Extending Effective Date Of The Food And Drug Administration's Diagnostic X-Ray Equipment Standard

B-164031(2)

Department of Health, Education, and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

SEPT. 23, 1974

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

The Honorable Edward I. Koch
House of Representatives

Dear Mr. Koch:

Pursuant to your request of July 14, 1973, and discussions with your office, this is our report on the Food and Drug Administration's extension of the effective date of its diagnostic X-ray equipment standard.

The Administration is part of the Department of Health, Education, and Welfare. We obtained formal written comments from the Department on matters in the report.

We do not plan to distribute this report further unless you agree or publicly announce its contents. In this connection, we want to invite your attention to the fact that this report contains a recommendation to the Secretary of HEW which is set forth on page 11. As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions he has taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report. When we obtain your agreement to release the report, we will make it available to the Secretary and the four committees for the purpose of setting in motion the requirements of section 236.

Sincerely yours,

Elmer B. Staats

Comptroller General
of the United States

Contents

ABBREVIATIONS

BRH	Bureau of Radiological Health
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
RCH&S Act	Radiation Control for Health and Safety Act
TEPRSSC	Technical Electronic Product Radiation Safety Standards Committee

COMPTROLLER GENERAL'S
REPORT TO
THE HONORABLE EDWARD I. KOCH
HOUSE OF REPRESENTATIVES

EXTENDING EFFECTIVE DATE OF THE FOOD AND DRUG ADMINISTRATION's DIAGNOSTIC X-RAY EQUIPMENT STANDARD

Department of Health, Education, and Welfare B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

GAO was asked to look into the Food and Drug Administration's (FDA's) extension of the effective date of its diagnostic X-ray equipment standard. It also was asked for

--information on applicability of the standard to existing X-ray equipment (equipment manufactured before effective date of the standard) and

--an opinion from the Department of Health, Education, and Welfare(HEW) as to whether diagnostic X-ray equipment could be regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, which requires a new drug introduced into interstate commerce to be safe and effective.

FINDINGS AND CONCLUSIONS

The Radiation Control for Health and Safety Act of 1968 (RCH&S Act) was enacted to protect the public from unnecessary exposure to harmful radiation emitted by electronic products.

The act provides for establishment of a program which includes developing and administering performance standards to control radiation from electronic products.

FDA, a constituent agency of HEW, is responsible for administering the RCH&S Act. FDA's Bureau of Radiological Health (BRH) carries out the daily operations of FDA's electronic product radiation control program.

In 1968 BRH began developing a regulatory standard covering diagnostic X-ray equipment. It submitted drafts to professional and scientific associations; Federal, State, and local radiation control agencies; and X-ray equipment manufacturers for their written comments. The proposed standard was revised on the basis of these comments. (See p. 2.)

This standard was published in its final version in the August 15, 1972, Federal Register and was to become effective on August 15, 1973.

On June 12, 1973, however, the Commissioner, FDA, extended the effective date of the standard to August 1, 1974. (See p. 3.)

FDA's basis for extension

FDA extended the effective date of its standard to insure the uninterrupted availability of X-ray diagnostic services to the public.

On the basis of comments from interested parties, FDA determined that adherence to the original effective date of the standard would have resulted in shortages of diagnostic X-ray equipment and disruptions to State radiation control programs. This could have adversely affected the delivery of medical care to the public.

X-ray equipment manufacturers claimed they needed additional lead-time to develop and redesign X-ray equipment which would comply with the standard. The majority of manufacturers who commented requested that the standard's effective date be extended from 3 to 26 months. (See p. 5.)

State and local radiation control agencies also wanted an extension. In most cases State regulations would have to be amended to comply with the requirements of the RCH&S Act and to maintain effective controls on equipment after its installation. (See p. 6.)

FDA estimated that, during the first month following the standard's implementation in August 1973, only about 500 new acceptable X-ray units could have been manufactured. This represents only about half the average monthly sales volume of such units.

On the basis of FDA's analysis, the availability of new acceptable X-ray units would progressively improve each month. However, it would require about 1 year for the units' supply to equal the established average monthly sales of X-ray units. Because the standard could affect the availability of X-ray components, the need for an extension also applied to them. (See p. 7.)

