.

I would be satisfied if, in response to your question at the end of paragraph 2, if a definition of "qualified individual" could be added to the standard based on the language of 21 CFR111.12 (c). I believe this would provide some limitations on the determination of what would constitute an appropriately qualified individual.

Regarding accreditations, I am aware of the scope of accreditations of laboratories, having spent 8 years on the Board of Directors of the Canadian Association for Laboratory Accreditation, and understand that under normal conditions, accreditation is provided for specific chemicals or chemical groups for which the laboratory's services are provided.

I would hope that there might be some way in future to include provision requiring a general accreditation to ISO 17025 (without specifying particular herbs, chemicals or foods) as the accreditation process provides demonstration of good laboratory practices and competence particularly related to documentation of test protocols used and sample tracking.

On this point, I shall offer it (the topic of writing a general provision about accreditation to 17025) to Stan Hazen as a possible discussion topic for the Council, but leave this alone for 173.

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From: Hoffman, Joan [<mailto:jhoffman@nsf.org>]
Sent: August-02-11 12:52 PM
To: 'duncan.ellison@videotron.ca'
Cc: 'Paula Brown'; Hoffman, Joan
Subject: Comment #03236: Appropriately qualified individual

Dear Mr. Ellison:

Thank you for your ballot and comments on NSF/ANSI 173 – 2010, Dietary Supplements, regarding the Methods/QC Update.

The term qualified is consistent with the language in the 21 CFR Part 111 cGMP in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. Specifically in part 21 CFR 111.12 (a) it states "You must have qualified employees who manufacture, package, label, or hold dietary supplements." In (c) it states "Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions." In your opinion, would it add value to the standard to include a definition for "qualified individual" which draws from the language of the regulation (21CFR111.12(c))?

In response to the proposal for requiring accredited laboratories, I believe this would prove to be very restrictive criteria, and many food labs and nearly all QC labs in dietary supplement manufacturers would have difficulty complying. Often the accreditation that is common in the US is accreditation to ISO17025. This accreditation is linked to a specific scope—where the ideal situation is that the lab is using the same method frequently throughout the year so that a 3rd party auditor can verify the lab is performing in a way consistent with the written methods. Accreditation works well when the lab does the exact same method for all samples (like heavy metals in herbs, fish oil testing for PCBs, etc.). It is more difficult and costly to apply to vitamins, identity tests, herbal marker compounds, in all kinds of different product types, where multiple variations in the methods may be needed to optimize the methods for the situation at hand. Once a method is on an accreditation scope and a change is made to how you perform this, you need to file with your accessor to have them determine the impact of the change and whether it would require an on-site visit to modify the scope. Some industries do require accreditation (e.g., bottled water, toys), but contract food labs and in-plant QC labs in the food and dietary supplements industry have not been held to these requirements. I believe it is important that the wording and the requirements in standards be consistent with the particular regulatory/industry/user group for which the standard is written. As you indicate, since it relates to public health and food safety, this is an important topic to think about. At the same time, those working in the area of standards development need to establish requirements that can be practically applied by the industry.

Thank you for the role you play in the development of quality standards. If it would be better to discuss this topic via a phone call, please feel free to contact me:

Kerri LeVanseler
 Technical Manager
 Chemistry Laboratory
 NSF International
 Phone: 734-827-6815
 E-mail: levanseler@nsf.org

Thank you for considering this response, which we hope addresses your concerns. If you have additional comments, or wish to discuss these points further, please contact me directly.

Thank you, again, for your thorough review.

Paula N. Brown, Chair
 Joint Committee on Dietary Supplements

cc: J. Hoffman

Subject: Appropriately qualified individual

Category: Substantive

Comment

While balloting positively for this amendment, I would like to raise the broader issue, for future consideration, as to whether or not it is sufficient to leave these determinations to an [undefined] "appropriately qualified individual". Elsewhere in the existing standard there is a single reference to "an accredited laboratory". It would seem to me that in matters as important as those dealt with by the amendment, at the least the term "appropriately qualified" in respect to the individual might be better specified.

Proposal

The Joint Committee should consider whether or not the qualifications relevant might be specified, or the term "appropriately qualified individual" should become a defined term. As a continuation of this concern, since it relates to food safety and public health, I believe NSF should be considering a general requirement for the use of accredited laboratories. I intend to raise this as a topic for discussion at the upcoming Council Meeting.

Changes

status=Addressed

owner_id=jhoffman

response updated

Comment Number: #03236

Submitter: Joan Hoffman

Date submitted: 2011-07-22 05:49:46

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