LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to prepare ultrathin slices of fixed and embedded tissue so that they may be observed with an electron microscope during investigations to determine the elucidation of the ultrastructure of cells that make up tissues of the body. Application received by Commissioner of Customs: June 19, 1972.

Docket No. 72-00627-33-46500. Applicant: University of Chicago, 950 East 59th Street, Chicago, IL 60637. Article: Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to cut ultrathin sections of brains and nerve tissues and liver from rhesus monkeys. This involves a research project on the chronic effects of methamphetamine administration. Application received by Commissioner of Customs: June 19, 1972.

Docket No. 72-00628-33-46040. Applicant: Oak Ridge Associated Universities, Post Office Box 117, Oak Ridge, TN 37380. Article: Electron Microscope, Model Elmiskop 101. Manufacturer: Siemens AG, West Germany. Intended use of article: The article is intended to be used to examine the fine structure and isolated molecular components of normal and malignant human and experimental animal tissues. The experiments to be conducted include studies on the cellular and subcellular localization of the tumor-localizing radionuclide ^{67}Ga using high-resolution autoradiography on tissue sections and on isolated cellular components; similar materials in experimental animals after whole-body acute and chronic x-irradiation to determine the effect of x-irradiation on the ability of cells and their molecular components to concentrate or localize ^{67}Ga. Application received by Commissioner of Customs: June 16, 1972.

Docket No. 72-00630-55-17500. Applicant: University of Washington, Purchasing Department, Seattle, Wash. 98195. Article: Two Recording Current Meters. Manufacturer: Ivar Aanderaa, Norway. Intended use of article: The article is intended to be used in a study of the currents in the Beaufort Sea area in conjunction with the Arctic Ice Deformation Joint Experiment which will involve work by graduate students on research projects. Application received by Commissioner of Customs: June 16, 1972.

Docket No. 72-00631-33-79200. Applicant: Veterans Administration Hospital, 4150 Clement Street, San Francisco, CA 94121. Article: Water Still and Condenser. Manufacturer: L. V. D. Scorah, MSc., United Kingdom. Intended use of article: The article is intended to be used in redistilling water to obtain the extreme purity needed in many special techniques in Metabolic and Endocrine Function studies. Application received by Commissioner of Customs: June 16, 1972.

Docket No. 72-00632-33-46040. Applicant: City Hospital Center at Elmhurst, 79-01 Broadway, Elmhurst, NY 11373. Article: Electron Microscope, Model HS-8 Mark II. Manufacturer: Hitachi Ltd., Japan. Intended use of article: The article is intended to be used to study the complicated and chronic changes involved in human renal disease using a newly developed technique in which lanthium hydroxide is injected on a tracer. In addition, protein-labeled antibodies have been obtained and will be used as an adjunct to these studies. The study of human placental membranes especially in toxemia of pregnancy using a recently developed technique for isolating placental basement membrane will also be carried out. The isolation techniques will also be used to obtain antibodies in experimental animals and to determine the possible role of immunological mechanisms in placental disease. The article will also be used for the instruction of electron microscopy techniques to residents, educational fellows, medical and premedical students. Application received by Commissioner of Customs: June 16, 1972.

Docket No. 72-00633-33-43780. Applicant: Washington University, 4911 Barnes Hospital Plaza, St. Louis, MO 63110. Article: Leisegang Stereocameracolposcope, Model IIIb. Manufacturer: Leisegang Feinmechanik-Optik Gmbh & Co., West Germany: Intended use of article: The article is intended to be used in the following gynecologic research projects:

(1) Monitor of the effects of birth control pills and intrauterine contraceptive devices on the cervix uteri;

(2) Examination of patients with abnormal Papanicolaou smears (cancer screening tests) and biopsies of suspicious lesions taken under direct vision.

Photographs taken with the article of various lesions of the cervix, uteri, and vulva will be used in the teaching of medical students and medical doctors in the residency training in obstetrics and gynecology. Application received by Commissioner of Customs: June 19, 1972.

SETH M. BODNER,
Director, Office of Import Programs.

[FR Doc.72-11309 Filed 7-20-72;8:53 am]

NORTHWESTERN UNIVERSITY

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 F.R. 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 72-00298-65-86300. Applicant: Northwestern University, The Technological Institute, 2145 Sheridan Road, Evanston, IL 60201. Article: Viscoelastometer, Model DDV-II. Manufacturer: Toyo Measuring Instruments Co., Ltd., Japan. Intended use of article: The article is intended to be used to assess the modulus of highly crystalline materials and relate it to existing knowledge of microstructure, study the effects of various levels of crystallinity on the mechanical losses due to noncrystalline regions and determine dynamic mechanical data needed to complement morphological information of polyethylene and polypropylene fibers.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: The foreign article provides a load sensitivity of 5×10^{-3} grams and 1×10^{-6} centimeters displacement. The most closely comparable domestic instrument, the Rheometrics mechanical spectrometer, manufactured by Rheometrics, Inc., provides a sensitivity of 100 grams full scale with no displacement sensitivity given. We are advised by the National Bureau of Standards (NBS) in its memorandum dated June 5, 1972, that the capabilities for a load sensitivity of 5×10^{-3} grams and 1×10^{-6} centimeters displacement are pertinent to the purposes for which the article is intended to be used.

We, therefore, find that the Rheometrics mechanical spectrometer is not of equivalent scientific value to the foreign article for such purposes as the article is intended to be used. NBS also advises that it knows of no domestically manufactured instrument which is scientifically equivalent to the foreign article for the applicant's intended uses.

SETH M. BODNER,
Director, Office of Import Programs.