According to BRH, the standard had created some confusion among manufacturers and State and local radiation control agencies that could have seriously affected the delivery of medical care. (See p. 8.)

BRH did not provide timely guidance to manufacturers

BRH delays in responding to manufacturers' requests for interpretations of the standard, and in effecting timely publication of guidelines explaining the standard's requirements, contributed to the need to extend the effective date. These delays were caused by the large number of requests concerning the standard, the technical complexity of many of them, and the limited staff available to respond. (See p. 9.)

Not until February 1973 (16 months after the proposed standard's publication and 6 months after the publication of the final version) did BRH provide manufacturers with guidelines on the requirements of the standard. (See p. 9.)

FDA plans to issue additional standards covering other radiation-emitting electronic products. FDA should, to the extent feasible, provide specific guidelines explaning requirements when the standards are promulgated. This could contribute to more timely and effective implementation of the standards.

Existing equipment not covered by standard

The diagnostic X-ray equipment standard, which has been promulgated under authority of the RCH&S Act, will apply to all diagnostic X-ray equipment manufactured after August 1, 1974.

According to FDA, equipment manufactured before this date will not

have to comply with the standard because it is not reasonable or technically feasible. (See p. 13.)

FDA proposed amendments to the standard requiring all diagnostic X-ray equipment reassembled, rebuilt, or refurbished on or after August 1, 1974, to comply with the standard. After comments from manufacturers, State and local agencies, physicians, and others, however, FDA determined that the applicable date for proposed amendments should be revised from August 1, 1974, to August 1, 1979.

Adherence to the August 1, 1974 date could have led to a reduction in availability of diagnostic X-ray services in areas unable to afford the purchase of new equipment. FDA concluded that it would be in the public interest to allow a gradual phasing out of noncertified components and subsystems.

As revised, the amendments provide that on or after August 1, 1979, major components installed into any existing system in the process of assembling, reassembling, rebuilding, or repair must be certified as being in conformance with the standard. Also, on or after that date, all units which are sold, moved to a different location, and reassembled would have to comply with the standard. (See p. 14.)

HEW's opinion on applicability of FD&C Act to medical X-ray equipment

GAO asked HEW's Assistant General Counsel, Food and Drug Division, whether diagnostic X-ray equipment could be regulated under section 505 of the FD&C Act, as amended, which requires FDA's approval of a new drug's safety and efficacy before it is introduced into interstate commerce.

HEW's Assistant General Counsel said it is not possible to provide a definitive opinion on this matter because it has never been the subject of court adjudication. He stated, however, that it appears X-ray machines would fall within the category of basic aids used in a hospital's routine operation and thus would be regarded as devices rather than as drugs. (See p. 17.)

RECOMMENDATION

The Secretary of HEW should direct the Commissioner, FDA, to provide, where feasible, specific guidelines explaining requirements of future standards covering radiation-emitting electronic products at the time such standards are promulgated. (See p. 11.)

AGENCY ACTIONS AND UNRESOLVED ISSUES

HEW concurred with GAO's recommendation and advised GAO that the Department's policy is to develop standards that are technically and legally sound and to insure that all essential requirements are fully explained to interested parties prior to promulgation.

HEW pointed out, however, that the diagnostic X-ray standard presented unusual problems in technical development and that the problems involved in its promulgation resulted from the unusual complexity of the standard.

HEW said the FDA procedures will provide for adequate and timely guidance for future standards. (See p. 12.)

CHAPTER 1

INTRODUCTION

In a July 14, 1973, letter, Congressman Edward I. Koch asked us to obtain certain information concerning the Food and Drug Administration's (FDA's) extension of the effective date for its diagnostic X-ray equipment standard. In addition, we were to obtain (1) information on the standard's applicability to existing X-ray equipment (equipment manufactured before the standard's effective date) and (2) an opinion from the Department of Health, Education, and Welfare (HEW) as to whether diagnostic X-ray equipment could be regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended (21 U.S.C. 301). The section requires FDA's approval of a new drug's safety and efficacy before it is introduced into interstate commerce.

