Implementation Deferred for General Chapters <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures

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The Chair of the USP Council of Experts, in consultation with the Executive Committee of the Council of Experts, has deferred proposed 5.60.30 Elemental Impurities in General Notices. This proposed revision suggested a May 1, 2014 date linking General Chapters <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures to drug product monographs in the United States Pharmacopeia (USP). As such, section 5.60.30 will not be included in the General Notices that will be published in USP 37–NF 32, and therefore there is no requirement for any drug product in the USP–NF to comply with <232> and <233> at this time. The proposed omission of General Chapter <231> Heavy Metals also has been deferred.

These deferrals will allow USP to work closely with ICH Q3D to align their activities with the implementation of General Chapters <232> and <233>. The deferral also allows USP to work with those affected by the new elemental impurity standards. In this regard, USP plans to form an Advisory Group on the Implementation of General Chapters <232> and <233>.

The Council of Experts Executive Committee appreciates the thoughtful comment letters on proposed General Notices section 5.60.30.

For General Notices questions, please contact Mario Sindaco (301-816-246 or mys@usp.org). For technical questions related to General Chapters <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures, please contact Kahkashan Zaidi (kxz@usp.org or 301-816-8269).