Accordingly, the Board hereby amends Part 296 of its Economic Regulations (14 CFR Part 296) as follows:

1. Amend the Table of Contents to Part 296 by revoking and reserving the listing for § 296.41, Charter trips in overseas and foreign air transportation over routes of a certificated carrier.

2. Revoke and reserve § 296.41.

(Secs. 101(3), 204 and 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 737, 743 and 771; 49 U.S.C. 1301(3), 1324, and 1386).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-20439 Filed 7-15-77;8:45 am]

SUBCHAPTER D—SPECIAL REGULATIONS

[Regulation SPR-128, Amdt. 5; Docket No 29940]

PART 371—ADVANCE BOOKING CHARTERS

Amendment To Allow Fee for Substitutions

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This rule amends the Advance Booking Charter rule to allow charter operators to charge a fee of up to 25 dollars for making substitutions for withdrawing participants, except in the case of charters to certain European countries. The action was initiated by a petition from the Charter Travel Corporation.

DATES: Effective: August 14, 1977. Adopted: July 11, 1977.

FOR FURTHER INFORMATION CONTACT:

Richard B. Dyson, Office of General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue NW., Washington, D.C. 20428, 202-673-5444.

SUPPLEMENTARY INFORMATION: By SPDR-54, 42 FR 5367, January 28, 1977, the Board proposed to amend Part 371, Advance Booking Charters (ABC), to allow charter operators, when a substitute is found for a canceling participant, to charge the participant a fee to cover administrative expenses. The proposed amendment to § 371.14(a), in response to a petition by Charter Travel Corporation, would add an exception to the rule that all money must be refunded to a canceling participant if a substitute is found, to allow a fee of up to 25 dollars to cover the expenses involved in the substitution.

The reason for the proposal is that the present rule, by requiring charter operators to refund the entire charter price to a withdrawing participant, amounts to a disincentive for the operator to find substitutes and to some extent counteracts the intent of the substitution provision. The proposed amendment would exclude charters to countries of the European group for which the ABC rule has a longer booking period (Belgium, the Federal Republic of Germany, Finland, France, Ireland, Italy, the Netherlands, Switzerland, and the United Kingdom).

Comments were received from the Board's Office of the Consumer Advocate (OCA), Charter Travel/Brendan Tours, Gogo International, American Travel Abroad, California Holidays, Hawaiian Holidays, Unitours, and Duncan Travel Service. All of the comments generally supported the proposal to allow a substitution fee. While some agreed that the 25-dollar limit was reasonable, others argued that the rule should set no maximum on the fee, and that the amount should be a business decision of the charter operators. The Board does not agree with this position. Although the fees charged will be set forth in the operator-participant contracts, it seems likely that a substantial percentage of participants do not read the provisions carefully, do not fully understand them, do not adequately evaluate the possibility and the consequences of having to withdraw from the charter, or assume that charters are identical in this respect and are unwilling or unable to shop for the best terms. In these circumstances, a measure of consumer protection, limiting the fees to an amount that would cover reasonable costs, is found desirable.

OCA suggested that the allowed fee for ABC substitutions should, to avoid consumer confusion, be consistent with that for Travel Group Charters (14 CFR Part 372a), which is 5 percent of the charter price. As suggested in the proposal, the Board finds a flat maximum preferable to a percentage, since it is not clear that the expenses incurred in arranging substitutions vary according to the price of the charter. As for changing the TGC rule to conform to this ABC amendment, it does not appear justified at this time. The TGC rule differs from the ABC rule in various respects, including the obligation of participants to share the total cost of the charter price. Consequently, it is by no means clear that the TGC substitution charge should also be changed without instituting a separate rulemaking. Whether such a new proceeding is warranted appears doubtful, since in terms of volume, the TGC rule has largely been supplanted by the ABC rule.

Several commenters objected to the exclusion of "European" charters from the substitution fee allowance. The reasons for differing rules for charters to that group of countries were discussed in some detail in the preamble to the issuance of the ABC rule, SPR-110, 41 FR 37763, September 8, 1976. As stated in that issuance, "the Board believes that, in the interest of promoting travel and harmony in aviation relations with our principal European partners, the ABC rule should strive for international acceptability and commonality of charter rules with the European countries comprising the major charter destinations of United States travelers." 41 FR 37764-5. The proposed exclusion of European charters from the amendment to make substitution easier was based on a judgment by the Board that it would further these interests. The Board adheres to that position in this issuance.

ISSUANCE OF AMENDMENT

Accordingly, in 14 CFR Part 371, Advance Booking Charters, the Civil Aeronautics Board amends § 371.14(a) to read as follows:

§ 371.14 Substitution for charter participants named on filed list.

Substitutes may be arranged for charter participants at any time preceding departure, only in accordance with the following:

(a) The charter participant for whom a new participant is substituted shall receive a full refund of all monies paid to the charter operator with respect to the charter, except that, with respect to non-European charters, the charter operator may reserve the right to retain an administrative fee of not more than 25 dollars for effecting the substitution.

* * * * *

(Secs. 101, 204, 401, 402, 416, Federal Aviation Act of 1958, as amended; 72 Stat. 737, 743, 754, 757, 771; 49 U.S.C. 1301, 1324, 1371, 1372, 1386.)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-20549 Filed 7-15-77;8:45 am]

SUBCHAPTER D—SPECIAL REGULATIONS

[Regulation SPR-129, Amdt. 9; Docket No. 27145]

PART 375—NAVIGATION OF FOREIGN CIVIL AIRCRAFT WITHIN THE UNITED STATES

Transit Flights; Scheduled International Air Service Operations

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment will require that foreign carriers by air desiring to operate transit flights pursuant to the terms of the International Air Services Transit Agreement (59 Stat. 1693) file a Notice of such proposed transit flights fifteen days prior to the commencement of such flights, and provides that the Board by Order of Notification may prevent inauguration or continuation of any such flights pending further procedures for consideration of any question which may exist as to the operation of those flights under the Agreement.

DATES: Effective: September 10, 1977. Adopted: July 12, 1977.

FOR FURTHER INFORMATION CONTACT:

Peter B. Schwarzkopf, Assistant to the General Counsel, International Affairs, Civil Aeronautics Board, 1825 Connecticut Avenue NW., Washington, D.C. 20428, 202-673-5436.