[FR Doc.72-11310 Filed 7-20-72;8:53 am]

RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER

Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 F.R. 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket No. 72-00367-33-46500. Applicant: Rush-Presbyterian-St. Luke's Medical Center, 1753 West Congress Parkway, Chicago, IL 60612. Article: Ultramicrotome, Om U2. Manufacturer: C. Reichert Optische Werke AG, Austria. Intended use of article: The article is

intended to be used to section human tumors, virus-induced animal tumors, tumor cell lines, cells infected in vitro with oncogenic viruses, and concentrated virus preparations to study virus-host interrelationships in these materials striving toward the elucidation of the mechanism(s) responsible for cellular transformation and virus expression, repression, and derepression.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Reasons: Examination of the applicant's thin sections under the electron microscope will provide optimal information when such sections are uniform in thickness and have smoothly cut surfaces. Conditions for obtaining high quality sections depend to a large extent on the properties of the specimen being sectioned (e.g., hardness, consistency, toughness, etc.), the properties of the embedding media and the geometry of the block. In connection with a prior case (Docket No. 69-00118-33-46500) which relates to the duty-free entry of an identical foreign article, the Department of Health, Education, and Welfare (HEW) advised that "Smooth cuts are obtained when the speed of cutting (among such [other] obvious factors as knife edge condition and angle) is adjusted to the characteristics of the material being sectioned." In connection with another prior case (Docket No. 69-00665-33-46500) relating to the duty-free entry of a similar foreign article, HEW advised that "The range of cutting speeds and a capability for the higher cutting speeds is * * * a pertinent characteristic of the ultramicrotome to be used for sectioning materials that experience has shown difficult to section." In connection with still another prior case (Docket No. 70-00077-33-46500) relating to the duty-free entry of a similar foreign article, HEW advised that "ultrathin sectioning of a variety of tissues having a wide range in density, hardness etc." requires a maximum range in cutting speed and, further, that "The production of ultrathin serial sections of specimens that have great variation in physical properties is very difficult." The foreign article has a cutting speed range of 0.5 to 20 millimeters/second (mm./sec.). The most closely comparable domestic instrument is the Model MT-2B ultramicrotome manufactured by Ivan Sorvall, Inc. (Sorvall). The Sorvall Model MT-2B ultramicrotome has a cutting speed range of 0.09 to 3.2 mm./sec. We are advised by HEW in its memorandum of (June 30, 1972) that cutting speeds in excess of 4 mm./sec. are pertinent to the applicant's research studies. We, therefore, find that the Model MT-2B ultramicrotome is not of equivalent scientific value to the foreign article for such purposes as this article is intended to be used.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

SETH M. BODNER,
Director,
Office of Import Programs.

[FR Doc. 72-11311 Filed 7-20-72;8:53 am]

Office of the Secretary

CHILDREN'S SLEEPWEAR

Notice of Amendment to Flammability Standard To Provide for Sampling Plan

On April 18, 1972, there was published in the FEDERAL REGISTER (37 F.R. 7628) a notice of finding that an amendment to the Standard for the Flammability of Children's Sleepwear, DOC FF 3-71 (36 F.R. 14062), was needed to provide for a sampling plan to protect the public against unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage. A proposed sampling plan, which was preliminarily found to protect the public against such unreasonable risk, was published in the same FEDERAL REGISTER notice. It was also preliminarily found that the proposed sampling plan was reasonable, technologically practicable, and appropriate, and stated in objective terms, and that the proposed sampling plan was limited to young children's sleepwear, and fabrics or related materials which are intended or promoted for use in children's sleepwear, and which have been determined to present the unreasonable risk specified above.

The comments received in response to the above-referenced publication of the proposed sampling plan have been reviewed and analyzed. The reports of the members of the National Advisory Committee for the Flammable Fabrics Act on that proposed plan have also been reviewed and considered. Appropriate changes in the proposed sampling plan based on those reviews, considerations, and analyses and based also on additional investigations and research have been made. Based on these actions, it is hereby found that the sampling plan contained in the amendment to the Standard for the Flammability of Children's Sleepwear (DOC FF 3-71) as set out in full at the end hereof:

(a) Is needed for young children's sleepwear to protect the public against unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage;

(b) Is reasonable, technologically practicable, and appropriate, and is stated in objective terms; and

(c) Is limited to young children's sleepwear, and fabrics of related materials which are intended or promoted for use in children's sleepwear, and which have been determined to present the unreasonable risk specified in (A) above.

Applicability of Sampling Plan. As is the case with all flammability standards issued under the Flammable Fabrics Act, the sampling plan applies to all domestic and imported children's sleepwear as defined in the Standard.

Effective Date of Amendment. The present children's sleepwear standard (DOC FF 3-71) becomes effective July 29, 1972, with a proviso temporarily requiring a permanent and conspicuous cautioning label for noncomplying goods manufactured during the 12-month period after the effective date of the Standard. All goods manufactured after July 29, 1973, are required to comply. An amendment to a flammability standard issued under the Flammable Fabrics Act normally becomes effective 12 months from the date on which such amendment is promulgated unless the Secretary of Commerce finds for good cause shown that an earlier or later date is in the public interest and publishes the reason for such finding.

It is hereby found that good cause has been shown that an earlier effective date of this amendment is in the public interest. This finding is based on information received by this Department which indicates that compliance with the children's sleepwear standard will be substantially accelerated by the addition of a sampling plan. Accelerated compliance would result in making larger quantities of flame resistant sleepwear available much sooner than would be possible without the sampling plan, thereby providing children with increased protection against unreasonable risk of the occurrence of fire leading to death or personal injury. Therefore, as stated in the notice accompanying the proposed sampling plan amendment, this amendment will be effective July 29, 1972. Further, the Standard for the Flammability of Children's Sleepwear, together with this amendment thereto, will continue to be effective July 29, 1972, with a proviso temporarily requiring a permanent and conspicuous cautioning label for noncomplying goods manufactured during the 12-month period after the effective date of the Standard.

Further, section 553 of title 5, United States Code, requires publication of an amendment to a flammability standard at least 30 days prior to its effective date unless it is found that good cause exists otherwise and the reason for such good cause is published with the amendment.

It is hereby found that good cause exists for the publication of the amended standard less than 30 days prior to its effective date for the reasons set forth above in connection with the finding that the amended standard should be effective earlier than 12 months from its publication.

Reissuance of the Standard. Inclusion of the sampling plan in the children's sleepwear standard requires that certain portions of the Standard be revised. Accordingly, section .1 "Definitions" is

amended by revising paragraph (e) thereof and adding paragraphs (i), (j), (k), (l), and (m). In addition, paragraph (b) of section .4 "Test Procedure" is revised and changes have been made in sections .2(b), .3(b) and .4(d)(4) plus former section .4(a)(12) has been deleted. Additionally, minor nonsubstantive corrections have been made in section .4(a)(1) and in drawings numbered 1, 3, and 4 appended to the Standard.

