DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[DOCKET NO. 95D-0014]

Draft Proposed Regulations on Quality Standards and Certification Requirements for Mammography Facilities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of draft proposed regulations.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft proposed regulations prepared by the Center for Devices and Radiological Health (CDRH) to implement the Mammography Quality Standards Act of 1992 (MQSA). The drafts contain minimum quality standards for mammography facilities in the following areas: Personnel standards, medical outcomes audits, medical records and mammography reports, quality assurance, mobile mammography, accreditation bodies, implant imaging, mammography equipment, variances, consumer complaint mechanism, and quality control. The proposed regulations are being developed to implement the MQSA (Pub. L. 102-539), which was enacted to establish quality standards for mammography. The MQSA requires that, to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be both accredited by an approved accrediting body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accrediting bodies and to certify facilities has been delegated by the Secretary to FDA.

Pursuant to authorization from Congress, FDA promulgated interim regulations to ensure that mammography facilities meet minimum quality standards. These regulations, which were published in the Federal Register on December 21, 1993 (58 FR 67558 and 58 FR 67565), and amended on September 30, 1994 (59 FR 49808), became effective on October 1, 1994, and will remain in effect until final regulations are promulgated.

FDA is currently developing proposed regulations for quality standards in various subject areas, including the 11 areas referenced above. Under the MQSA, FDA established a National Mammography Quality Assurance Committee (NMQAC) to advise the agency on the appropriate level of quality standards for mammography facilities and accrediting bodies. Advanced drafts of proposed regulations are provided routinely to all members of the advisory committee for their advice and recommendation, and periodic public meetings of the advisory committee are being held.

An advisory committee meeting was held on January 23 through January 25, 1995. The meeting was announced in the Federal Register of December 21, 1994 (59 FR 65776). It was held at the Dupont Plaza Hotel, Embassy Room, 1500 New Hampshire Ave. NW., Washington, D.C.

In order to gather additional information on these particular topics, FDA decided to share the drafts of these proposed regulations with certain individuals who were invited as guests to the January 23 through 25, 1995, advisory committee meeting to enable them to provide comments at the meeting on the feasibility of efficient implementation of these draft proposed standards by the radiology community. These invited guests have particular expertise in one or more of the areas addressed by the draft proposals. The agency is publishing this notice in order to make the same draft documents available to the general public.

Although all members of the general public will have an opportunity to comment on the proposed regulations when they are published in the spring of 1995, interested persons who wish to comment on the draft proposals may submit written comments to the Dockets Management Branch (address above) on or before April 11, 1995. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft proposed regulations and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA will consider any comments received in developing final regulations. Dated: January 23, 1995.

William K. Hubbard, Interim Deputy Commissioner for Policy.

Federal Register / Vol. 60, No. 17 / Thursday, January 26, 1995 / Proposed Rules
guidance regarding the program and specifically delineates the prohibition on participation by violent offenders. Detailed program guidelines and application materials for the Fiscal year 1995 Drug Court Program will be available in early 1995.

DATES: All comments must be received by February 27, 1995.

ADDRESSES: All comments should be addressed to Reginald L. Robinson, Deputy Assistant Attorney General, Office of Justice Programs, 633 Indiana Avenue NW, Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: The Department of Justice Response Center at 1-800-421-6770 or (202) 307-1480.

SUPPLEMENTARY INFORMATION:

Overview of Title V-Drug Courts

Federal discretionary grants are being made available under the Violent Crime Control and Law Enforcement Act of 1994, Title V, Public Law 103-322, 108 Stat. 1796 (September 13, 1994), 42 U.S.C. 3796ii-3796ii-8 [hereinafter the “Act”] to states, units of local government, Indian tribal governments, and state and local courts for assistance with drug court programs. The Act gives the Attorney General and, through statutory authority contained in the Omnibus Crime Control and Safe Streets Act, an authorized designee (in this case the Assistant Attorney General for the Office of Justice Programs), the authority to make grants to the above mentioned entities for drug court programs that involve continuing judicial supervision over non-violent offenders with substance abuse problems and the integrated administration of sanctions and services including: (1) mandatory periodic testing for the use of controlled substances or other addictive substances during any period of supervised release or probation for each participant; (2) substance abuse treatment for each participant; (3) diversion, probation, or other supervised release involving the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress; and (4) programmatic, offender management, and aftercare services such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each participant requiring such services.

Section 50001 of Title V of the Act requires that regulations be issued to ensure exclusion of violent offenders from the inclusion of violent offenders in programs. This proposed rule responds to that requirement. To more fully develop and define the grant program and to provide direction and guidance to potential applicants, program guidelines will be issued subsequent to the publication of this proposed rule. This Supplementary Information section is intended, in part, to elicit comment on a broad range of issues relevant to the development and implementation of those program guidelines.