SUPPLEMENTARY INFORMATION: In notice of proposed rulemaking SPDR-39,[1] the Board proposed amendment of Part 375 of its Special Regulations (14 CFR Part 375) so as to revise the provisions of section 375.45 thereof which relate to authority for the navigation of foreign civil aircraft in scheduled international air services in transit over the United States. Section 375.45 presently grants a blanket authorization to foreign carriers, pursuant to the regulations, to perform transit flights in U.S. air space pursuant to the provisions of the International Air Services Transit Agreement (59 Stat. 1693), subject to the advance approval of the Administrator of the Federal Aviation Administration for the route proposed to be followed. Transit flights to be performed other than pursuant to the provisions of the International Air Services Transit Agreement require a special application and issuance of a Foreign Aircraft Permit pursuant to the provisions of section 375.70. The proposed amendment to section 375.45 would have required a specific application and issuance of a Foreign Aircraft Permit, pursuant to section 1108(b) of the Act, prior to commencement of any transit flights in U.S. air space, whether or not performed pursuant to the International Air Services Transit Agreement.

The Board pointed out in its rulemaking notice that under the existing section 375.45 provisions, it was contemplated that the Administrator of the Federal Aviation Administration would exercise the function of determining whether a particular operation did, in fact, fall within the scope of rights granted pursuant to the International Air Services Transit Agreement. However, it had recently come to the Board's attention that the Administrator construed his function under this regulation as strictly one of issuing safety or traffic control approval, and that an alternative administrative avenue was required in order to provide an orderly means for resolution of issues as to whether particular transit flights fall within the scope of the International Air Services Transit Agreement, or should otherwise be authorized.[2]

Comments in support of the proposed rule have been filed by the Air Transport Association on behalf of ten U.S. domestic carriers, Pan American World Airways, Inc., and the American Society of Travel Agents. Comments opposing the proposed rule have been filed by the Swiss Air Transport Company, Ltd. (Swissair), and Air Europe International, S.A. ("Air Europe"), a Luxembourg carrier by air which had previously proposed certain operations between Tijuana, Mexico and Luxembourg, in transit across United States air space.

The Department of State filed a comment which basically agrees that the United States Government should have a means to deal with the problem of transit flights unauthorized by the International Air Services Transit Agreement, but suggesting that alternative procedures be considered which would be less burdensome on foreign carriers legitimately exercising rights granted pursuant to that Agreement. A comment of the Department of Transportation similarly supports any appropriate effort by the Board to utilize procedures to prevent abuse of the International Air Services Transit Agreement, but also expresses concern with the Board's imposition of an unnecessary burden upon legitimate air transit operations.

Reply comments have been filed by the Air Transport Association and Pan American, emphasizing the need for control over foreign carrier transit operations, and urging the immediate adoption of the proposed rule.

Upon consideration of the comments, the Board finds merit in the concern expressed by the Department of State, the Department of Transportation, and Swissair, to the effect that the proposed rule may constitute an unnecessary burden upon legitimate transit services operated in full conformity with the International Air Services Transit Agreement and that other alternatives may provide an equally effective solution to the problem of questionable operations, while minimizing the burdens imposed. The Board retains its view, nevertheless, that appropriate procedures should be adopted pursuant to which the Board will have an opportunity to examine, and, to the extent necessary, to withhold authority for transit operations which appear to raise questions of legitimacy under the Transit Agreement, pending appropriate resolution of such questions. In this connection the Board notes that a proposed operation, allegedly under authority of the Transit Agreement, might raise questions whether such operations, even if between two foreign points, may be in air transportation, and hence not authorized pursuant to the Transit Agreement (at least in the absence of issuance of a section 402 permit authorizing such operations in accordance with the requirements of the Federal Aviation Act). It may also raise questions whether such authority should be withheld, pursupant to Section 5 of Article I of the Transit Agreement, "in any case where it (the Board) is not satisfied that substantial ownership and effective control are vested in nationals of a contracting State, or in case of failure of such air transport enterprise to comply with the laws of the State (United States) over which it operates, or to perform its obligations under this Agreement."

The Board has concluded, on the other hand, that the objective of the proposed regulations can be achieved by requiring a Notice of Proposed Transit Flights Pursuant to the International Air Services Transit Agreement to be filed with the Board (Director, Bureau of Operating Rights) not less than 15 days in advance of the proposed commencement of the transit flights, accompanied by certain minimal data which will permit the Board to make a preliminary determination as to whether any questions exist as to the legitimacy of the proposed operation. The Board will, therefore, revise the proposed rule to provide for the filing of such a Notice, and following such a timely filing, if no questions appear to exist, to permit the proposed operations to be conducted without further authorization from the Board. However, if on the basis of the Notice filing the Board concludes that a question exists as to whether (1) the proposed services are authorized pursuant to the terms of the International Air Services Transit Agreement; (2) substantial ownership and effective control are vested in nationals of a State party to the International Air Services Transit Agreement; (3) the proposed operations will be in compliance with the laws of the United States, the Board's regulations, or the provisions of of this section; or (4) the operator or its government have performed their obligations under the International Air Services Transit Agreement, the Board would issue an order notifying the carrier of the existence of such questions. Upon issuance of such order of notification, the carrier would be precluded from performing such operations unless or until the questions were resolved by further proceedings, the nature of which would be determined by the Board. The notification would, except as otherwise specified by the Board, preclude operation of any flights which had been proposed to be operated subsequent to the issuance of such order of notification pending the completion of such proceedings. The carrier would be authorized to commence or recommence such transit operations only upon issuance of a Foreign Aircraft Permit pursuant to the provisions of section 1108(b) of the Act, specifically authorizing the operations.[3]

The Board wishes to make it clear that the intent of the revised regulation is only to minimize the burden upon transit operators where it appears from the face of their Notice filing that there is no question as to the right of such carrier to perform the proposed transit operations pursuant to the provisions of the International Air Services Transit Agreement. The issuance of an order notifying the carrier that a question exists as to the legitimacy of the proposed operations should in no sense be considered a determination of such questions. Such an order would be a determination only that further inquiry is required to resolve the questions which had arisen. In this connection, carriers should be advised that the burden to establish clearly the existence of rights under the International Air Services Transit Agreement, and the absence of any circumstances pursuant to which such rights might appropriately

[1] November 1, 1974, 39 FR 39293, November 6, 1974.

[2] The Board noted that in the usual case, where the applicant's home government was a signatory of the International Air Services Transit Agreement, it was anticipated that appropriate approval would be routinely granted.

[3] In the event of issuance of such an order of notification, the carrier's Notice of Proposed Transit Flights would be treated as an application for a Foreign Aircraft Permit authorizing such transit operations.

be withheld or revoked pursuant to Section 5 of Article I of the International Air Services Transit Agreement, rests with such carriers. Therefore, it will be essential for a carrier to include in the advance Notice of Proposed Transit Flights Pursuant to the International Air Services Transit Agreement, all data that is necessary to remove any question as to the legitimacy or appropriateness of the proposed operations. The failure to include sufficient data in this respect could be expected to lead to issuance of an order notifying that a question exists, and would invite further procedures for resolution of such questions before such operations would be authorized.