In the light of the foregoing and the nonsubstantive corrections to the Standard, heretofore announced in the FEDERAL REGISTER of November 12, 1971 (36 F.R. 21717), reissuance of the Standard to include all changes is considered appropriate. The Standard is reissued as the Standard for the Flammability of Children's Sleepwear (DOC FF 3–71, as amended) and is appended hereto.

It is emphasized that the only substantive change made to the Standard involves the amendment necessary to include the sampling plan. This reissuance does not affect the effective date of the Standard, announced in the FEDERAL REGISTER of July 29, 1971 (36 F.R. 14062). The Standard is effective July 29, 1972, with a proviso temporarily requiring a permanent and conspicuous cautioning label for noncomplying goods manufactured until July 29, 1973. All goods manufactured on and after July 29, 1973, are required to comply with the Standard.

Issued July 17, 1972.

PETER G. PETERSON,
Secretary of Commerce.

CHILDREN'S SLEEPWEAR

STANDARD FOR THE FLAMMABILITY OF CHILDERN'S SLEEPWEAR

[DOC FF 3–71; As amended]

.1 Definitions.
.2 Scope and Application.
.3 General Requirements.
.4 Test Procedure.
.5 Labeling Requirements.

.1 *Definitions.* In addition to the definitions given in section 2 of the Flammable Fabrics Act, as amended (sec. 1, 81 Stat. 568; 15 U.S.C. 1191), and § 7.2 of the Procedures (33 F.R. 14642, Oct. 1, 1968), the following definitions apply for the purposes of this Standard:

(a) "Children's Sleepwear" means any product of wearing apparel up to and including size 6X, such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for a sleeping or activities related to sleeping. Diapers and underwear are excluded from this definition.

(b) "Size 6X" means the size defined as 6X in Department of Commerce Voluntary Product Standard, previously identified as Commercial Standard, CS 151–50 "Body Measurements for the Sizing of Apparel for Infants, Babies, Toddlers, and Children." [1]

[1] Copies available from the National Technical Information Service, 5285 Port Royal Street, Springfield, VA 22151.

(c) "Item" means any product of children's sleepwear, or any fabric or related material intended or promoted for use in children's sleepwear.

(d) "Trim" means decorative materials, such as ribbons, laces, embroidery, or ornaments. This definition does not include (1) individual pieces less than 2 inches in their longest dimension, provided that such pieces do not constitute or cover in aggregate a total of more than 20 square inches of the item, or (2) functional materials (findings), such as zippers, buttons, or elastic bands, used in the construction of garments.

(e) "Test Criteria" means the maximum char length and residual flame time which a sample or specimen may exhibit in order to pass an individual test.

(f) "Char Length" means the distance from the original lower edge of the specimen exposed to the flame in accordflame in accordance with the procedure specified in ".4 Test Procedure" to the end of the tear or void in the charred, burned, or damaged area, the tear being made in accordance with the procedure specified in .4(d)(2).

(g) "Residual Flame Time" is defined as the time from removal of the burner from the specimen to the final extinction of molten material or other fragments flaming on the base of the cabinet.

(h) "Afterglow" means the continuation of glowing of parts of a specimen after flaming has ceased.

(i) "Fabric Piece" (Piece) means a continuous, unseamed length of fabric, one or more of which make up a unit.

(j) "Fabric Production Unit" (Unit) means any quantity of finished fabric up to 5,000 linear yards for normal sampling or 10,000 linear yards for reduced sampling which has a specific identity that remains unchanged throughout the Unit except for color or print pattern as specified in .4(b)(1). For purposes of this definition, finished fabric means fabric in its final form after completing its last processing step as a fabric except for slitting.

(k) "Garment Production Unit" (Unit) means any quantity of finished garments up to 500 dozen which have a specific identity that remains unchanged throughout the Unit except for size, trim, findings, color, and print patterns as specified in .4(b)(1).

(l) "Sample" means five test specimens.

(m) "Specimen" means an 8.9 x 25.4 cm. (3.5 x 10 in.) section of fabric. For garment testing the specimen will include a seam or trim.

.2 *Scope and Application.* (a) This Standard provides a test method to determine the flammability of items as defined in .1(c).

(b) All items as defined in .1(c), are subject to requirements of this standard.

.3 *General Requirements*—(a) *Summary of Test Method.* Five conditioned Specimens, 8.9 x 25.4 cm. (3.5 x 10 in.), are suspended one at a time vertically in holders in a prescribed cabinet and subjected to a standard flame along their bottom edge for a specified time under controlled conditions. The char length and residual flame time are measured.

(b) *Test Criteria.* The test criteria when the testing is done in accordance with ".4 Test Procedure" are:

(1) *Average Char Length.* The average char length of five specimens shall not exceed 17.8 cm. (7.0 in.).

(2) *Full Specimen Burn.* No individual specimen shall have a char length of 25.4 cm. (10 in.).

(3) *Residual Flame Time.* No individual specimen shall have a residual flame time greater than 10 seconds.

.4 *Test Procedure*—(a) *Apparatus*—(1) *Test Chamber.* The test chamber shall be a steel cabinet with inside dimensions of 32.9 cm. (12 15/16 in.) wide, 32.9 cm. (12 15/16 in.) deep, and 76.2 cm. (30 in.) high. It shall have a frame which permits the suspension of the specimen holder over the center of the base of the cabinet at such a height that the bottom of the specimen holder is 1.7 cm. (¾ in.) above the highest point of the barrel of the gas burner specified in .4(a)(3) and perpendicular to the front of the cabinet. The front of the cabinet shall be a close fitting door with a glass insert to permit observation of the entire test. The cabinet floor shall be covered with a piece of asbestos paper, whose length and width are approximately 2.5 cm. (1 in.) less than the cabinet floor dimensions and whose thickness is a nominal 0.3 cm. (⅛ in.). A piece of asbestos paper at least 15.2 x 15.2 cm. (6 x 6 in.) and of nominal thickness of 0.15 cm. (1/16 in.) or less shall be used to catch the drips or other fragments and this latter paper shall be changed after each specimen which drips has been tested. The cabinet to be used in this test method is illustrated in Figure 1 and detailed in Engineering Drawings, Nos. 1 to 7.