FDA's REGULATION OF X-RAY EQUIPMENT

FDA, a constituent agency of HEW, is responsible for administering the Radiation Control for Health and Safety Act of 1968 (RCH&S Act), (42 U.S.C. 263b), which was enacted to protect the public from unnecessary exposure to harmful radiation emitted by electronic products. The RCH&S Act defines radiation as

--any ionizing or nonionizing electro-magnetic or particulate radiation; or

--any sonic, infrasonic, or ultra-sonic wave which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

Under the RCH&S Act, FDA must establish an electronic-product radiation control program. This program includes (1) the development and administration of performance standards controlling the radiation emitted from electronic products and (2) the support of research by public and private organizations of the effects and control of the emissions.

FDA's Bureau of Radiological Health (BRH)[1] is responsible for carrying out the day-to-day operations of FDA's electronic-product radiation control program.

DEVELOPMENT OF DIAGNOSTIC X-RAY EQUIPMENT STANDARD

Before the enactment of the RCH&S Act, BRH had begun development of a voluntary performance standard for diagnostic X-ray equipment. As a result of the act, material developed as part of the voluntary standard was to be used as part of a mandatory standard. By September 1969 BRH had completed a preliminary draft of the proposed mandatory standard.

During the standard's development, BRH submitted drafts of the proposed standard to professional and scientific associations, Federal and State agencies, and manufacturers for their consideration and written comments. BRH considered the views and recommendations of the organizations and individuals whose comments had been solicited and made several technical and procedural revisions to the proposed standard.

BRH's draft was submitted to the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) for review and comment at its meeting on March 15 and 16, 1971. The Committee, which was established pursuant to the RCH&S Act, is composed of 15 members; five each from government agencies, industry, and the general public. The members must be qualified in the technical aspects of electronic-product radiation safety by training and experience in one or more fields of science or engineering. BRH is required under the RCH&S Act to consult with TEPRSSC before prescribing any standard. The Committee reviews all proposed standards and makes recommendations to BRH for improvement.

In an April 29, 1971, letter, the Chairman, TEPRSSC, submitted the Committee's comments to BRH. In May 1971 BRH revised the proposed standard taking the comments into consideration.

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[1]BRH became a part of FDA in May 1971. Before May 1971 BRH was a part of HEW's Environmental Health Service and until December 1968, it was called the National Center for Radiological Health.

On October 8, 1971, the proposed performance standard was published for public comment in the Federal Register. A 60-day official comment period was provided to give interested parties time to comment and submit evidence of objections, if any, to the standard. BRH received written comments from 61 individuals and organizations, including X-ray equipment manufacturers. In general, the proposed standard was favorably received and the proposed effective date was not challenged by any manufacturer during the official comment period.

BRH again revised the proposed standard on the basis of comments received during the 60-day public comment period. The revisions included clarification of the standard's intent and provisions for alternate means of achieving the same degree of radiation protection.

The standard requires that diagnostic X-ray equipment manufactured after the effective date incorporate certain new radiation control features, such as collimators which restrict the X-ray beam to the area of clinical interest, to reduce patient and operator exposure during X-ray examinations. In addition the standard provides that manufacturers of diagnostic X-ray equipment meet certain product labeling and reporting requirements. The RCH&S Act defines a manufacturer as any person engaged in the business of manufacturing, assembling, or importing radiation-emitting electronic products.

The standard was published in its final version in the August 15, 1972, Federal Register and was to become effective 1-year after final publication.

On June 12, 1973, the Commissioner, FDA, by publishing an official notice in the Federal Register, extended the effective date of the standard to August 1, 1974.

CHAPTER 2

FDA's BASIS FOR EXTENSION

FDA extended the effective date of its diagnostic X-ray equipment standard from August 15, 1973, to August 1, 1974, to insure the uninterrupted availability of X-ray diagnostic services to the public. FDA determined that adherence to the original effective date would have resulted in shortages of diagnostic X-ray equipment and disruptions to State radiation control programs in the year after the standard's implementation that could have adversely affected the delivery of medical care.

Although the potential equipment shortage and its effect on the delivery of medical care were primary considerations for extending the effective date of the standard, it appears that FDA's delay in providing detailed guidelines, requested by equipment manufacturers, also contributed to the need to extend the effective date of the standard.

REQUESTS FOR EXTENSION

In February 1973 the National Electrical Manufacturers Association and several X-ray equipment manufacturers requested that the Commissioner, FDA, extend the effective date of the standard. The manufacturers claimed they needed additional leadtime to develop and redesign X-ray equipment which would comply with the standard. They said they could not provide equipment that complied with the standard by August 1973, and, if an extension was not granted, there would be equipment shortages which could adversely affect the availability of health care to the public.

