

11-7-84

TS-798:JKIM:11-02-84:Rm.343ET:382-3971:Disk#3

Ms. Joanne Westcott
Executive Secretariat
Center for Devices and
Radiological Health
Department of Health &
Human Services, FDA
Rockville, Maryland 20857

Dear Ms. Westcott:

This is in response to your October 3, 1984 letter to Bill Waugh. That letter and its enclosure posed a number of questions about the presence of polychlorinated biphenyls (PCBs) in x-ray tube heads and transformers, and about the regulations governing such equipment. While the Environmental Protection Agency (EPA) does not have a list of electrical equipment manufactured with PCB dielectric fluid, the agency is aware that PCBs have been used in various parts of health diagnostic equipment as well as in many transformers produced prior to the January 1, 1979 ban. This response gives an overview of the EPA regulations that would apply should the equipment contain PCBs.

The PCB regulations administered by EPA encompass PCBs in all equipment except where more stringent regulations are applicable. After consulting with Mr. Palmer of the Food and Drug Administration (FDA) as you suggested, EPA has determined that PCBs in x-ray equipment are regulated solely by EPA. The PCB regulations published by EPA (see 40 CFR 761) control the manufacture, processing, distribution in commerce, use, servicing, storage and disposal of equipment containing PCBs.

The manufacture of PCBs was prohibited as of January 1, 1979. Equipment manufactured after January 1, 1979 should not contain PCB dielectric fluid. The dielectric fluid in x-ray transformers and tube heads manufactured prior to 1979 could contain PCBs. It may be possible to determine if equipment manufactured prior to 1979 originally contained PCB fluids by contacting the original manufacturer. However, since PCB levels could have changed over time due to servicing activities, the only certain way to ascertain the presence and levels of PCBs is to test the dielectric fluid.

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CONCURRENCES

SYMBOL	ORIGINATOR						
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SURNAME	<i>[Signature]</i>	<i>Rudynich</i>	<i>[Signature]</i>	<i>Breece</i>			
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Should non-leaking tube heads and transformers contain PCBs, they would be considered as separate items and apart from the rest of the x-ray equipment. On August 25, 1982 (47 FR 37342), EPA authorized the use of PCB-containing transformers for the remainder of their useful lives under certain use, servicing and disposal conditions. The use of fluid containing PCBs in x-ray tube heads is not authorized. All tube heads containing PCBs will need to be disposed of in accordance with the regulations (40 CFR 761.60). If x-ray tube heads or transformers containing PCBs are leaking, the entire x-ray machine will be considered a PCB article and will be subject to disposal requirements.

The concerns raised by Mr. Lightburn^{edk} and Mr. Johnson on the servicing of oil containing components of x-ray machines are serious ones, if the oil does contain PCBs. The servicing and maintenance practices described in Mr. Peakes' memorandum do not meet servicing requirements for PCB-containing transformer dielectric fluid. It is not possible to fully explore the regulatory constraints on the use of oil containing x-ray equipment until determinations are made as to the presence and levels of PCBs.

We again refer you to 40 CFR part 761 and encourage you and the others concerned to contact us with more specific information. Please remember that the use of x-ray tube heads containing any amount of PCBs is prohibited. If you have any further questions, please contact Denise Keehner of my staff at (202) 382-3933.

Sincerely,

(SIGNED) DON R. CLAY

Don R. Clay, Director
Office of Toxic Substances.