The material to be included in the Notice of Proposed Transit Flights constitutes the minimum which the Board considers necessary to make the preliminary determination as to the legitimacy or appropriateness of the proposed operation. Thus, the notice will require a statement of nationality of any direct or indirect interest or stock ownership of the operator or carrier providing the services, but details need be provided only to the extent there exists nationality interests other than that of the State of incorporation or citizenship. Similarly, only such nonnational citizenship of corporate officers or directors need be disclosed. However, if any such nonnational citizenship does exist, with respect to any stock or other direct or indirect interest in the operator or carrier performing the service, or of a corporate officer or director, the nationality and full extent of such interest or corporate influence must be disclosed. Failure to make such full disclosure will inevitably require the issuance of a notice of the existence of a question, and further procedures for resolution of the question before operations can be commenced or continued. There will also be required to be included in the advance Notice filing copies of any advertisements or publications of the proposed service in the United States, since, obviously, such advertisements may constitute the basis of a holding out pursuant to which an air operation performed between two points wholly outside the United States might constitute "air transportation" to or from the United States. Changes in information required to be included in the Notice, with the exception of minor changes in schedules or routing, would also be filed.

The transit carrier may incorporate in a single Notice its proposals for scheduled service for a limited period or for indefinite duration. However, the failure of the Board to issue an order notifying the carrier that a question exists prior to the initial flight shall not be construed as an approval or condoning of any subsequent flight which, as noted, would require the prior specific issuance of a Foreign Aircraft Permit if operated at any time subsequent to issuance of an order notifying the carrier that a question exists. Operators of aircraft registered in countries not parties to the International Air Services Transit Agreement will be required to make special application to the Board under section 375.70, and to obtain a Foreign Aircraft Permit in advance of commencement of the proposed flights, in accordance with existing procedures.

We have considered the arguments of Air Europe and Swissair that the proposed regulation is inconsistent with the provisions of the International Air Services Transit Agreement, and respective bilaterals in effect between the United States and other countries. We find such arguments to have no merit. Apart from numerous other considerations, it is sufficient to point out that the specific right granted pursuant to Section 5 of Article I to withhold or revoke the transit authority on the basis of lack of satisfaction as to ownership or control, or compliance with United States laws (including the obtaining of any authorization required pursuant to the Federal Aviation Act, a provision specifically set forth in the standard bilateral agreement) necessarily contemplates that governments may require carriers to submit sufficient data to enable them to determine whether the provisions of the International Air Services Transit Agreement, or Section 5 of Article I thereof, are applicable. And we reiterate, in contrast to the position of Swissair, that we consider that the burden rests upon the carrier to establish that he is entitled to any rights which may be afforded by any applicable international agreements.

The Department of Transportation requests that the reference to approval by the Administrator be deleted from the regulation in order to avoid any implication that the Administrator would exercise a function other than safety air traffic control. We have deleted the reference as requested. However, carriers should be aware that the deletion does not in any way relieve them of the responsibility for full compliance with the Federal Air Regulations in conducting transit, or any other operations, as specifically set forth in section 375.22 of the regulations. The rule provides that a copy of the Notice of Proposed Transit Flights be served upon the Department of State and the Administrator of the Federal Aviation Administration. This will afford an opportunity for these Executive Departments to transmit to the Board any relevant matters pertaining to the proposed operation.

The rule will be made effective 60 days after the date of its adoption. This will provide ample opportunity for foreign carriers conducting existing transit operations to timely file the required Notice of Proposed Transit Flights 15 days prior to the effective date of the Rule.

We have considered all other contentions and have concluded that section 375.45 should be amended in the manner set forth below.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends Part 375 of the Board's Special Regulations (14 CFR 375), effective September 10, 1977, as follows:

1. Amend the Table of Contents and the title to Subpart E by revising the title to Subpart E to read as follows:

Subpart E—Operations Requiring Specific Preflight Authorization or Filing

2. Amend § 375.45 to read as follows:

§ 375.45 Transit flights; scheduled international air service operations.

(a) *Requirement of notice.* Scheduled international air services proposed to be operated pursuant to the International Air Services Transit Agreement in transit across the United States may not be undertaken by foreign civil aircraft unless the operator[1] of such aircraft, and (if other than the operator) the carrier offering such service to the public, has, not less than 15 days prior to the date of commencement of such service, filed a Notice of Proposed Transit Flights Pursuant to the International Air Services Transit Agreement in accordance with the provisions of paragraphs (b) and (c) below.

(b) *Filing of the notice.* An original and two copies of the Notice shall be filed with the Director, Bureau of Operating Rights, Civil Aeronautics Board. Copies of the Notice shall be served upon the Department of State and the Administrator, Federal Aviation Administration. The filing date shall be the date of actual receipt by the Board.

(c) *Content of notice.* A "Notice of Proposed Transit Flights Pursuant to the International Air Services Transit Agreement" shall be clearly labled as such, and as a minimum shall set forth, with whatever detail may be necessary, the following information:

(1) The name, country of organization, and nationality of all ownership and control interests, of the operator; and, if other than the operator, of the carrier offering the services to the public. If any interest (direct or indirect) in the operator or offeror of services is held by nationals of a country other than the country of organization or citizenship, the nature and extent of such interest must be fully disclosed. If any officer or director of the operator or carrier offering the services is a national of a country other than the country of organization or citizenship, the position and duties of such officer or director, and his relevant position in relation to other officers and directors must similarly be fully disclosed.

(2) The State of Registration of the aircraft proposed to be operated.

(3) A full description of the proposed operations including the type of operations (passenger, property, mail, or combination), date of commencement, duration and frequency of flights, and routing (including each terminal and intermediate point to be served).

(4) A statement as to whether or not any advertisement or publication of the proposed operations has been made in the

[1] Any person leasing an aircraft with crew is considered to be an operator of such aircraft. See 14 CFR 218.

United States. If there has been any advertisement or publication of the operations in the United States, copies of all such advertisements or publications should be included.

Any change with respect to these matters (minor changes in schedules or routing excepted), shall also be filed with the Board's Bureau of Operating Rights.