(2) *Specimen Holder.* The specimen holder is designed to permit suspension of the specimen in a fixed vertical position and to prevent curling of the specimen when the flame is applied. It shall consist of two U-shaped 0.20 cm. (14 ga. USS) thick steel plates, 42.2 cm. (16⅝ in.) long, and 8.9 cm. (3.5 in.) wide, with aligning pins. The openings in the plates shall be 35.6 cm. (14 in.) long and 5.1 cm. (2 in.) wide. The specimen shall be fixed between the plates, which shall be held together with side clamps. The holder to be used in this test method is illustrated in Figure 2 and detailed in Engineering Drawing No. 7.

(3) *Burner.* The burner shall be substantially the same as that illustrated in Figure 1 and detailed in Engineering Drawing No. 6. It shall have a tube of 1.1 cm. (0.43 in.) inside diameter. The input line to the burner shall be equipped with a needle value. It shall have a variable orifice to adjust the height of the flame. The barrel of the burner shall be at an angle of 25° from the vertical. The burner shall be equipped with an adjustable stop collar so that it may be positioned quickly under the test speci-

men. The burner shall be connected to the gas source by rubber or other flexible tubing.

(4) *Gas Supply System.* There shall be a pressure regulator to furnish gas to the burner under a pressure of 129±13 mm. Hg (2½±¼ lbs. per sq. in.) at the burner inlet.

(5) *Gas.* The gas shall be at least 97 percent pure methane.

(6) *Hooks and Weights.* Metal hooks and weights shall be used to produce a series of loads for char length determinations. Suitable metal hooks consist of No. 19 gauge steel wire, or equivalent, made from 7.6 cm. (3 in.) lengths of the wire, bent 1.3 cm. (0.5 in.) from one end to a 45° angle hook. The longer end of the wire is fastened around the neck of the weight to be used and the other in the lower end of each burned specimen to one side of the burned area. The requisite loads are given in Table 1.

TABLE 1—ORIGINAL FABRIC WEIGHT [1]

g./sq. m.	(oz./sq. yd.)	Loads	
		g.	(lb.)
Less than 101	(Less than 3.0)	54.4	(0.12)
101 to 207	(3.0 to 6.0)	113.4	(.25)
207 to 338	(6.0 to 10.0)	226.8	(.50)
Greater than 338	(Greater than 10.0).	340.2	(.75)

[1] Weight of the original fabric, containing no seams or trim, is calculated from the weight of a specimen which has been conditioned for at least 8 hours at 21±1.1° C. (70±2° F.) and 65±2 percent relative humidity. Shorter conditioning times may be used if the change in weight of a specimen in successive weighings made at intervals of not less than 2 hours does not exceed 0.2 percent of the weight of the specimen.

(7) *Stopwatch.* A stopwatch or similar timing device shall be used to measure time to 0.1 second.

(8) *Scale.* A linear scale graduated in millimeters or 0.1 inch divisions shall be used to measure char length.

(9) *Circulating Air Oven.* A forced circulation drying oven capable of maintaining the specimens at 105±2.8° C. (221±5° F.), shall be used to dry the specimen while mounted in the specimen holders.[2]

(10) *Desiccator.* An air-tight and moisture-tight desiccating chamber shall be used for cooling mounted specimens after drying. Anhydrous silica gel shall be used as the desiccant in the desiccating chamber.

(11) *Hood.* A hood or other suitable enclosure shall be used to provide a draft-free environment surrounding the test chamber. This enclosure shall have a fan or other suitable means for exhausting smoke and/or toxic gases produced by testing.

(b) *Specimens and Sampling*—(1) *General.* The test criteria of .3(b) shall be used in conjunction with the following fabric and garment sampling plan, or any other approved by the Department of Commerce that provides at least the equivalent level of fire safety to the consumer. Alternate sampling plans submitted for approval shall have operating characteristics such that the probability of Unit acceptance at any percentage defective does not exceed the corresponding probability of Unit acceptance of the following sampling plan in the region of the latter's operating characteristic curves that lies between 5 and 95 percent acceptance probability.

Different colors or different print patterns of the same fabric may be included in a single Fabric or Garment Production Unit, provided such colors or print patterns demonstrate char lengths and residual flame times that are not significantly different from each other as determined by previous testing of at least three Samples from each color or print pattern to be included in the Unit.

Garments with different trim and findings may be included in a single Garment Production Unit providing the other garment characteristics are identical except for size, color, and print pattern.

For fabrics whose flammability characteristics are not dependent on chemical additives or chemical reactants to fiber, yarns, or fabrics, the laundering requirement of .4(d)(4) is met on subsequent Fabric Production Units if results of testing an initial Fabric Production Unit demonstrate acceptability according to the requirements of .4(b)(2), Normal Sampling, both before and after the appropriate laundering.

If the fabric has been shown to meet the laundering requirement, .4(d)(4), the garments produced from that fabric are not required to be laundered.

Each Sample (five specimens) for all Fabric Sampling shall be selected so that two specimens are in one fabric direction (machine or cross-machine) and three specimens are in the other fabric direction except for the additional Sample selected after a failure, in which case, all five specimens shall be selected in the same fabric direction in which the specimen failure occurred.

Fabric Samples may be selected from fabric as outlined in .4(b)(2) Fabric Sampling or, for verification purposes, from randomly selected garments.

Multilayer fabrics shall be tested with a hem of approximately 2.5 cm. (1 in.) sewn at the bottom edge of the specimen with a suitable thread and stitch. The specimen shall include each of the components over its entire length. Garments manufactured from multilayer fabrics shall be tested with the edge finish at the bottom edge of the specimen which is used in the garment.

(2) *Fabric Sampling.* A Fabric Production Unit (Unit) is either accepted or rejected in accordance with the following plan:

Normal Sampling. Select one Sample from the beginning of the first Fabric Piece (Piece) in the Unit and one Sample from the end of the last Piece in the Unit, or select a sample from each end of the Piece if the Unit is made up of only one Piece. Test the two selected Samples. If both Samples meet all the Test Criteria of .3(b), accept the unit. If either or both of the Samples fail the 17.8 cm. (7.0 in.) average char length criterion, .3(b)(1), reject the Unit. If two or more of the individual specimens, from the 10 selected specimens fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), reject the Unit. If only one individual specimen, from the 10 selected specimens, fails the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), select five additional specimens from the same end of the Piece in which the failure occurred, all five to be taken in the fabric direction in which the specimen failure occurred. If this additional Sample passes all the test criteria, accept the Unit. If this additional Sample fails any part of the test criteria, reject the Unit.