In a March 9, 1973, letter, BRH solicited evidence and rationale for or against extending the effective date from about 100 equipment manufacturers, manufacturers' associations, and national public and professional groups, including medical and dental associations and State radiation control agencies. BRH also invited representatives from the various organizations to attend a meeting on March 30, 1973, to further discuss the matter.

On the basis of responses to its March 9 letter and on testimony offered during the March 30 meeting, BRH believed that implementing the standard in August 1973 would pose

some problem for the manufacturers. However, insufficient detailed information had been presented to document the expected effect. Therefore, on April 17, 1973, BRH sent a second letter to manufacturers, State radiation control agencies, and others requesting more specific and technical information.

During the entire evaluation period, written responses were received from 55 individuals or organizations, and 26 persons testified at the March 30, 1973, meeting.

Responses from manufacturers

Of the 35 manufacturers and related organizations which responded, 27 manufacturers, 1 manufacturers' association, and the Veterans Administration Supply Service[1] requested an extension of the standard's effective date. The requests were for extensions from 3 to 26 months--12 were for 1 year or more, 6 were for 3 to 6 months, and the other 11 did not indicate a time period. The remaining six manufacturers either stated they did not need an extension or did not indicate whether one was needed.

The manufacturers indicated that an extension was needed mainly to

--obtain BRH's interpretation of the standard and clarification regarding acceptable test methods for certification of X-ray equipment,

--develop and redesign X-ray equipment to comply with the standard,

--develop instructions and manuals for users and assemblers of equipment,

--train equipment assemblers, and

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[1]For purposes of this report we have categorized the Veterans Administration Supply Service as a manufacturer because its mission is to refurbish diagnostic X-ray equipment used in Veterans Administration hospitals.

--develop and submit required control and model change reports to BRH.

Also, manufacturers indicated that, if the standard had gone into effect on August 15, 1973, there would have been a shortage of both complete X-ray units and components and subsystems. Complete X-ray units include equipment which is sold in an assembled form, such as mobile radiographic, mobile fluoroscopic, dental, podiatric, and mammographic units. Major components include tube housing assemblies, generators, controls, and beam limiting devices. Subsystems include groups of components sold by manufacturers as single catalog items, such as tables with attached radiographic and fluoroscopic image receptors.

Responses from State and local radiation control agencies

Eighteen State and local radiation control agencies submitted comments to BRH concerning the effective date of the X-ray standard. Of these, 16 expressed support for extending the effective date. Six requested a 1-year extension, and 10 did not specify a time period.

The agencies favoring the extension indicated that it was needed primarily to

--clarify the provisions of the standard and the relationship between the State and Federal requirements, including the State's role in implementing the Federal standard;

--revise State regulations to conform to the Federal standard as required by the RCH&S Act;

--develop enforcement programs designed to insure compliance with the standard; and

--assess the adequacy of the supply of certified X-ray equipment to meet the health needs in the State.

The two agencies which opposed the extension asserted that the industry was generally prepared to meet the standard and that if an extension was granted it should be granted only with respect to selected provisions of the standard.

Responses from others

Two professional medical associations commented on the effective date of the standard. The American Dental Association did not favor an extension on the grounds that it would delay the benefits of safer equipment to dental patients. The Association indicated, however, that postponement of the standard's implementation could be appropriate if adherence to the August 15, 1973, effective date would restrict the use of X-rays as a diagnostic tool in dentistry.

The American College of Radiology had no objections to extending the effective date if such an extension would result in a significant improvement in the ability of the X-ray industry to provide equipment which met the technical provisions of the standard and the primary objectives of the radiologist for clinical service and versatility. However, it would be concerned if an extension of the effective date resulted in "unloading" nonconforming equipment, which could not be modified to meet the standard on the market.

FDA'S RATIONALE FOR EXTENSION

On September 27, 1973, the Director, BRH, told us many manufacturers did not adequately evaluate the requirements, or the total effect, of the new standard. The Director stated that, on the basis of FDA's evaluation of data submitted by manufacturers, it became clear that the manufacturers could not produce equipment which would comply with the standard by August 1973.