(d) *Authorized operations.* If the operator and the carrier offering services to the public (if different from the operator) have filed a "Notice of Proposed Transit Flights Pursuant to the International Air Services Transit Agreement," at least 15 days before the date of commencement of the proposed operations in accordance with paragraphs (a), (b) and (c) above, the described operations may be commenced and performed without further authorization from the Board, unless or until the Board issues an order notifying the operator and/or the carrier offering the services to the public that, considering the matters submitted in the Notice, the Board is of the view that a question may exist as to whether (1) the proposed services are authorized pursuant to the terms of the International Air Services Transit Agreement; (2) substantial ownership and effective control are vested in nationals of a State party to the International Air Services Transit Agreement; (3) the proposed operations will be in compliance with the laws of the United States, the Board's Regulations, or the provisions of this section; or (4) the operator or its government have performed their obligations under the International Air Services Transit Agreement.

(e) *Prohibited operations.* If the Board issues an order of notification as described in paragraph (d) above, neither the operator, nor the carrier offering the services to the public, shall commence the proposed operations, or, except as may be otherwise specified in the order, operate any flights subsequent to receipt of the order, unless or until the Board issues a Foreign Aircraft Permit pursuant to the provisions of section 1108(b) of the Act specifically authorizing such operations.

(f) *Foreign Aircraft Permit—Application and Procedures.* If the Board issues an Order of Notification as described in paragraph (d) above, the carriers' Notice of Proposed Transit Flights Pursuant to the International Air Services Transit Agreement shall be treated as an application for the required Foreign Aircraft Permit, and further procedures on such application shall be as directed by the Board.

(g) *Short notice filing.* Nothing in this section shall be construed as precluding the filing of an application for a Foreign Aircraft Permit to perform transit operations pursuant to the International Air Services Transit Agreement less than 15 days in advance of the proposed operation; *Provided:* That, no such flights shall be operated unless or until a specific Foreign Aircraft Permit authorization has been issued by the Board.

(h) *Nature of privilege conferred.* Air transportation is not authorized under this section, and the burden rests upon each operator and carrier to show that the contemplated operations will not constitute air transportation within the meaning of the Federal Aviation Act. In addition, each operator and carrier has the burden of demonstrating that the proposed operations are authorized pursuant to the International Air Services Transit Agreement, and that the appropriate authorization should not be withheld pursuant to Section 5 of Article I thereof. Stopovers for the convenience or pleasure of the passengers are not authorized under this section and stops other than for strictly operational reasons shall not be made. The consolidation on the same aircraft of an operation under this section with a service authorized under section 402 of the Act is not authorized by this section. Any authorization or permit granted by this section is nontransferable, and may be withheld, revoked, suspended, withdrawn, or cancelled by the Board, without notice or hearing, if required by the public interest. Operators of aircraft registered in countries not parties to the International Air Services Transit Agreement shall make special application to the Board under § 375.70.

(Sections 204(a) and 1108(b) of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 798, 49 U.S.C. 1324, 1508.)

By the Civil Aeronautics Board:

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc.77-20550 Filed 7-15-77;8:45 am]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

PART 1025—RULES OF PRACTICE FOR ADJUDICATIVE PROCEEDINGS

Interim Rules of Practice for Adjudicative Proceedings Under Consumer Product Safety Act and Flammable Fabrics Act

Correction

In FR Doc. 77-17690 appearing on page 31431, in the issue for Tuesday, June 21, 1977, on page 31437, the 3rd column, paragraph (e) should be corrected to read as follows:

§ 1025.31 General provisions governing discovery.

* * * * *

(e) *Sequence and timing of discovery.* Discovery may commence at any time after filing of the answer. Unless otherwise provided in these Rules or by order of the Presiding Officer, methods of discovery may be used in any sequence and the fact that a party is conducting discovery, whether by deposition or otherwise, shall not operate to delay any other party's discovery.

* * * * *

On page 31442, § 1025.48(a) should read as follows:

§ 1025.48 Official docket.

(a) The official docket in adjudicatory proceedings will be maintained in the Office of the Secretary and will be available for public inspection during normal working hours (8:30 a.m. to 5 p.m.) Monday through Friday.

* * * * *

PART 1028—PROTECTION OF HUMAN SUBJECTS

Issuance of Regulations

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: This rule prescribes procedures and requirements for the protection of human subjects applicable to all Commission contracts, grants, or other agreements supporting research or related activities in which human subjects are involved.

The rule is intended to assure that before work is performed under such an agreement, any risk to human subjects has been fully evaluated and demonstrated to be justified by the value of the information to be gained. Also the rule requires that the individual subjects or their legal representatives give consent to incurring the risk only after being fully apprised of all the circumstances and of all the risks.

EFFECTIVE DATE: August 17, 1977.

FOR FURTHER INFORMATION CONTACT:

Albert F. Esch, M.D., Medical Director, Consumer Product Safety Commission, Washington, D.C. 20207. (301-492-6641.)

SUPPLEMENTARY INFORMATION: On September 2, 1976, the Consumer Product Safety Commission published for comment a proposed rule (41 FR 37120) to provide procedures and requirements for the protection of human subjects in research or related activities carried out under Commission grants, contracts, or similar agreements. Comments received are addressed below.

DISCUSSION OF COMMENTS

1. A few comments pointed out that §§ 1028.10(b) (1) and (2) of the proposed rule could be read to require that sample copies of consent forms, to be retained by organizational committees, must be copies of the executed consent form. The subsections have been changed. Only unsigned, but otherwise complete, samples are required to be retained in the committee's records. The executed consent form may be retained by an organization officer responsible for administering performance of the agreement.

2. One comment questioned whether § 1028.1(c), in stating that Part 1028 does not apply to opinion surveys, questionnaires, or to solicitation of information about past events, might disregard risks to the privacy of individuals and the

confidentiality of information collected. The Commission believes that privacy and confidentiality for information collected as described in § 1028.1(c) are adequately protected by the terms of the Privacy Act and the Freedom of Information Act and the Commission rules thereunder (16 CFR Part 1015 and 16 CFR Part 1014 (42 FR 10491, February 22, 1977) respectively); Therefore, no change has been made in § 1028.1(c).

3. A few comments pointed out confusing language in §§ 1028.13 and 1028.14. This language has been eliminated as unnecessary. Other minor corrections of errors and language clarifications have been made throughout the rules in response to the comments.

4. Almost all of the comments received requested that the Commission accept institutional general assurances approved by the Department of Health Education, and Welfare under its Protection of Human Subjects Rules (45 CFR Part 46). The comments also requested that no special assurance be required of an institution which has had its general assurance approved. The basis of these requests was the avoidance of unnecessary duplication of paperwork. The Commission agrees with the comments, and changes have been made accordingly to §§ 1028.2(f), 1028.2(g), 1028.4, 1028.5, 1028.12, and 1028.16(b)(2).

