
[Deferred Proposal: General Notices and Requirements, 5.60.40 Impurities that are Unusually Toxic and/or Mutagenic](#)

Type of Notice: General Announcement

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This Notice provides a status update and additional information regarding the deferral of the proposed Interim Revision Announcement (IRA) to *General Notices and Requirements* 5.60.40, published in *PF* 46(3) [May-June 2020].

As a background, a new subsection, 5.60.40. *Impurities that are Unusually Toxic and/or Mutagenic*, was proposed to be added to the *General Notices and Requirements* as a Proposed IRA in *PF* 46(3) [May–June 2020]. The purpose of the new subsection was to ensure that users are aware of their responsibility to identify and control mutagenic and unusually toxic impurities at safe levels as required by the applicable regulatory authority, or as described in ICH M7 *Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*. The proposal was intended to address potential safety concerns resulting from very toxic impurities not being controlled at appropriate levels in cases where a reporting threshold or disregard limit is included in official *USP–NF* monographs, as outlined in the Compendial Notice titled [Reporting Threshold in USP–NF Monographs: Proposed Policy Change for Public Comment](#). The proposal also addressed stakeholders’ feedback received in [response](#) to the Compendial Notice recommending *USP–NF* include a statement of the applicability of risk evaluation and controls provided by ICH M7 Guidelines.

In accordance with the Rules and Procedures of the Council of Experts, USP is publishing the [comments received](#) from the stakeholders on the IRA proposal. Based on these comments and in accordance with USP Guideline on Use of Accelerated Processes, the USP Council of Experts (CoE), which is responsible for revision of the General Notices and Requirements, has deferred the proposal. USP will continue to engage stakeholders on the topic of impurities that are unusually toxic and/or mutagenic.

Should you have any questions, please contact Jessica Simpson (jcs@usp.org).