Reduced Sampling. The level of sampling required for fabric acceptance may be reduced provided the preceding 15 Units of the fabric have all been accepted using the Normal Sampling plan.

The Reduced Sampling plan shall be the same as for Normal Sampling except that the quantity of fabric in the Unit may be increased to 10,000 linear yards.

Select and test two Samples in the same manner as in Normal Sampling. Accept or reject the Unit on the same basis as with Normal Sampling.

Reduced Sampling shall be discontinued and Normal Sampling resumed if a Unit is rejected.

Tightened Sampling. The level of sampling required for acceptance shall be increased when a Unit is rejected under the Normal Sampling plan. The Tightened Sampling shall be the same as Normal Sampling except that one additional Sample shall be selected and cut from a middle Piece in the Unit. If the Unit is made up of less than two Pieces, the Unit shall be divided into at least two Pieces. The division shall be such that the Pieces produced by the division shall not be smaller than 100 linear yards or greater than 2,500 linear yards. If the Unit is made up of two Pieces, the additional Sample shall be selected from the interior end of one of the Pieces. Test the three selected Samples. If all three selected Samples meet all the test criteria of .3(b), accept the Unit. If one or more of the three selected Samples fail the 17.8 cm. (7.0 in.) average char length criterion, .3(b)(1), reject the Unit. If two or more of the individual specimens, from the 15 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), reject the unit. If only one individual specimen, of the 15 selected Specimens fails the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), select five additional specimens from the same end of the same Piece in which the failure occurred, all five to be taken in the fabric direction in which the Specimen failure occurred. If this additional Sample passes all the test criteria, accept the Unit. If this additional Sample fails any part of the test criteria, reject

[2] Option 1 of ASTM, D2654–67T, "Method of Test for Amount of Moisture in Textile Materials," describes a satisfactory oven (1970 Book of ASTM Standards, Part 24, published by the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103).

the Unit. Tightened Sampling may be discontinued and Normal Sampling resumed after five consecutive Units have all been accepted using Tightened Sampling. If Tightened Sampling remains in effect for 15 consecutive Units, production of the specific fabric in Tightened Sampling must be discontinued until that part of the process or component which is causing failure has been identified and the quality of the end product has been improved.

Disposition of Rejected Units. The Piece or Pieces which have failed and resulted in the initial rejection of the Unit may not be retested, used, or promoted for use in children's sleepwear as defined in .1(a) except after reworking to improve the flammability characteristics and subsequent retesting in accordance with the procedures in Tightened Sampling.

The remainder of a rejected Unit, after removing the Piece or Pieces the failure of which resulted in Unit rejection, may be accepted if the following test plan is successfully concluded at all required locations. The required locations are those adjacent to each such failed Piece. (Required locations exist on both sides of the "Middle Piece" tested in Tightened Sampling if failure of that Piece resulted in Unit rejection.) Failure of a Piece shall be deemed to have resulted in Unit rejection if Unit rejection occurred and a Sample or specimen from the Piece failed any test criterion of .3(b).

The Unit should contain at least 15 Pieces for disposition testing after removing the failing Pieces. If necessary for this purpose, the Unit shall be demarcated into at least 15 approximately equal length Pieces unless such division results in Pieces shorter than 100 linear yards. In this latter case, the Unit shall be demarcated into roughly equal length Pieces of approximately 100 linear yards each. If such a division results in five Pieces or less in the Unit for each failing Piece after removing the failing Pieces, only the individual Piece retest procedure (described subsequently) may be used.

Select and cut a Sample from each end of each adjoining Piece beginning adjacent to the Piece which failed. Test the two Samples from the Piece. If both Samples meet all the test criteria of .3(b), the Piece is acceptable. If one or both of the two selected Samples fail the 17.8 cm. (7.0 in.) average char length criterion, .3(b)(1), the Piece is unacceptable. If two or more of the individual Specimens, from the 10 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), the Piece is unacceptable. If only one individual specimens, from the 10 selected specimens, fails the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), select five additional specimens from the same end of the Piece in which the failure occurred, all five to be taken in the fabric direction in which the specimen failure occurred. If this additional Sample passes all the test criteria, the Piece is acceptable. If this additional Sample fails any part of the test criteria, the Piece is unacceptable.

Continue testing adjoining Pieces until a Piece has been found acceptable. Then continue testing adjoining Pieces until three successive adjoining Pieces, not including the first acceptable Piece, have been found acceptable or until five such Pieces not including the first acceptable Piece, have been tested, whichever occurs sooner. Unless three successive adjoining Pieces have been found acceptable among five such Pieces, testing shall be stopped and the entire Unit rejected without further testing. If three successive Pieces have been found acceptable among five such Pieces, accept the three successive acceptable Pieces and the remaining Pieces in the Unit.

Alternatively, individual Pieces from a rejected Unit containing three or more Pieces may be tested and accepted or rejected on a Piece-by-Piece basis according to the following plan, after removing the Piece or Pieces, the failure of which resulted in Unit rejection.

Select four Samples (two from each end) from the Piece. Test the four selected Samples. If all four Samples meet all the Test Criteria of .3(b), accept the Piece. If one or more of the Samples fail the 17.8 cm. (7 in.) average char length criterion, .3(b)(1), reject the Piece. If two or more of the individual Specimens, from the 20 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(1), and/or the 10 second residual flame time criteria, .3(b)(3), reject the Piece. If only one individual specimen, from the 20 selected specimens, fails the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), select two additional Samples from the same end of the Piece in which the failure occurred. If these additional two Samples meet all the Test Criteria of .3(b), accept the Piece. If one or both of the two additional Samples fail any part of the Test Criteria, reject the Piece.

The Pieces of a Unit rejected after retesting may not be retested, used, or promoted for use in children's sleepwear as defined in .1(a) except after reworking to improve the flammability characteristics, and subsequent retesting in accordance with the procedures set forth in Tightened Sampling.

Records. Records of all Unit sizes, test results, and the disposition of rejected Pieces and Units must be maintained by the manufacturer upon the effective date of this Standard. Rules and regulations may be established by the Federal Trade Commission.

(3) *Garment Sampling.* The garment sampling plan is made up of two parts: (1) Prototype Testing and (2) Production Testing. Prior to production, prototypes must be tested to assure that the design characteristics of the garment are acceptable. Garment Production Units (Units) are then accepted or rejected on an individual Unit basis.