5. One comment emphasized the burden of keeping general assurances continuously updated and on file with several government agencies and requested that organizations not be required to file a copy of a Department of Health, Education, and Welfare (DHEW)-approved general assurance with the Commission. The commenter apparently assumed that the Commission intends to maintain a duplicate of the entire DHEW file of assurances; this is not the case. The Commission believes that its activities which involve subjects at risk will be relatively infrequent and will never approach the number of comparable activities sponsored by the DHEW. Therefore, organizations should not submit copies and updates of DHEW-approved general assurances to the Commission as a matter of course. Copies of current DHEW-approved assurances should only be submitted in connection with a grant or contract proposal. Grantees or contractors will be expected to notify the Commission of changes in DHEW-approved general assurances only during the period of performance of the Commission grant or contract. Section 1028.4 has been changed to clarify this procedure.

6. One comment expressed the belief that no third person ought to be allowed to consent to exposure of another to nontherapeutic risks. This comment was directed at §§ 1028.3(b)(1) and 1028.10(b)(1) which would permit informed consent, by a legally authorized representative of the subject, to the undertaking of non-therapeutic risks when the risks are so outweighed by the importance of the information to be gained as to warrant a decision to allow the subjects to accept the risks. The comment also asserted that this procedure would violate the Constitution. The Commission has no doubt that the procedure is constitutionally valid and well established in the law. Persons who undertake some risks to themselves or to those for whom they are responsible, in order to improve the safety of the rest of the community, perform an irreplaceable service. The objective of the regulation is to make certain that the risks are well defined, are clearly justified in the circumstances, and are considered fully by the subjects or their legally authorized representatives. No changes have been made in response to the comment.

7. One comment suggested that submission of certifications, in connection with proposals by organizations which have general assurances, not be required at the time the proposal is submitted as normally required by § 1028.11. The comment pointed out that working constraints often make this deadline a difficult one to meet. The Commission believes that section 1028.11 presently contains sufficient discretion for its officers, in any particular case, to defer the due date for submission of certifications to any convenient date prior to award. The Commission expects that this discretion will be exercised to avoid undue burdens on those submitting proposals. No changes have been made to section 1028.11.

Comment Beyond Scope

A comment was received from the Department of Health, Education, and Welfare. This comment suggested that the Commission procedures under the Poison Prevention Packaging Act of 1970 (PPPA), 16 CFR Part 1700, be amended to require informed consent and institutional review committee requirements for any testing data acquired by use of human subjects which is submitted to the Commission with a request for an exemption under the PPPA. The Commission will consider such an amendment. Since such an amendment would be beyond the scope of the proposed rule presently under consideration, no changes have been made in response to this comment.

Accordingly, 16 CFR Part 1028 is established as set forth below.

Effective date: This regulation shall become effective August 17, 1977.

Signed at Washington, D.C., on July 19, 1977.

Richard E. Rapps,
Secretary, Consumer Product Safety Commission.

Sec.

Authority: Consumer Product Safety Act (15 U.S.C. 2051–81), the Federal Hazardous Substances Act (15 U.S.C. 1261–74), the Flammable Fabrics Act (15 U.S.C. 1191–1204), the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471–76), and the Refrigerator Safety Act (15 U.S.C. 1211–14).

§ 1028.1 Applicability.

(a) The requirements of this Part 1028 are applicable to all Consumer Product Safety Commission contracts or grants or other agreements supporting research or standards or regulations or related activities in which human subjects are involved.

(b) The Commission may on occasion by publication in the Federal Register, or by other appropriate means, designate activities, including specific programs, methods, or procedures, that necessarily fall within the scope of this Part 1028 or to which this Part 1028 is inapplicable.

(c) The requirements of this Part 1028 do not apply to opinion surveys, questionnaires, or to solicitation of information about past events.

§ 1028.2 Definitions.

(a) "Organization" means any public or private institution or agency, including Federal, State, and local government agencies.

(b) "Cooperative activity" means any activity which involves organizations in addition to the grantee, prime contractor under the Consumer Product Safety Act.

(c) "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical or psychological injury, as a consequence of participation as a subject in any research, development or related activity.

(d) "Informed consent" means the knowing consent of an individual, or a legally authorized representative, able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary for such consent include:

(1) A fair explanation (including the purpose) of the procedures to be followed, with identification of any experimental procedures.

(2) A description of any attendant discomforts and risks reasonably to be expected.

(3) A description of any benefits reasonably to be expected.

(4) Disclosure of any appropriate alternative procedures that might be advantageous for the subject.

(5) An offer to answer any inquiries concerning the procedures.

(6) Instruction that the person is free at any time to withdraw his or her consent and discontinue participation in the project or activiy without prejudice to the subject at risk.

(e) "Commission" means the Consumer Product Safety Commission and any officer or employee of the Consumer Product Safety Commission to whom authority has been delegated.

(f) "Approved assurance" means a document that fulfills the requirements of this Part 1028 and is approved by the Commission or a document that fulfills the requirements of 45 CFR Part 46 and is approved by the Department of Health, Education, and Welfare.

(g) "Certification" means the official organizational notification to the Commission in accordance with the requirements of this Part 1028 that a project or activity involving human subjects at risk has been reviewed and approved by the organization in accordance with the "approved assurance" on file at the Commission or at the Department of Health, Education, and Welfare.

(h) "Legally authorized representative" means an individual authorized under applicable law to give consent on behalf of a prospective subject's participation in the particular activity or procedure.

(i) "Committee" means the committee of the organization established in compliance with § 1208.6(b)(2) of this Part 1028.

§ 1028.3 Policy.

(a) Safeguarding the rights and welfare of subjects at risk in activities supported by the Commission is primarily the responsibility of the organization that has received funds from or that is accountable to the Commission for the support of its activity. To provide for the adequate discharge of such responsibility by the organization, the Commission's policy is that no activity involving human subjects to be supported by the Commission shall be undertaken unless a committee of the organization has reviewed and approved such activity and the organization has submitted to the Commission a certification of such review and approval in accordance with the requirements of this Part 1028.

(b) The committee's review shall determine whether the human subjects will be placed at risk and, if risk is involved, whether:

(1) The risks to the subjects are so outweighed by the sum of the benefit to the subjects and the importance of the knowledge to be gained as to warrant a decision to allow the subjects to accept these risks.

(2) The rights and welfare of the subjects will be adequately protected.

(3) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this Part 1028.

(4) The conduct of the activity will be reviewed at timely intervals.

(5) A qualified psychologist, doctor of medicine, or other appropriate professional, having established emergency medical procedures, will oversee each test.

(c) No grant or contract or other agreement involving human subjects at risk shall be made to an individual unless he or she is affiliated with or sponsored by an organization that can and does assume responsibility for the subjects at risk involved.

§ 1028.4 Submission of assurances.

