U.S. Readies X-Ray Machine Standards Aimed at Reducing Exposure of Patients

Radiation

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WASHINGTON -- The Federal Government is readying standards aimed at significantly reducing unnecessary exposure to medical X-rays and improving the performance of X-ray equipment.

The new requirements, being prepared by the Department of Health, Education and Welfare, will force many manufacturers to modify their equipment and could increase the cost of some machines. But Federal experts look for substantial benefits, both to the public and to practicing physicians.

The standards will require the use on many machines of automatic devices to limit the size of the X-ray beam, so that patients will be exposed only to the amount of radiation necessary for film-taking. X-ray films come in varying sizes, and failure to adjust the radiation beam precisely to the size of the plate causes the patient a substantial amount of needless exposure, radiologists say.

"If all X-ray exams were taken at the proper field size, it could reduce exposure by about one-third," says Dr. Russell H. Morgan, chairman of the radiology department at Johns Hopkins School of Medicine in Baltimore.

The new standards will require manufacturers to include electronic or mechanical focusing devices on their machines. The devices, called "collimators," would prevent technicians from taking pictures if the X-ray beam wasn't accurately restricted to the part of a patient's body covered by the film. The additional cost is estimated at $500 to $1,000; X-ray machines cost $50,000 or more.

A 1964 survey by the Public Health Service showed that failure to limit X-ray beams was the chief cause of excess patient exposure to diagnostic X-rays. At times, the beam irradiated two to four times the body area that was to be examined, which could pose significant health hazards.

Most Frequent Failures

The failure was noted most frequently among general practitioners and other nonradiologists. The danger was judged greatest when X-raying the pelvis and abdomen, where stray radiation could strike sensitive reproduction organs, with genetic effects.

The new standards also will require equipment that consistently reproduces the same pictures when the same settings are used for exposure time, energy and current. Not only will this "reproducibility" requirement lead to higher quality X-ray pictures and standardization of techniques, experts say, but it also should cut down on retaking poor pictures—another source of patient overexposure.

The National Electrical Manufacturers Association, a trade group, has issued voluntary reproducibility standards covering new X-ray machines. The mandatory Federal standards would apply during a machine's entire useful life, as long as 15 years. If machines were defective, the manufacturers could be required to recall and repair them.

Still to be determined is the leeway to be allowed for reproducibility. Currently, HEW is considering a 5% maximum variation when identical settings are used and 10% when adjustments are made but the same result is desired. For example, an X-ray technician might increase the current and decrease exposure time, much as a photographer adjusts camera settings.

Industry Predicts Problem

The industry argues it will have trouble meeting the 10% tolerance, and a further problem for HEW is whether to relax the standards to acommodate lower performance levels as the machines get older.

Whatever figure is decided on, the manufacturers will be required to tell doctors the frequency and type of maintenance needed to maintain it. "Collimation and reproducibility are our goals," declares Robert Elder, director of HEW's division of electronic products.

Although difficulties could arise over details, the basic requirements aren't expected to produce major controversy with the manufacturers. Some of them already have moved to install automatic beam-limiting devices. Most, however, would have to add this equipment and make other modifications to assure reproducibility, HEW experts predict.

The requirements would affect an estimated 35 manufacturers or distributors, including such domestic producers as General Electric Co., Westinghouse Electric Corp. and Litton Industries Inc. Major importers include Siemens Medical of America Inc. and North American Philips Corp.

The X-ray standards will be issued under the 1968 Radiation Control Act, which gives HEW authority to regulate electronic devices. The department already has established standards to limit unintentional radiation from television sets and microwave ovens, but the diagnostic X-ray requirements will be the first major endeavor for devices designed to emit radiation. Standards will be issued later for X-ray machines used to treat patients and for industrial purposes.

Diagnostic X-ray machines, which take medical and dental X-ray pictures, were dealt with first because they produce most of the X-ray exposure to the public. However, the standards also apply to fluoroscopes, which let the physician observe the patient without photography.

The standards are likely to be issued next January, but interested parties will be given a chance to comment on them before they take final effect. A transition period will be provided for some requirements, such as automatic collimation.

HEW intends to tighten the standards as time goes on and more technical data become available. "We elected to take a chunk that we could enforce now," explains William Properzio, chief of HEW's X-ray exposure control laboratory. "Because of the vast changes and complexity of equipment," he adds, "from time to time there will probably be added requirements."

Question of Used Machines

The standards raise a difficult regulatory question of control over used equipment, as the radiation law applies only to new equipment. As a partial step, however, the new standards will specify requirements for one key component of X-ray machines, the tube housing, which is usually replaced more than once during the life of the equipment. The technical electronic product radiation safety standards committee, an advisory panel that passes on all such radiation standards, is eager to expand this control to other machine components.

In addition, state regulatory authorities, which license and inspect X-ray machines, are likely to be guided by the Federal standards. It is hoped that the states will toughen their requirements for used equipment based on the Federal standards for new machines.

But the touchiest issue centers on preventing doctors from taking unnecessary X-rays in the first place. Critics say one of the most common causes of too much X-raying is the desire of many doctors to protect themselves against malpractice suits by taking all available diagnostic steps, even though X-rays in many cases might not be needed. The practice is particularly prevalent in hospital emergency rooms where accident victims are treated, critics charge.

The radiation law, of course, doesn't deal with the way physicians practice medicine. But Dr. Morgan at Johns Hopkins, a key member of the HEW advisory committee, believes that more regulation is necessary. He suggests that the committee may end up recommending increased Federal authority in this area, a highly controversial concept.