Statement of the Problem

More than half of all individuals brought into the criminal justice system have substance abuse problems. Many of these individuals are non-violent offenders who repeatedly cycle through the court, corrections and probation systems without help to change their behavior. The underlying problem of such non-violent substance abuse abuse and coexists. This non-violent drug offender faces little certainty of punishment and represents a long term recurring problem for both the criminal justice system and society.

In too many cases, the criminal justice system fails to subject non-violent, drug abusing offenders to intervention measures that provide the mix of services and sanctions necessary to change their behavior or, if necessary, coerce abstinence. Some courts and prosecutors, however, have cost-effectively addressed the problem through the use of treatment drug courts. Their results suggest that “drug courts” can significantly enhance the offender’s opportunity to break the cycle of substance abuse and crime. Those who are coming into contact with the criminal justice system for the first time may be particularly susceptible to effective early intervention.

Indeed, research and evaluation demonstrate that the “drug court” approach is effective in reducing both drug abuse and drug-related crime. The Drug Court discretionary grant program of Title V seeks to support the development of innovative measures that provide courts additional resources to assure certainty of punishment for drug abusing offenders through the integrated administration of services and sanctions, including close supervision and coerced abstinence.

The Violent Crime Control and Law Enforcement Act of 1994

The Department of Justice (Department) recognizes that no single model exists for an effective drug court. To the contrary, the Department believes there may be a variety of valid approaches that may be effective with non-violent offenders with substance abuse problems. Consequently, the Drug Court grant program will maintain flexibility in providing funds to support the development of a variety of initiatives that coordinate treatment and coerced abstinence.

The Department also recognizes the great diversity in the structure and operation of state and local courts and criminal justice systems. Hence, the Department is committed to a flexible approach that allows jurisdictions to tailor local initiatives to best suit their needs and local conditions. Program flexibility, however, is necessarily balanced by statutory requirements concerning the design and administration of the funded programs. Accordingly, Drug Court programs that receive grant awards must:

- Exclude violent offenders from program participation;
- Include a long-term strategy and detailed implementation plan;
- Explain the applicant’s inability to fund the program adequately without federal assistance;
- Use federal support to supplement, and not supplant, State, Indian Tribal, and local sources of funding that would otherwise be available;
- Identify related governmental or community initiatives which complement or will be coordinated with the proposal;
- Consult with all affected agencies and insure that there will be appropriate coordination with all affected agencies in the implementation of the program;
- Certify that participating offenders will receive continuing judicial supervision by one or more designated judges with responsibility for the drug court program;
- Specify plans for obtaining necessary support and continuing the proposed program following the conclusion of Federal support; and
- Describe the methodology that will be used in evaluating the program.

Consistent with Congressional intent, program evaluation will be crucial. Grant recipients will be required to cooperate with a national evaluation team throughout their involvement with the program. Recipients will also be required to provide for independent evaluation of the impact and effectiveness of their funded programs. The following issues will be especially important in determining whether programs receiving grants under this initiative are effective: (1) Reduction in recidivism rates of program participants, (2) maintenance of acceptable substance abuse treatment completion rates among program participants, (3) decreased drug use by program participants, and (4) maintenance of a cost effective program.
in relation to the overall criminal justice system.

**FY 1995 Drug Court Initiative**

The Fiscal Year 1995 Department of Justice Appropriations Act, Public Law 103–317, has allocated $29 million for the Drug Court grant programs. Eligibility of applicants to receive grants will be based on requirements of the statute and these regulations, as well as assurances and certifications specified in detailed program guidelines and application materials that will be available in early 1995 for the Fiscal Year 1995 Drug Court initiative.

While detailed program guidelines will follow the publication of this notice of proposed rulemaking, the Department has made some broad programmatic decisions upon which it welcomes comment. Three types of funding will be available under this program during Fiscal Year 1995. First, planning funding will be available for those jurisdictions that express interest in initiating a drug court, but have not engaged in the comprehensive planning necessary to make such a program successful. Second, jurisdictions currently operating drug court programs may seek funding to expand, enhance, or augment these ongoing efforts.

Finally, for those jurisdictions that have engaged (or are currently engaged) in a comprehensive drug court planning process, funding may be available to implement the plans their efforts have produced.

**Call for Comments Concerning the Drug Court Initiative**

Substance abuse-related offender case management is primarily a state and local issue; thus, the Drug Court grant program contemplates collaboration between federal and state and local agencies. State and local government officials were involved in Congressional hearings and meetings that guided the development of this legislation and will continue to be involved as the Department moves forward in developing this regulation, establishing policy guidance, and implementing program guidelines. At this time, comments are welcome regarding the basic program design requirements described in § 93.4 of the proposed rule, and to the entire scope of the program.

**Administrative Requirements**

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b), Principles of Regulation. This rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and, accordingly, this rule has not been reviewed by the Office of Management and Budget.