FDA believed that implementing the standard in August 1973, as originally intended, would have resulted in equipment shortages that could have adversely affected the delivery of medical care to the public. For example, FDA estimated that during the first month after such implementation only about 500 new X-ray systems, which would comply with the standard, could have been manufactured. This represents only 50 percent of the average monthly sales volume of such systems. Therefore, 50 percent of these systems that normally would have been available for sale would not have been available. On the basis of FDA's analysis, the availability of new X-ray systems would progressively improve with each succeeding month. However, it would require about a year for the supply of certified systems to equal the established average monthly sales of X-ray systems. Because the standard could affect the availability of X-ray components, the need for an extension also applied to them.

Recognizing the need for adequate supplies of certified X-ray equipment, FDA has urged manufacturers to make every effort to provide this equipment at the earliest practical date. By announcement in the July 31, 1973, Federal Register the Commissioner, FDA, established a policy providing for early certification of new X-ray equipment. The Director, BRH, told us the extension of the standard's effective date would be mitigated by the degree to which manufacturers are able to use the provision for early certification. As of May 1974 two manufacturers had certified X-ray equipment under this provision.

According to the Director, the States are expected to help provide support to the Federal Government in enforcing compliance with the Federal standard through State inspections. BRH was concerned that these inspections would have required State radiological health protection agencies to curtail other radiological health protection activities.

Section 360(F) of the RCH&S Act requires that State regulations which are applicable to the same aspect of performance of an electronic product must be identical to the Federal standard. In most cases, State regulations would have to be amended to comply with the requirements of the RCH&S Act and to maintain effective controls on equipment after its installation. Comments submitted by the States to BRH indicated that about 1 year would be required for the completion of such amendments and the establishment of enforcement capabilities.

According to BRH, the standard had created some confusion on the part of manufacturers and State and local radiation control agencies that could have adversely affected delivery of medical care to the public. BRH concluded that this risk did not appear justified when considering the probability that, in the short run, the unnecessary radiation exposure to the public could be expected to be relatively small. This was especially evident when measured against the possible long-run adverse effect on the delivery of medical care that could have resulted had the effective date of the standard not been extended.

BRH believed, therefore, the extension was necessary to be able to provide clarification and to develop guidelines concerning various elements of the standard, including required

test procedures. Also the extension was intended to give State and local agencies sufficient time to develop enforcement procedures and to train personnel in implementing these procedures.

BRH DID NOT PROVIDE TIMELY GUIDANCE TO MANUFACTURERS

BRH delays in responding to manufacturers' requests for interpretations of the diagnostic X-ray equipment standard and in effecting timely publication of guidelines, which explain the standard's requirements, contributed to the need to extend the effective date. These delays were caused by the large number of requests concerning the standard, the technical complexity of many of them, and the limited staff available to respond.

It was not until February 1973 (16 months after the proposed standard's publication and 6 months after the publication of the final version) that BRH provided X-ray equipment manufacturers with guidelines on the requirements of the standard. The guidelines were presented in two documents.

One document, entitled "Interpretations On The Performance Standard For Diagnostic X-Ray Systems, 21 CFR, Part 278.213," contains answers to the various questions which had been posed by manufacturers. The other document, entitled "A Guide For The Submission Of Information On Diagnostic X-Ray Systems And Their Major Components That Are Applicable To The Performance Standard, 21 CFR, 278.213," outlines reporting and record-keeping requirements.

Several manufacturers in requesting an extension of the effective date of the standard complained that delays in getting official answers to questions from FDA involving the standard's interpretations made it impossible for them to meet the standard's requirements by August 15, 1973. At the March 30, 1973, meeting with FDA, a number of manufacturers said they were still unsure of the standard's requirements.

One of the largest manufacturers complained that written interpretations which it had received from BRH differed from verbal ones enough to necessitate new technical approaches to several diagnostic X-ray products. In a February 26, 1973, letter to the Commissioner, FDA, the general manager of the X-ray systems department of this manufacturer stated:

"[The company] on September 29, 1972, submitted a letter to the Bureau of Radiological Health requesting clarification of the rules and standards. In verbal discussions with BRH personnel on September 25th relative to these questions, certain interpretations were expressed which BRH cautioned were not official. Lacking any ability to get better information, [the company] had to proceed on design changes based on these interpretations. When final official answers were received in the BRH letter of January 18, 1973, five (5) answers were different from the original interpretations expressed at the September 25, 1972, meeting.

