



CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

RESOLUTION

Relating to: Reduced protection from x-ray exposure resulting from the proposed revisions to the Federal Performance Standard for Diagnostic Equipment and their Major Components (FPS).

- WHEREAS:** X-rays represent the largest source of man-made ionizing radiation exposure;
- WHEREAS:** The purpose of Public Law 90-602, The Radiation Control for Health and Safety Act of 1968, was to protect the public from unnecessary exposure to radiation from electronic products;
- WHEREAS:** The proposed revisions to 21 CFR 1020 are in some cases based on outdated studies which no longer reflect the current usage of radiation producing machines in the United States;
- WHEREAS:** State Radiation Control Programs cooperatively inspect and, through state standards, enforce the requirements of the FPS;
- WHEREAS:** States are prohibited from adopting machine-based standards which are more restrictive than the FPS;
- WHEREAS:** The installation of non-certified components has continued beyond the expectation stated in the cost-benefit analysis used to justify the requirements under 21 CFR 1020, resulting in the continuation of unnecessary x-ray exposures to the public;
- WHEREAS:** The current FPS is difficult to interpret the responsibilities of assemblers and the enforcement for the regulatory agencies;
- WHEREAS:** The current FPS only addresses part of the usage of x-rays in the healing arts, leaving a void in the manufacturing standards for therapeutic equipment;

NOW BE IT RESOLVED:

Any change to the FPS shall ensure that radiation exposures to both the public and to machine operators are maintained as low as reasonably achievable;

NOW BE IT FURTHER RESOLVED:

Any change to the FPS shall result in the further reduction of unnecessary radiation exposures;

NOW BE IT FURTHER RESOLVED:

Elimination of any existing criteria shall be based on current, validated data;

NOW BE IT FURTHER RESOLVED:

Revisions to the FPS shall be drafted in consultation with representatives of State Radiation Control Programs;

NOW BE IT FURTHER RESOLVED:

There shall be a mandatory phase-out of the installation of non-certified components;

NOW BE IT FURTHER RESOLVED:

FDA shall pursue the refinement and clarification of the FPS; and

NOW BE IT FURTHER RESOLVED:

FDA shall pursue the incorporation of standards for therapy radiation producing machines.

The Executive Board has considered and recommended that the resolution does pass.

Accepted by CRCPD Membership 5/5/90
Original signed by Charles M. Hardin, Executive Director