(a) Recipients or prospective recipients of Commission support under a grant or contract or other agreement involving subjects at risk shall provide written assurance complying with the requirements of this Part 1028. Each assurance shall embody:

(1) A statement of compliance with Commission requirements for initial and continuing guidelines, including identification of the committee and a description of its review procedures; or

(2) In the case of special assurances concerned with single activities or projects, a report of initial findings of the committee and of its proposed continuing procedures.

(b) Such assurance shall be executed by an individual authorized to act for the organization and to assume on behalf of the organization the obligations imposed by this Part 1028.

(c) If an organization has a general assurance on file with the Department of Health, Education, and Welfare, it need only notify the Commission of this fact and submit a copy of the approved general assurance to the Commission at the time it submits a proposal for a grant, contract, or other agreement. Recipients of such support must notify the Commission of any changes made to the DHEW-approved assurance during the period of performance of the agreement.

§ 1028.5 Types of assurances.

(a) *General assurances.* A general assurance describes the review and implementation procedures applicable to all Commission-supported activities conducted by an organization, regardless of the number, location, or types of its components or field activities. General assurances will be required from organizations having two or more concurrent Commission-supported projects or activities involving human subjects. Section 1028.6 prescribes the minimum requirements for general assurances.

(b) *Special assurances.* A special assurance describes the review and implementation procedures applicable to a single activity or project. A special assurance will not be solicited or accepted from an organization which has an approved general assurance on file at the Commission or at the Department of Health, Education, and Welfare. Section 1028.7 prescribes the minimum requirements for special assurances.

§ 1028.6 Minimum requirements for general assurances.

(a) General assurances shall be submitted in the form and manner as the Commission may require in "The Institutional Guide to CPSC's Policy on Protection of Human Subjects," which can be obtained, upon request, from the Commission.

(b) As part of its general assurance, the organization must include implementing guidelines that specifically provide for:

(1) A statement of principles that will govern the organization in the discharge of its responsibilities for protecting the rights and welfare of subjects. This may include appropriate existing codes or declarations, or statements formulated by the organization itself. It is to be understood that no such principles supersede Commission policy or applicable law.

(2) A committee that will conduct initial and continuing reviews in accordance with the policy outlined in § 1028.3. Such committee or committee structure shall meet the following requirements:

(i) The committee must be composed of not less than five persons with varying backgrounds to assure complete and adequate review of activities commonly conducted by the organization. The committee must be sufficiently qualified through the maturity, experience, and expertise of its members and diversity of its membership to insure respect for its advice and counsel for safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the committee must be able to ascertain the acceptability of proposals in terms of organizational commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. The committee must therefore include persons whose concerns are in these areas.

(ii) The committee members shall be identified to the Commission, by name, earned degree (if any), position or occupation and representative capacity, and by other pertinent indications of experience such as board certification, licenses, etc., sufficient to describe each member's chief anticipated contributions to committee deliberations. Any employment or other relationship between each committee member and the organization shall be identified; for example, full-time employee, part-time employee, member of governing panel or board, paid consultant, or unpaid consultant. Changes in committee membership shall be reported to the Commission in such form and at such times as the Commission may require.

(iii) No committee member shall be involved in either the initial or continuing review of an activity in which he or she has a conflicting interest, except to provide information requested by the committee.

(iv) The committee shall not consist entirely of persons who are officers, em-

ployees, or agents of, or who are otherwise associated with, the organization (apart from their membership on the committee).

(v) The committee shall not consist entirely of members of a single professional group.

(vi) The committee's quorum shall be defined and shall not be less than a majority of the members convened to carry out the committee's responsibilities under the terms of the assurance.

(3) The procedures the organization will follow in its initial and continuing review of proposals and activities.

(4) The procedures the committee will follow (i) to provide advice and counsel to activity directors and investigators with regard to the committee's actions and (ii) to insure prompt reporting to the committee of proposed changes in an activity and of unanticipated problems involving risk to subjects or others.

(5) The procedures the organization will follow to maintain an active and effective committee and to implement the committee's recommendations.

(6) A statement as to how often the committee will meet to provide for continuing review. Such review must occur at least annually.

§ 1028.7 Minimum requirements for special assurances.

(a) Special assurances shall be submitted in the form and manner prescribed by paragraph (b) of this section.

(b) An acceptable special assurance shall: (1) Identify the specific grant, contract, or developmental standard or regulation involved by its number (if known), its full title, and the name of the activity or project director, principal investigator, fellow, or other person immediately responsible for the conduct of the activity. The assurance shall be signed by the individual members of a committee that complies with the requirements of § 1028.6(b)(2) and shall be endorsed by an appropriate organization official.

(2) Describe the makeup of the committee and the training, experience, and background of its members in accordance with § 1028.6(b)(2)(ii).

(3)(i) Describe in general terms the risks to the subject that the committee recognizes as inherent in the activity and (ii) justify the committee's decision that these risks are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant the committee's decision to permit the subject to accept these risks.

(4) Describe the informed-consent procedures to be used and attached documentation required by § 1028.10.

(5) Describe the procedures the committee will follow (i) to insure prompt reporting to the committee of any proposed changes in the activity and of any unanticipated problems involving risks to subjects or others and (ii) to insure that any such problems are promptly reported to the Commission.

§ 1028.8 Evaluation and disposition of assurances.

(a) All assurances submitted in accordance with §§ 1028.6 and 1028.7 shall be evaluated by the Commission through its officers and employees and such experts or consultants as it determines to be appropriate. The Commission's evaluation shall take into consideration, among other pertinent factors, the adequacy of the proposed committee in the light of the anticipated scope of the applicant organization's activities and of the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in the light of the probable risks, and the size and complexity of the organization.

(b) On the basis of the evaluation of an assurance pursuant to paragraph (a) of this section, the Commission shall either approve the assurance, enter into negotiations to develop a more satisfactory assurance, or disapprove the assurance. The Commission may determine the period during which any particular approved assurance or class of assurances shall remain effective and/or may otherwise condition or restrict the approval. Pending completion of negotiations for a general assurance, the Commission may require an organization otherwise eligible for such an assurance to submit special assurances.

§ 1028.9 Obligation to obtain informed consent; prohibition of exculpatory clauses.

Any organization proposing to place any subject at risk is obligated to obtain and document legally effective informed consent. No such informed consent, oral or written, obtained under an assurance provided pursuant to this Part 1028 shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any legal rights, including any release of the organization or its agents from liability for negligence.

§ 1028.10 Documentation of informed consent.

(a) The actual procedure utilized in obtaining legally effective informed consent and the basis for committee determinations that the procedures are adequate and appropriate shall be fully documented.