"As a result of these answers, [the company] is replanning and rescheduling many products to allow design time for incorporation of additional changes. * * *."

In its February 26, 1973, letter, the manufacturer also commented that:

"On February 9, 1973, the Bureau of Radiological Health issued a letter * * * attaching a "Guide for the Submission of Information on Diagnostic X-Ray Systems and Their Major Components, etc." The letter states that the BRH will not allow a manufacturer to certify an X-ray product as meeting requirements unless the Bureau has reviewed and judged adequate a report submitted in the format of the guideline, including paragraph titling and numbering. The letter further requires the resubmission of all previously submitted reports on those models which are to be certified, in accordance with the guideline. Both the format and content of the Guide and the requirement for approval by the Bureau of Radiological Health prior to certification represent new interpretations and possibly amendments to the regulations.

"The Guide is an entirely new requirement and does not fit at all the format that [the company] has used in the past years to prepare initial and annual reports for the Bureau. There will be approximately 40 or 50 reports of from 15 to 30

pages each, plus all publications and instructions indexed properly to cover our product scope. This is a massive job requiring approximately 6 man-years of specialized engineering effort before approximately mid-year, 1973 (to allow Bureau time for evaluation and decisions and, if favorable, for [the company] to issue Change Notices to control application of certification labels before August 15, 1973). We have no assurance that the Bureau will be able to review these submittals prior to the date of August 15."

CONCLUSIONS

On the basis of its analysis of information presented by X-ray equipment manufacturers, FDA determined that about a 1-year extension of the effective date of its diagnostic X-ray equipment standard was necessary to insure the uninterrupted availability of X-ray diagnostic services to the public. FDA concluded that adherence to the August 15, 1973, effective date would have resulted in equipment shortages and disruptions to State radiation control programs that could easily have adversely affected the delivery of medical care. According to FDA, the risk of provoking such an effect did not appear justified when considering the probability that, in the short run, any unnecessary radiation exposure to the public caused by the extension could be expected to be relatively small.

FDA's delays in responding to manufacturers' requests for interpretation of the standard and in effecting timely publication of guidelines detailing requirements of the standard contributed to the need to extend the standard's effective date. Since FDA plans to issue additional standards covering other radiation-emitting electronic products, to the extent feasible, it should provide guidelines explaining requirements of the standard at the time the standards are promulgated. This could contribute to more timely and effective implementation of the standard.

RECOMMENDATION TO THE SECRETARY OF HEW

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to provide, where feasible, specific guidelines explaining requirements of future standards covering radiation-emitting electronic products at the time such standards are promulgated.

AGENCY COMMENTS

HEW concurred with our recommendation and advised us that the Department's policy is to develop standards that are technically and legally sound and to insure that all essential requirements are fully explained to interested parties before promulgation. (See app. I.)

HEW pointed out, however, that the diagnostic X-ray standard presented unusual problems in technical development because several levels of manufacturers were involved, ranging from large electronic component suppliers to many small end-product assemblers. In addition, according to HEW, the variety of equipment covered by the standard caused some misinterpretation of the applicability of the standard.

HEW said that the FDA procedures will provide for adequate and timely guidance for future standards.

CHAPTER 3

EXISTING EQUIPMENT NOT COVERED BY STANDARD

The RCH&S Act provides FDA with authority to set standards for radiation emitting electronic products. Section 358(a)(1)(C) of the RCH&S Act provides that FDA, in prescribing a performance standard, should give consideration to the reasonableness and technical feasibility of such standard as applied to a particular electronic product.

The diagnostic X-ray equipment standard, which has been promulgated under authority of the RCH&S Act, will apply to all diagnostic X-ray equipment manufactured on or after August 1, 1974, the standard's effective date. According to FDA, existing equipment (manufactured before August 1, 1974) will not have to comply with the standard because it is not reasonable or technically feasible to require all such equipment to comply. Accordingly, FDA has proposed amendments to revise the standard to provide a phased upgrading of existing equipment.