The Assistant Attorney General for the Office of Justice Programs, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

**List of Subjects**

Grant Programs, Judicial Administration.

For the reasons set out in the preamble, Title 28, Chapter I, of the Code of Federal Regulations is proposed to be amended by adding a new Part 93 consisting of Subpart A as set forth below.

**PART 93—PROVISIONS IMPLEMENTING THE VIOLENT CRIME CONTROL AND LAW ENFORCEMENT ACT OF 1994**

**Subpart A—Drug Courts**

Sec. 93.1 Purpose.

93.2 Statutory authority.

93.3 Definitions.

93.4 Grant authority.

93.5 Exclusion of violent offenders.

**Subpart B—[Reserved]**


**Subpart A—Drug Courts**

§ 93.1 Purpose.

This part sets forth requirements and procedures to ensure that grants to States, State courts, local courts, units of local government, and Indian tribal governments, acting directly or through agreements with other public or private entities, exclude violent offenders from participation in programs authorized and funded under this part.

§ 93.2 Statutory authority.


§ 93.3 Definitions.

(a) State has the same meaning as set forth in section 901(a)(2) of the Omnibus Crime Control and Safe Streets Act of 1968, as amended.

(b) Unit of Local Government has the same meaning as set forth in section 901(a)(3) of the Omnibus Crime Control and Safe Streets Act of 1968, as amended.

(c) Assistant Attorney General means the Assistant Attorney General for the Office of Justice Programs.

(d) Violent offender means a person who either—

(i) Is currently charged with or convicted of an offense during the course of which:

(ii) There occurred the use of force against the person of another; or

(iii) There occurred the death of, or serious bodily injury to, any person; without regard to whether proof of any of the elements described herein is required to convict; or

(2) Has previously been convicted of a felony crime of violence involving the use or attempted use of force against a person with the intent to cause death or serious bodily harm.

§ 93.4 Grant authority.

(a) The Assistant Attorney General may make grants to States, State courts, local courts, units of local government, and Indian tribal governments, acting directly or through agreements with other public or private entities, for programs that involve:

(i) Continuing judicial supervision over offenders with substance abuse problems who are not violent offenders, and

(ii) The integrated administration of other sanctions and services, which shall include—

(A) Mandatory periodic testing for the use of controlled substances or other addictive substances during any period of supervised release or probation for each participant;

(B) Substance abuse treatment for each participant;

(C) Diversion, probation, or other supervised release involving the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress; and

(iv) Programmatic, offender management, and aftercare services such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each participant who requires such services.

(b) Applications for grants under this program shall be made at such times and in such form as may be specified in guidelines or notices published by the Assistant Attorney General.

Applications will be evaluated according to the statutory requirements of the Act and the programmatic goals.
specified in the applicable guidelines. Grantees must comply with all statutory and program requirements applicable to grants under this program.

§93.5 Exclusion of violent offenders.
   (a) The Assistant Attorney General will ensure that grants to States, State courts, local courts, units of local government, and Indian tribal governments, acting directly or through agreements with other public or private entities, exclude violent offenders from programs authorized and funded under this part.
   (b) No recipient of a grant made under the authority of this part shall permit a violent offender to participate in any program receiving funding pursuant to this part.
   (c) Applicants must certify as part of the application process that violent offenders will not participate in programs authorized and funded under this part. The required certification shall be in such form and contain such assurances as the Assistant Attorney General may require to carry out the requirements of this part.
   (d) If the Assistant Attorney General determines that one or more violent offenders are participating in a program receiving funding under this part, such funding shall be promptly suspended, pending the termination of participation by those persons deemed ineligible to participate under these regulations.
   (e) The Assistant Attorney General may carry out or make arrangements for evaluations and request information from programs that receive support under this part to ensure that violent offenders are excluded from participating in programs hereunder.

Subpart B—[Reserved]

Laurie Robinson,
Assistant Attorney General, Office of Justice Programs.

For further information contact: Mr. Randy Terry, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides, and Toxics Management Division, Region IV Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365. The telephone number is 404/347-3555, ext. 4212.

Supplementary Information: For additional information see the direct final rule which is published in the rules section of this Federal Register.


Patrick M. Tobin,
Acting Regional Administrator.
[FR Doc. 95-1935 Filed 1-25-95; 8:45 am]
BILlING CODE 6560-50-F

40 CFR Part 180

Urea-Formaldehyde Copolymer; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to expand the current exemption from the requirement of a tolerance for residues of urea-formaldehyde copolymer (CAS Reg. No. 9011-05-6), when used as an inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.1001(d) to include uses as a solid diluent, filler and/or carrier and to modify the minimum molecular weight from 30,000 to 20,000. Ciba-Geigy Corp. requested this proposed regulation.

DATES: Written comments, identified by the document control number (OPP 300383), must be received on or before February 27, 1995.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not