

EDITORIAL NOTE

The following position paper on documentation of pathology peer review was the result of discussions leading to and following the publication of perspectives on peer review in *Toxicologic Pathology* in late 1996. The Regulatory Affairs Committee of STP drafted this position in response to the published perspectives, member input, and discussions with other organizations. The position was approved by the STP Executive Committee in June 1997.

COMMENTARY

Documentation of Pathology Peer Review

Position of the Society of Toxicologic Pathologists

Recommendations on the process of pathology peer review have been presented previously by the Society of Toxicologic Pathologists (4). For purposes of the current discussion, the primary purpose of pathology peer review is to verify the accuracy of the toxicologically significant microscopic findings. Peer review is not employed to corroborate every detail of every histologic finding, but to ensure that treatment-related findings are properly identified and consistently diagnosed. A peer review may also verify other findings (i.e., spontaneous disease or experimental procedural effects) that might modify the treatment-related effects. Audit processes (i.e., slide accountability) are not a primary part of peer review, but may be included as an ancillary procedure. The quality of the histologic preparations, including missing tissues, becomes a part of the peer review if it impacts the overall interpretation. Specific procedures of the review may vary, depending upon the purpose of the review. In any event, it is the responsibility of the reviewing pathologist to ensure that the method of review employed is sufficient to verify the accuracy of the histopathologic findings.

The documentation of pathology peer review should include the methods used during the peer review process, including animals with complete review of all slides, target organs reviewed along with the specific toxicologic endpoints examined, proliferative lesions reviewed, and any other special procedures followed during the peer review process. The documentation should also include a statement that the final microscopic diagnoses represent a consensus of the study and peer review pathologists.

Worksheets of detailed findings of the primary and peer review pathologists need not be retained. These are the equivalent of "pathology workfiles" and are not raw data. The position of the STP is that the tissue section represents the original raw data (3). However, some regulatory authorities and some companies contend that the slide is not raw data, but is a specimen from which the raw data (final pathology report) can be reconstructed (2).

Given either nuance of semantics, the slides must be retained and microscopic findings can be regenerated at any future time by a review of the slides.

The following documentation of pathology peer review is appropriate for peer review by in-house and external reviewers:

The name, qualifications, and affiliation of the pathologist(s) conducting the review

The purpose of the review (i.e., routine, verification of a specific lesion)

The process of the review (i.e., which tissues were examined, what information was available to the reviewer)

A statement that the findings in the final (signed) report are the consensus of the primary and reviewing pathologists

If the pathologists do not agree, a description of the process employed to resolve the differences and arrive at a final interpretation should be clearly stated.

Note: Although the documentation of peer review cited above is appropriate from a scientific basis, there are currently regulatory constraints on some forms of peer review, specifically review by pathology working groups under certain circumstances. The documentation required for a pathology working group reevaluating the diagnoses of a carcinogenicity study previously submitted to the Environmental Protection Agency is much more extensive and includes listings of original diagnoses, the reviewing pathologist's diagnoses, and the findings of the pathology working group (1).

REFERENCES

1. Environmental Protection Agency (1994). Pesticide Regulation (PR) Notice 94-5.
2. Lepore PD (1996). Pathology raw data. *Toxicol. Pathol.* 24: 147.
3. Society of Toxicologic Pathologists (1987). Society of Toxicologic Pathologists' position paper on audit trials on microscopic pathology data. *Toxicol. Pathol.* 15: 377.
4. Society of Toxicologic Pathologists (1991). Peer review in toxicologic pathology: Some recommendations. *Toxicol. Pathol.* 19: 290-292.