PROPOSED REVISIONS TO STANDARD

Since the promulgation of the diagnostic X-ray standard, questions arose regarding its applicability to existing diagnostic X-ray equipment which is subsequently rebuilt or reassembled on or after August 1, 1974. To clarify this matter, FDA proposed the addition of two new sections (21 CFR 278.102 and 21 CFR 278.103) to 21 CFR 278[1] to amend the standard to require all diagnostic X-ray equipment reassembled, rebuilt, or refurbished on or after August 1, 1974, to comply with the standard.

Proposed section 278.102, Policy on Assembly of Diagnostic X-ray Equipment, would require that components sold to a purchaser and assembled into an existing diagnostic X-ray system on or after August 1, 1974, be only those components which have been certified by the manufacturers to be in conformance with the standard.

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[1]Effective October 15, 1973, 21 CFR 278 was recodified as 21 CFR 1000.

Proposed section 278.103 addressed the applicability of the standard to diagnostic X-ray equipment originally assembled before August 1, 1974, but subsequently rebuilt or reassembled on or after that date. Under this section rebuilding, refurbishing, or reassembly of X-ray equipment, except for the reassembly of a system in a new location without an associated change of ownership, would be considered manufacturing within the meaning of the RCH&S Act, and, therefore, such equipment would be required to comply with the standard.

The proposed new sections were published in the Federal Register of February 28, 1973, for public review and comment. On the basis of comments from manufacturers, State and local radiation control agencies, physicians, and others, the applicable date for the proposed amendments was revised from August 1, 1974, to August 1, 1979.

Comments received on proposed amendments

Fifteen letters commenting on the proposed section 278.102 were received. Of these, 11 were from manufacturers of diagnostic X-ray equipment or their associations, and 4 were from State and local radiation control agencies. The letters from manufacturers generally opposed the amendment on the grounds that it would not allow the installation of uncertified components sold to a purchaser after the August 1, 1974, effective date. Certain components are specifically made for particular model machines and, therefore, in many cases, certified components could not be readily adapted to fit existing equipment. Several manufacturers asserted that they anticipated financial losses from inventories of uncertified equipment and that these losses would lead to a cost increase of their products to the medical community.

Two State and local radiation control agencies opposed the amendment for reasons similar to those stated by manufacturers, and two suggested modifications for the purpose of clarification.

A total of 169 letters were received commenting on the proposed section 278.103 from physicians, physicians' organizations, State and local radiation control agencies, manufacturers, professional associations, and others.

One hundred and eight letters, which were received from physicians and physicians' organizations, almost unanimously opposed the proposed amendment because upgrading current equipment to meet the standard was not considered possible or economically feasible. Therefore, uncertified equipment requiring rebuilding or reassembly after the effective date of the standard would have to be discarded, resulting in the total loss of trade-in value. The major concern was that the policy would seriously reduce the availability of older X-ray equipment for use in low workload facilities, such as those located in rural areas, which cannot afford new equipment. This would result in a serious impairment of medical care in these areas.

Thirty-six representatives of State and local radiation control agencies expressed similar objections. They were also concerned that the proposal would discourage owners of X-ray equipment from adding improvements since this action might be considered rebuilding and might necessitate upgrading the entire unit to meet all the requirements of the standard. Two agencies favored the proposed amendment.

The remainder of those commenting generally expressed the opinion that some requirements concerning "remanufactured" equipment should be adopted.

FDA's evaluation of comments

After assessing the comments received from various interested parties, FDA concluded that the proposed amendments should be revised. FDA was particularly concerned with section 278.103, as proposed, because it could have led to the removal from service of some recently manufactured useful equipment which would normally be resold and reassembled. This, according to FDA, could have led to a reduction in the availability of diagnostic X-ray services in areas unable to afford the purchase of new equipment.

Representatives of the medical profession said X-ray equipment has a normal useful life of 5 to 7 years in high

workload facilities, such as those located in metropolitan area hospitals. They also said that the sale of X-ray units from these facilities constitutes a major source of X-ray equipment for use in rural areas and private practice.

Therefore, FDA concluded that, to insure the continued availability of equipment to such areas, 5 years after the August 1, 1974, effective date of the standard should be allowed in which noncertified components could be assembled or reassembled into systems which do not contain certified components. After this time, only certified components would be allowed to be assembled or reassembled into a diagnostic X-ray system. FDA anticipates that within 5 years most equipment in use in high workload facilities would be certified, and because these facilities are the major source for used equipment, eventually equipment in all facilities will be upgraded. FDA believes that it would be in the public interest to allow a gradual phasing out of noncertified components and subsystems.