Edge finishes such as hems and binding are excluded from testing except that when trim is used on an edge the trim must be subjected to prototype testing. Seams attaching findings are excluded from testing.

Prototype Testing. Preproduction prototypes of a garment style or type shall be tested to assure that satisfactory garment specifications in terms of flammability are set up prior to production.

Seams. Make three Samples (15 specimens) using the longest seam type and three Samples using each other seam type 10 inches or longer that is to be included in the garment. Prior to testing, assign each specimen to one of the three Samples. Test each set of three Samples and accept or reject each seam design in accordance with the following plan:

If all three Samples meet all the test criteria of .3(b), accept the seam design. If one or more of the three Samples fail the 17.8 cm. (7 in.) average char length criterion, .3(b)(1), reject the seam design. If three or more of the individual Specimens from the 15 selected specimens fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), reject the seam design. If only one of the individual specimens from the 15 selected specimens fails the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), accept the seam design.

If two of the individual specimens, from the 15 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), select three more Samples (15 specimens) and retest. If all three additional Samples meet all the test criteria of .3(b), accept the seam design. If one or more of the three additional Samples fail the 17.8 cm. (7 in.) average char length criterion, .3(b)(1), reject the seam design.

If two or more of the individual specimens, from the 15 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), reject the seam design. If only one of the individual specimens, from the 15 selected specimens, fails the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criteria, .3(b)(3), accept the seam design.

Trim. Make three Samples (15 specimens) from each type of trim to be included in the garment. Specimens shall be prepared by sewing or attaching the trim to the center of the vertical axis of an appropriate section of untrimmed fabric, beginning the sewing or attachment at the lower edge of each specimen. The sewing or attachment shall be made in the manner in which the trim is to be attached in the garment.

Sewing or otherwise attaching the trim shall be done with thread or fastening material of the same composition and size to be used for this purpose in the garment and using the same stitching or seam type. The trim shall be sewn or fastened the entire length of the specimen. Prior to testing, assign each specimen to one of the three Samples. Test the sets of three Samples and accept or reject the type of trim and design on the same basis as seam design.

Production Testing. A Unit is either accepted or rejected according to the following plan:

From each Unit select at random sufficient garments and cut three Samples (15 specimens) from the longest seam type. No more than five specimens may be cut from a single garment. Prior to testing, assign each specimen to one of the three Samples. All specimens cut from a single garment must be included in the same Sample. Test the three selected Samples. If all three Samples meet all the test criteria of .3(b), accept the Unit. If one or more of the three Samples fail the 17.8 cm. (7 in.) average char length criterion, .3(b)(1), reject the Unit. If four or more of the individual specimens, from the 15 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(2), and/or the 10 second residual flame time criterion, .3(b)(3), reject the Unit. If three or less of the individual specimens, from the 15 selected specimens, fail the 25.4 cm. (10 in.) char length, .3(b)(2) and/or the 10 second residual flame time criteria, .3(b)(3), accept the Unit.

If the garment under test does not have a 10-inch seam in the largest size in which it is produced, the following selection and testing procedure shall be followed.

Select and cut specimens 8.9 cm. (3.5 in.) wide by the maximum available seam length, with the seam in the center of the specimen and extending the entire specimen length. Cut three Samples (15 specimens). These specimens shall be placed in specimen holders so that the bottom edge is even with the bottom of the specimen holder and the seam begins in the center of the bottom edge. Prior to testing, assign each specimen to one of the three Samples. All specimens cut from a single garment must be included in the same Sample.

Test the three Samples. If all three Samples pass the 17.8 cm. (7 in.) average char length criterion, .3(b)(1), and if three or less individual specimens fail by charring the entire specimen length and/or exceeding the 10 second residual flame time criterion, .3(b)(3), accept the Unit. If the Unit is not accepted in the above test, three Samples (15 specimens) of the longest seam type shall be made using fabric and thread from production inventory and sewn on production machines by production operators. The individual fabric sections prior to sewing must be no larger than 20.3 x 63.3 cm. (8 in. x 25 in.) and must be selected from more than one area of the base fabric. Test the three prepared Samples. Accept or reject the Unit as described previously in this subsection.

Disposition of Rejected Units. Rejected Units shall not be retested, used, or promoted for use in children's sleepwear as defined in .1(a) except after reworking to improve the flammability characteristics and subsequent retesting in accordance with the procedures set forth in garment production testing.

Records. Records of all Unit sizes, test results, and the disposition of rejected Units must be maintained by the manufacturer upon the effective date of this standard. Rules and regulations may be established by the Federal Trade Commission.

(4) *Compliance Market Sampling Plan by FTC.* The FTC may submit, for approval by the Secretary of Commerce, fabric and/or garment sampling plans for use in market testing of items covered by this standard. For approval, such plans shall define noncompliance of a production Unit to exist only when it is shown, with a high level of statistical confidence, those production Units represented by tested items which fail such FTC plans will, in fact, fail this standard.

Production Units found to be noncomplying under these provisions shall be deemed not to conform to this standard.

(c) *Mounting and Conditioning of Specimens.* The specimens shall be placed in specimen holders so that the bottom edge of each specimen is even with the bottom of the specimen holder. Mount the specimen in as close to a flat configuration as possible. The sides of the specimen holder shall cover 1.9 cm. (¾ in.) of the specimen width along each long edge of the specimen, and thus shall expose 5.1 cm. (2 in.) of the specimen width. The sides of the specimen holder shall be clamped with a sufficient number of clamps or shall be taped to prevent the specimen from being displaced during handling and testing. The specimens may be taped in the holders if the clamps fail to hold them. Place the mounted specimens in the drying oven in a manner that will permit free circulation of air at 105° C. (221° F.) around them for 30 minutes.[3]

Remove the mounted specimens from the oven and place them in the desiccator for 30 minutes to cool. No more than five specimens shall be placed in a desiccator at one time. Specimens shall remain in the desiccator no more than 60 minutes.

(d) *Testing*—(1) *Burner Adjustment.* With the hood fan turned off, use the needle valve to adjust the flame height of the burner to 3.8 cm. (1½ in.) above the highest point of the barrel of the burner. A suitable height indicator is shown in Engineering Drawing No. 6 and Figure 1.