(b) The documentation of consent shall employ one of the following three forms:

(1) A written consent document embodying the basic elements of informed consent. This may be read to the subject or to a legally authorized representative, but in any event the subject or a legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or a legally authorized representative. Sample copies of the consent form as approved by the committee are to be retained in its records.

(2) A "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the subject or a legally authorized representative. Written summaries of what is to be said to the participant shall be approved by the committee. The short form is to be signed by the subject or a legally authorized representative and by an auditor witness to the oral presentation and to the subject's or representative's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent and by the auditor witness. Sample copies of the consent form and of the summary as approved by the committee are to be retained in the committee's records.

(3) Modification of either of the primary procedures outlined in paragraph (b)(1) and (2) of this section. Granting permission to use modified procedures imposes additional responsibility upon the review committee and the organization to establish: (i) That the risk to any subject is minimal and (ii) that use of either of the primary procedures for obtaining informed consent would securely invalidate objectives of considerable immediate importance. The committee's reason for permitting the use of modified procedures must be individually and specifically documented in the committee's minutes and in reports of committee actions submitted to the files of the organization. All such modifications should be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation, as appropriate.

§ 1028.11 Certification; general assurances.

(a) *Timely review.* Any organization having an approved general assurance shall indicate in each application or proposal for support of activities covered by this part that it has such an assurance on file with the Commission, or with the Department of Health, Education, and Welfare. Unless the Commission provides otherwise, all proposals involving human subjects submitted by organizations having approved general assurances must be reviewed and, when found to involve subjects at risk, approved by the organizational committee prior to submission to the Commission. If the Commission provides for the performance or organizational review of a proposal after its submission to the Commission, processing of such proposal by the Commission shall under no circumstances be completed until such organizational review and approval has been certified. Unless the organization determines that human subjects are not involved, the proposal should be appropriately certified in the spaces provided on forms or one of the following certifications, as appropriate, should be typed on the lower right-hand margin of the page bearing the name of an official authorized to sign or execute applications or proposals for the organization:

Human Subjects: Reviewed, not at risk.
(Date)
Human Subjects: Reviewed, at risk, approved.
(Date)
(Signature)

(b) *Proposals not certified.* Proposals not properly certified, or submitted as not involving human subjects and found by the operating agency to involve human subjects, will be returned to the organization concerned.

§ 1028.12 Certification; special assurances.

(a) Organizations not having an approved general assurance must submit for each application or proposal involving human subjects a separate special assurance and certification of its review and approval.

(b) Such assurance and certification must be submitted within such time limit as the Commission may specify. An assurance and certification prepared in accordance with this Part 1028 and approved by the Commission shall be considered to have met the requirement for certification for the initial period concerned. If the terms of the grant, contract, or developmental standard or regulation recommend additional support periods, certification shall be provided by the organization with applications for continuation or renewal of support in the manner prescribed in § 1028.11(a).

§ 1028.13 Proposals lacking definite plans for involvement of human subjects.

Certain types of proposals are submitted with the knowledge that subjects probably will be involved within the project period but without definite plans for this involvement being included in the proposal. These include such activities as research, pilot, or developmental activities in which involvement depends upon such things as the completion of prior studies. Such proposals shall be reviewed and certified in the same manner as more definitive proposals. The initial certification indicates organizational approval of the applications as submitted and commits the organization to later review of the plans when completed. Such later review and certification to the Commission should be completed prior to the beginning of the budget period during which actual involvement of human subjects is to begin. Review and certification to the Commission must in any event be completed prior to involvement of human subjects.

§ 1028.14 Proposals submitted with the intent of not involving human subjects.

If a proposal's intent is not to involve human subjects, certification should not be included with the initial submission of the proposal. If in such a case, it later becomes appropriate to involve human subjects, the activity shall be reviewed and approved in accordance with the assurance of the organization prior to the involvement of subjects. In addition, no such activity shall be undertaken until the organization has submitted to the Commission (a) a certification that the activity has been reviewed and approved in accordance with this Part 1028 and (b) a detailed description of the proposed activity (including any protocol or similar document). Also, where Commission support is provided to project grants, contracts, or developmental standards or regulations, subjects shall not be involved prior to certification and organizational receipt of the Commission's approval and, in the case of contracts, prior to negotiation and approval of an amended contract description of work.

§ 1028.15 Evaluation and disposition of proposals.

(a) *Evaluation.* Notwithstanding any prior review, approval, and certification by the organization, all grants, contract proposals, and developmental standards or regulations involving human subjects at risk submitted to the Commission shall be evaluated by the Commission for compliance with this Part 1028 through its officers and employees and such experts or consultants as the Commission deems appropriate. This evaluation may take into account, among other pertinent factors, the apparent risks to the subjects, the adequacy of protection against the risks, the potential benefits of the activity to the subjects and others, and the importance of the knowledge to be gained.

(b) *Disposition.* On the basis of the evaluation of an application pursuant to paragraph (a) of this section and subject to such approval or recommendation by, or consultation with, appropriate councils, committees, or other bodies as may be required by law, the Commission shall either approve, defer for further evaluation, or disapprove support of the proposed activity in whole or in part. With respect to any approved grant, contract, or developmental standard or regulation, the Commission may impose conditions (such as restrictions on the use of certain procedures or subject groups, or requiring use of specified safeguards or informed consent procedures) when in its judgment such conditions are necessary for the protection of human subjects.

§ 1028.16 Cooperative activities.

(a) *Responsibility.* If in cooperative activities the grantee, prime contractor, or offeror under the Consumer Product Safety Act obtains access to some or all of the subjects involved through one or more cooperating organizations, the basic Commission policy applies and the grantee, prime contractor, or offeror remains responsible for safeguarding the rights and welfare of the subjects.

(b) *Organization with approved general assurance.* Initial and continuing review by the organization with approved general assurance may be carried out by one or a combination of procedures:

(1) *Cooperating organization with approved general assurance.* If the cooperating organization has on file with the Commission or with the Department of Health, Education, and Welfare an approved general assurance, the grantee, prime contractor, or offeror may carry out its own review or may request the cooperating organization to conduct its own review and report to the committee of the grantee, prime contractor, or offeror the cooperating organization's committee recommendations on those aspects of the activity that concern individuals for whom the cooperating organization has responsibility in accordance with its own assurance. At its discretion, the grantee, prime contractor, or offeror may concur with or further restrict the recommendations of the cooperating organization. It is the responsibility of the grantee, prime contractor, or offeror to maintain communication with the committees of the cooperating organization. The cooperating organization, however, shall promptly notify the grantee, prime contractor, or offeror whenever the cooperating organization finds the conduct of the project or activity within its purview to be unsatisfactory.