Accordingly, FDA has revised the proposed amendments to allow owners of noncertified equipment to install noncertified components until August 1, 1979. On or after August 1, 1979, any major components installed into any system in the process of assembly, reassembly, rebuilding, or repair must be certified.

The revised amendments were published for public review and comment in the Federal Register of December 3, 1973. As of May 14, 1974, FDA was considering the comments received on the revised amendments.

CHAPTER 4

HEW'S OPINION ON APPLICABILITY OF FD&C ACT TO MEDICAL X-RAY EQUIPMENT

Since radiation penetrates the body when a patient is exposed to it, we asked HEW's Assistant General Counsel, Food and Drug Division, whether diagnostic and therapeutic X-ray equipment could be regulated for safety and efficacy under section 505 of the FD&C Act, as amended. (See p. 1.)

In an October 4, 1973, letter, HEW's Assistant General Counsel informed us that it is not possible to provide a definitive opinion on this matter because it has never been the subject of court adjudication. He stated, however, that X-ray machines would fall within the category of basic aids used in a hospital's routine operation and thus would be regarded as devices rather than as drugs.

He also said there would be little reason to reclassify X-ray machines as drugs rather than devices, since the RCH&S Act provides for sound regulatory control of such machines. He pointed out that a brief review of the legislative history of the FD&C Act indicates that, in a few places, X-ray machines were referred to as devices. From 1938 to the present, FDA has regulated X-ray machines as devices; and, in view of the existing and longstanding interpretation, a court might well be reluctant to permit FDA to reclassify the products under the FD&C Act.

According to the Assistant General Counsel, under a controlling Supreme Court decision, the fact that something penetrates the body is not dispositive of its proper classification under the FD&C Act as many devices and cosmetics penetrate the body.

CHAPTER 5

SCOPE OF REVIEW

In our review, performed at FDA headquarters in Rockville, Maryland, we reviewed

--legislation, regulations, policies, procedures, and practices relating to FDA's radiological health programs;

--records and reports on FDA's action in extending the effective date of its diagnostic X-ray equipment standard and its proposed revisions to the standard concerning existing equipment; and

--comments of manufacturers, State and local radiation control agencies, and others concerning FDA's X-ray standard.

We also

--interviewed FDA officials in BRH responsible for the radiological health activities discussed in this report; and

--obtained the views of HEW's Assistant General Counsel, Food and Drug Division, as to whether diagnostic X-ray equipment could be regulated under section 505 of the FD&C Act.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

JUL 25 1974

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for comments on your draft report entitled, "Implementation of the Food and Drug Administration's Diagnostic X-Ray Equipment Standard and Related Matters." Our comments are enclosed.

Thank you for the opportunity to comment on this report in draft form.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

APPENDIX

DEPARTMENT COMMENTS ON THE GAO DRAFT REPORT TO CONGRESS ENTITLED
IMPLEMENTATION OF
THE FOOD AND DRUG ADMINISTRATION'S
DIAGNOSTIC X-RAY EQUIPMENT STANDARD
AND RELATED MATTERS

GAO RECOMMENDATION

The Secretary of HEW should direct the Commissioner, FDA, to provide, where feasible, specific guidelines explaining requirements of future standards covering radiation emitting electronic products at the time such standards are promulgated.

DEPARTMENT COMMENT

We concur. The Department's policy is to develop standards that are technically and legally sound and to insure that all essential requirements are fully explained to interested parties prior to promulgation. The diagnostic x-ray standard presented unusual problems in technical development because several levels of manufacturers were involved, ranging from large electronic component suppliers to many small end product assemblers. In addition, the variety of equipment covered by this standard caused some misinterpretation of the applicability of the standard. The report discusses these problems and the actions taken by the Food and Drug Administration to insure that all parties involved in the standard were aware of its requirements.

We believe that the problems involved in the promulgation of the diagnostic x-ray standard resulted from the unusual complexity of this standard and that the procedures of the Food and Drug Administration will provide for adequate and timely guidance for future standards.