Update on the Elemental Impurities General Chapters

<232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures

October 25, 2013

Background
On September 23, 2013, the Elemental Impurities Expert Panel met to review the Step 2 limits of the ICH Q3D Elemental Impurities Working Group, which were released in June 2013. At its meeting the Expert Panel recommended revisions to General Chapter <232> Elemental Impurities—Limits to partially align with the ICH Q3D limits. In addition, the Expert Panel recommended other minor editorial changes to both General Chapter <232> and General Chapter <233> Elemental Impurities—Procedures. On October 16-17, 2013 the General Chapters—Chemical Analysis Expert Committee met and endorsed the recommendations of the Expert Panel.

These revisions will be proposed according to the timeline below.

Revision Timeline

- **January 1, 2014:** USP pre-publishes on the USP Elemental Impurities Key Issues web page the proposed revisions to <232> and <233>. Subject to further discussion with the Council of Experts Executive Committee (which is responsible for General Notices), with input from the Elemental Impurities Implementation Advisory Group, USP also anticipates posting at this time an announcement regarding the date of implementation of <232> and <233> as specified in General Notices section 5.60.30.
- **March 1, 2014:** USP publishes the proposed revisions to <232> and <233> in PF 40(2) [March-April 2014] for public comment. Comments will be accepted only on the proposed revisions to the general chapters.
- **May 31, 2014:** The 90-day comment period ends (comment period is from March 1, 2014 through May 31, 2014).
- **June 2014:** The Expert Panel considers comments received on the proposed revisions and also reviews ICH Q3D Step 4 limits, which are expected in June 2014.
- **July-August 2014:** Expert Panel meets to make recommendations regarding any final revisions to the general chapters.
- **September 2014:** General Chapters—Chemical Analysis Expert Committee meets to review Elemental Impurities Expert Panel recommendations and consider final revisions to the general chapters.
- **October 2014:** The General Chapters—Chemical Analysis Expert Committee ballots on the revised General Chapters <232> and <233>, and the removal of General Chapter <231>. Note that the removal of <231> was previously proposed in PF 39(1). The removal of <231> will coincide with the implementation of General Chapters <232> and <233>.
- **October 2014:** USP pre-posts the approved revised General Chapters <232> and <233>, the Commentary, and a notice about the removal of General Chapter <231> on the USP Elemental Impurities Key Issues web page.
- **February 2015:** The approved revised General Chapters are published in the USP 38-NF 33 First Supplement, which publishes in February 2015 and becomes official August 1, 2015.
**Note:** USP anticipates that the implementation date for the General Chapters as elaborated in section 5.60.30 of General Notices is expected to be on or after the official date of the revised General Chapters.