Electron microscopy sample preparations and instrument operation are performed in a manner that minimizes risk to personnel.

ANP.57070 Hazardous Chemicals **Phase II**

The laboratory safely handles and disposes of osmium tetroxide, epoxy resins, and other hazardous chemicals.

NOTE: Osmium tetroxide is volatile and toxic. Exposure to its vapor can lead to blindness and serious respiratory complications. There must be a clearly stated and posted procedure addressing accidental spillage. Material for dealing with such a spill should be readily available, eg, corn oil and an absorbent such as saw dust. For US laboratories, disposal of osmium tetroxide must be according to OSHA regulations for toxic compounds. Epoxy resins are highly allergenic, and direct contact should be avoided. The laboratory must have documentation that personnel have been trained in the handling of these materials.

REFERENCES
1) Cooper K. Neutralization of osmium tetroxide in case of accidental spillage and for disposal. *Micros Soc Canada Bull.* 1988;8(3):24-28
2) Wenk PA. Disposal of histology stains. *Lab Med.* 1998;29:337-338
3) Clinical and Laboratory Standards Institute. *Clinical Laboratory Waste Management; Approved Guideline.* 3rd ed. CLSI Document GP05-A3. Clinical and Laboratory Standards Institute, Wayne, PA; 2011.

ANP.57100 X-Ray Leakage **Phase II**

The electron microscope is checked for x-ray leakage at the time of installation and after major repair.

NOTE: Periodic monitoring is also required for devices operating at 70,000 volts or above. Records of radiation leakage checks must be retained.

IN VIVO MICROSCOPY (IVM)

This section applies to In Vivo Microscopy (IVM) technologies for clinical practice, in which a physician views digitized or analog video or still image(s) or other data, and renders an interpretation that is included in a formal diagnostic report or in the patient record. The Ex Vivo Microscopy section of this checklist should be used for in vitro applications of these systems.

This checklist section applies to the application of IVM technologies for:
- *Intra-procedural guidance of biopsy or tissue excision*
- *Surgical (intraoperative) guidance*
- *Primary evaluation and/or diagnosis*
- *Screening*
- *Intra- or extra-institutional consultation*
- *Post-procedural evaluation and/or diagnosis*

Examples of IVM technologies include:
- *Confocal microscopy*
- *Optical coherence tomography (OCT)*
- *Multiphoton microscopy*
- *Optical spectroscopy and spectroscopic imaging*

This checklist section is NOT applicable to:
- *Informal reviews without formal reporting*

- *Educational or research-only use of these systems*

The providers of IVM services (acquisition and interpretation of IVM datasets) may be located entirely within a clinical department, the pathology department (laboratory), or may represent collaboration between a clinical department and the laboratory. The responsibility for checklist requirements rests with the IVM service. The IVM service must ensure that records to demonstrate compliance are available for review by the CAP inspection team, whether the records are located within a clinical department, the laboratory, or both.

DEFINITION OF TERMS

In vivo microscopy (IVM) dataset — Digitized or analog video or still images or other data (eg, spectroscopic data) generated by an IVM system that is utilized to render a diagnostic interpretation or to guide procedures.

Confocal microscopy — A non-invasive, high-resolution optical imaging technique that excludes out-of-focus light, enabling 'optical sectioning' and tomographic imaging of specimens that are thicker than the focal plane. Confocal microscopy can be performed directly on tissue or through an endoscope (confocal laser endomicroscopy or CLE). The latter may be either endoscopy-based (eCLE device built into the endoscope) or probe-based (pCLE device in a probe with fiber-optic cable for image transmission that can be inserted into the accessory port of a standard endoscope). Injection or topical application of a contrast is usually required.

Optical coherence tomography (OCT) — A non-invasive, high-resolution optical imaging technique that provides real-time 2-D and 3-D images of tissue architecture in vivo by mapping reflectivity of light waves focused onto the tissue. Variants of OCT technology include: Optical Frequency Domain Imaging (OFDI) and Full Field OCT (ff-OCT). Contrast agents are usually not required.

Multiphoton microscopy — A high-resolution fluorescence imaging technique that provides 2-D and 3-D tomographic images based on non-linear optical effects. It is also known as 2-photon, 3-photon, or nonlinear microscopy. Contrast agents are usually not required.

Optical spectroscopy — An optical technique that assesses the way in which the spectrum of light is changed by interaction with tissue. Examples include diffuse reflectance spectroscopy, fluorescence spectroscopy, and Raman spectroscopy. Measurements made with any of these techniques can be translated into false color spectroscopic images (optical spectroscopic imaging). Contrast agents are usually not required.

Additional information on IVM may be obtained using the CAP Pathology Resource Guide: In Vivo Microscopy.

Reference: Fitzmaurice M, Crawford JM, Fine JL, et al. *CAP Pathology Resource Guide: In Vivo Microscopy.* Version 8.0(1). Northfield, IL: College of American Pathologists; 2018.

Inspector Instructions:

	• IVM policies and procedures • Sampling of reports generated from reviews of datasets obtained by IVM • Sampling of records for personnel training • Sampling of records of rejected IVM datasets and notification of clinical personnel • Sampling of records documenting verbal reports • Completed validation study(ies) with review and approval • Quality management system including IVM
	• Review summary statements and supporting validation data to confirm that studies were performed using an adequate number of cases, data was evaluated, and summary statement was approved prior to implementation. If the data showed discordances or unacceptable variations, investigate how they were resolved.