(2) *Specimen Burning and Evaluation.* One at a time, the mounted specimens shall be removed from the desiccator and suspended in the cabinet for testing. The cabinet door shall be closed and the burner flame impinged on the bottom edge of the specimen for 3.0±0.2 seconds.[4] Flame impingement is accomplished by moving the burner under the specimen for this length of time, and then removing it.

If flaming drips or fragments are evident, measure the residual flame time to the nearest 0.1 second.

When afterglow has ceased, remove the specimen from the cabinet and holder, and place it on a clean flat surface. Fold the specimen lengthwise along a line through the highest peak of the charred or melted area; crease the specimen firmly by hand. Unfold the specimen and insert the hook with the correct weight as shown in Table 1 in the specimen on one side of the charred area 6.4 mm. (¼ in.) from the lower edge.

Tear the specimen by grasping the other lower corner of the fabric and gently raising the specimen and weight clear of the supporting surface.[5] Measure the char length as the distance from the end of the tear to the edge of the specimen exposed to the flame. After testing each specimen, vent the hood and cabinet to remove the smoke and/or toxic gases.

(3) *Report.* Report the value of char length, in centimeters (inches), and the residual flame time, in seconds, for each specimen, as well as the average char length for each set of five specimens.

(4) *Laundering.* The procedures described under .4(b), .4(c), and .4(d) shall be carried out on finished items (as produced or after one washing and drying) and after they have been washed and dried 50 times according to AATCC Test Method 124–1969.[6] Items which do not withstand 50 launderings shall be tested at the end of their useful service life.

Washing procedure 6.2(III), with a water temperature of 60°±2.8° C. (140 ±5° F.), and drying procedure 6.3.2(B), shall be used. Maximum load shall be 3.64 Kg. (8 pounds) and may consist of any combination of test samples and dummy pieces. Alternatively, a different number of times under another washing and drying procedure may be specified and used, if that procedure has previously been found to be equivalent by the Federal Trade Commission.

Such laundering is not required of items which are not intended to be laundered, as determined by the Federal Trade Commission.

Items which are not susceptible to being laundered and are labeled "dryclean only" shall be drycleaned by a procedure which has previously been found to be acceptable by the Federal Trade Commission.

For the purpose of the issuance of a guarantee under section 8 of the Act, finished sleepwear garments to be tested according to .4(b) need not be laundered or drycleaned provided all fabrics used

[3] If the specimens are moist when received, permit them to air dry at laboratory conditions prior to placement in the oven. A satisfactory preconditioning procedure may be found in ASTM D 1776–67, "Conditioning Textiles and Textile Products for Testing." ("1970 Book of ASTM Standards," Part 24, published by the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.)

[4] If more than 15 seconds elapse between removal of a specimen from the desiccator and the initial flame impingement, that specimen shall be reconditioned prior to testing.

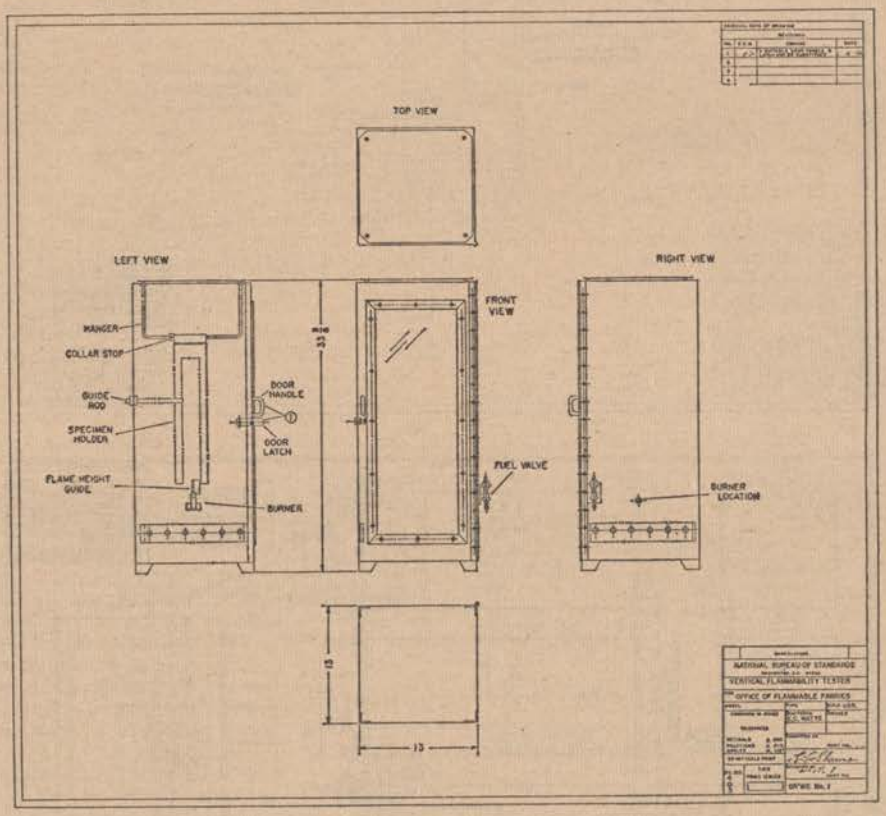
[5] A figure showing how this is done is given in AATCC 34–1969, Technical Manual of the American Association of Textile Chemists and Colorists, vol. 46, 1970, published by AATCC, Post Office Box 12215, Research Triangle Park, N.C. 27709.