(2) *Cooperating organization with no approved general assurance.* If the cooperating organization does not have an approved general assurance, a general or special assurance to the Commission may be negotiated that, if approved, will permit the grantee, prime contractor, or offeror to follow the procedure outlined in paragraph (b)(1) of this section.

(3) *Interorganizational joint review.* The grantee, prime contractor, or offeror may wish to develop an agreement with cooperating organizations. Representatives of cooperating organizations may be appointed as ad hoc members of the existing review committee of the grantee, prime contractor, or offeror; appointments for extended periods may be made if cooperation is on a frequent or continuing basis, such as between a medical school and a group of affiliated hospitals. All such cooperative arrangements must be approved by the Commission as part of a general assurance or as an amendment to a general assurance.

(c) *Organization with approved special assurance*—(1) *Responsibility.* While responsibility for initial and continuing review necessarily lies with the grantee, prime contractor, or offeror with approved special assurance, the Commission will also require approved assurances from those cooperating organizations having immediate responsibility for subjects.

(2) *Cooperating organization with approved special assurance.* If the cooperating organization has on file with the Commission an approved special assurance, the grantee, prime contractor, or offeror shall request the cooperating organization to conduct its own review of those aspects of the project or activity that will involve human subjects for which it has responsibility. The request shall be in writing and should provide for direct notification of the committee of the grantee, prime contractor, or offeror in the event that the cooperating organization finds the conduct of the activity to be unsatisfactory.

(3) *Cooperating organization with no approved special assurance.* If the cooperating organization does not have an approved special assurance on file with the Commission, it must submit to the Commission a general or special assurance that will be determined by the Commission to comply with the provisions of this Part 1028.

§ 1028.17 Organization's executive responsibility.

Specific executive functions to be conducted by the organization include policy development, policy promulgation, and continuing indoctrination of personnel. Appropriate administrative assistance and support shall be provided for the committee's functions. Implementation of the committee's recommendations through appropriate administrative action and follow-up is a condition of Commission approval of an assurance. Committee approvals, favorable actions, and recommendations are subject to review and disapproval or further restriction by the organization. Committee disapprovals; restrictions, or conditions cannot be rescinded or removed except by action of a committee described in the assurance approved by the Commission.

§ 1028.18 Organization's records.

Copies of all documents presented or required for initial and continuing review by the organization's review committee (such as committee minutes, records of subjects' consent, transmittals on actions, instructions, and reports of conditions resulting from committee deliberations addressed to the activity director) are to be retained by the organization, subject to the terms and conditions of grant, contractor, and development awards.

§ 1028.19 Reports.

Each organization with an approved assurance shall provide the Commission with such reports and other information as the Commission may require.

§ 1028.20 Early termination of awards; sanctions for noncompliance.

(a) If in the judgment of the Commission, an organization has failed to comply with the terms of this Part 1028 with respect to a particular Commission grant, contract, or developmental standard or regulation, the Commission may require that said grant, contract, or standard or regulation be terminated or suspended in the manner prescribed in applicable grant or procurement regulations.

(b) If in the judgment of the Commission, an organization has failed materially to discharge its responsibility for the protection of the rights and welfare of subjects in its care, the Commission may, upon reasonable notice to the organization of the basis for its judgment and after providing the organization with an opportunity for an informal conference, terminate the organization's eligibility to receive further Commission support, subject to the provisions of this Part 1028. Such ineligibility shall continue until it is shown to the Commission's satisfaction that the reasons therefor no longer exist.

(c) If in the judgment of the Commission, an individual, who is serving in the capacity of principal investigator, program director, or other position having responsibility for the scientific and technical direction of an activity, has failed materially to discharge his or her responsibilities for the protection of the rights and welfare of human subjects in his or her care, the Commission may, upon reasonable notice to the individual and to any organization whose grant, contract, or developmental standard or regulation may be involved, and after providing the individual and the organization with an opportunity for an informal conference, terminate the individual's eligibility to serve in such capacity with respect to any activity subject to the provisions of this Part 1028. Such ineligibility shall continue until it is shown to the Commission's satisfaction that the reasons therefor no longer exist.

§ 1028.21 Conditions.

The Commission may with respect to any grant, contract, or developmental standard impose additional conditions prior to or at the time of any award when in its judgment such conditions are necesary for the protection of human subjects.

[FR Doc.77-20480 Filed 7-15-77;8:45 am]

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCE ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATIVE AND ENFORCEMENT REGULATIONS

PART 1511—REQUIREMENTS FOR PACIFIERS

Banning of Hazardous Articles and Establishment of Safety Requirements

Correction

In FR Doc. 18778 appearing on page 33276 in the issue of Thursday, June 30, 1977, the effective dates appearing on page 33279 should read, "February 26, 1978."

Section 1500.18(a)(8) should read as follows:

§ 1500.18 Banned toys and other banned articles intended for use by children.

* * * * *

(8) Any pacifier that does not meet the requirements of 16 CFR Part 1511 and that is introduced into interstate commerce after February 26, 1978.

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Title 29—Labor

CHAPTER XXV—PENSION AND WELFARE BENEFIT PROGRAMS

SUBCHAPTER F—EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

Exemptions for the Provision of Services or Office Space to Employee Benefit Plans, the Investment of Plan Assets in Bank Deposits, the Provision of Bank Ancillary Services to Plans, and the Transitional Rule for the Provision of Services to Plans

Correction

In FR Doc. 77-17895, appearing at page 32389 in the issue of Friday, June 24, 1977, make the following changes:

1. On page 32392, first column, the 14th line of § 2550.408b-4(a) should read, "or § 2550.408b-4(b)(2) are met. Section" and the 11th from bottom line of § 2550.408b-4(a) should read, "tion 404, or other provisions of law which".

2. On page 32392, third column, the first word in the 22nd line, now reading "half", should read "behalf".

3. On page 32393, third column, the first line should read, "Act are met, a person serving as a fiduciary".

4. On page 32394, second column, the second line should read "of section 414(c)(4) of the Act."

Title 47—Telecommunication

CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

[FCC 77-476]

REREGULATION OF RADIO AND TELEVISION BROADCASTING

AGENCY: Federal Communications Commission.

ACTION: Order.

SUMMARY: As a result of continuing study of reregulation of broadcasting, rules for broadcast stations are amended to update certain rules, delete parts of others that are no longer necessary, and make corrections and editorial revisions for clarity.

DATES: Effective July 18, 1977.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Philip S. Cross, Broadcast Bureau, (202) 632-9660.

SUPPLEMENTARY INFORMATION:

Adopted: July 1, 1977.

Released: July 15, 1977.

1. As a result of its continuing study concerning the reregulation of broadcasting, the Commission has under con-