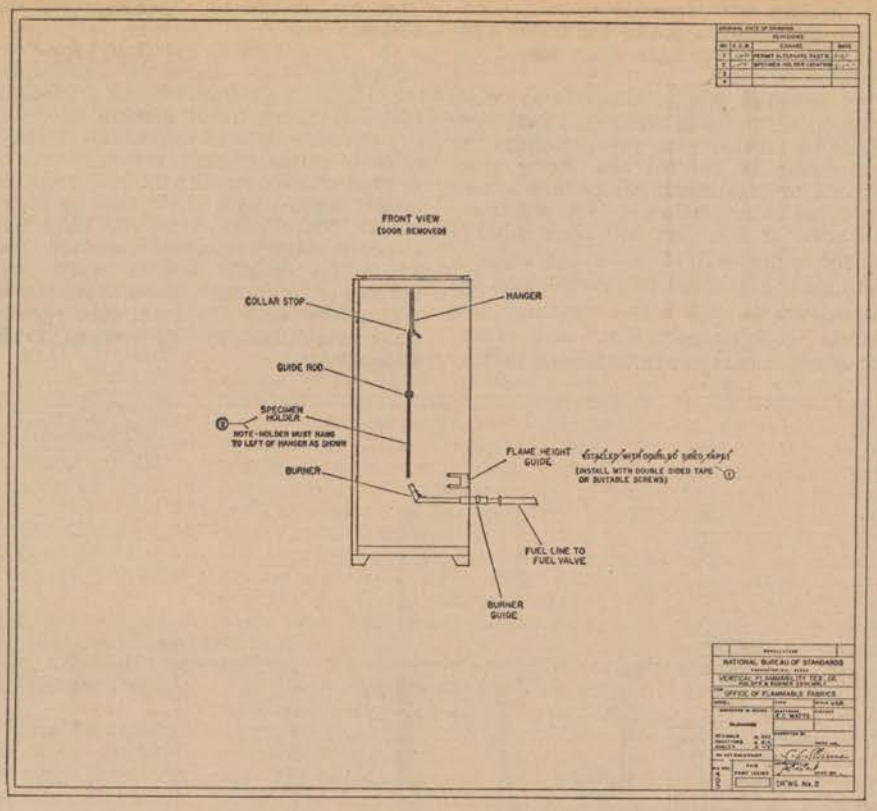
[6] Technical Manual of the American Association of Textile Chemists and Colorists, vol. 46, 1970, published by AATCC, Post Office Box 12215, Research Triangle Park, N.C. 27709.

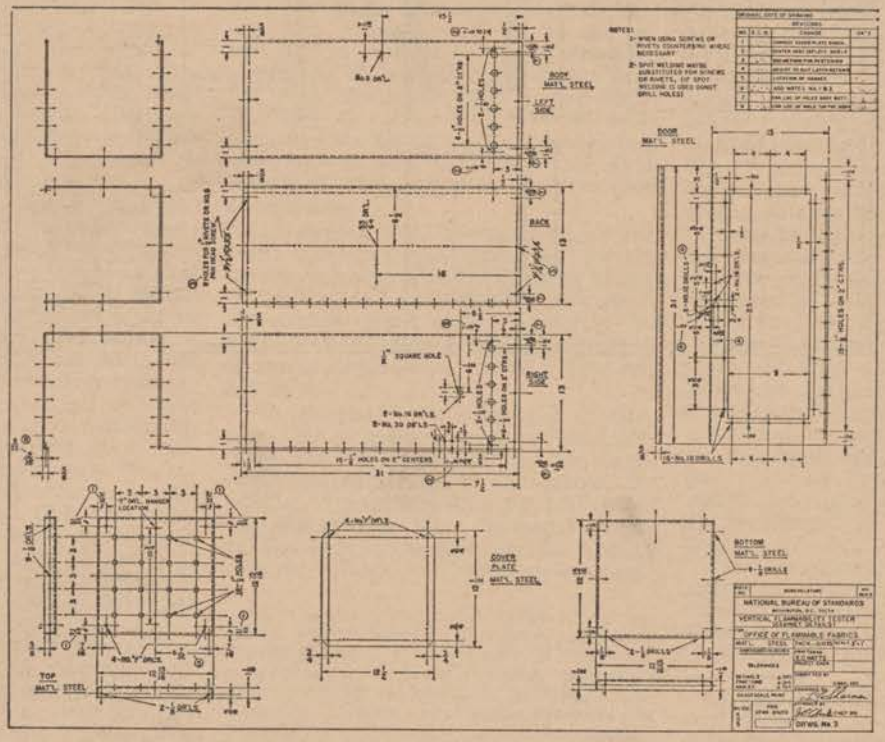
in making the garments (except trim) have been guaranteed by the fabric producer to be acceptable when tested according to .4(b).

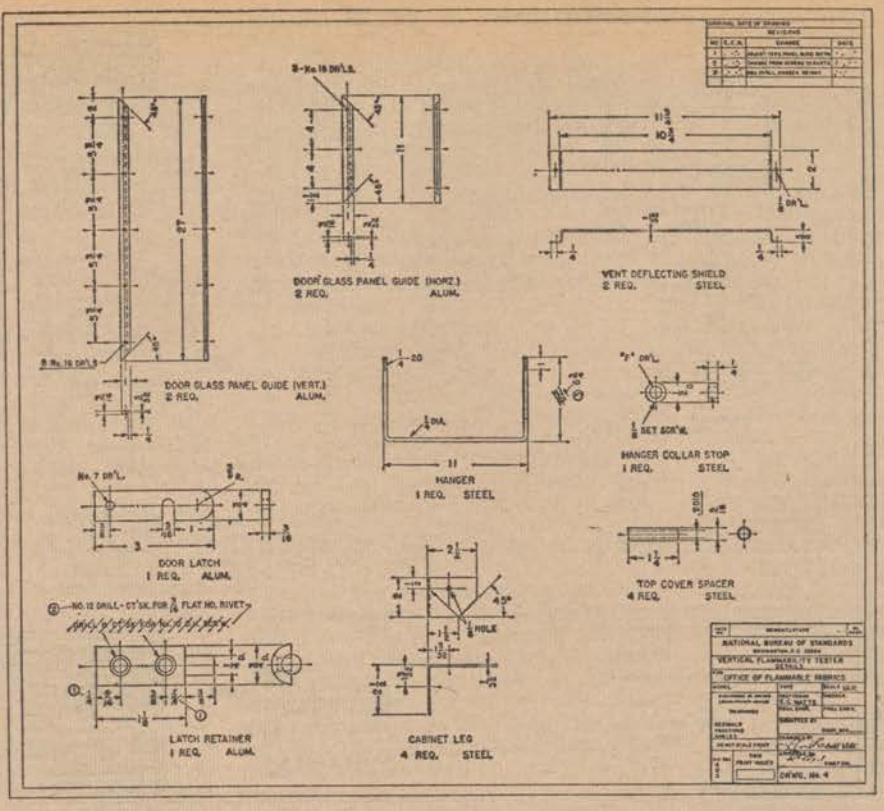
.5 *Labeling Requirements*—(a) *Care Labels.* All items of children's sleepwear shall be labeled with precautionary instructions to protect the items from agents or treatments which are known to cause deterioration of their flame resistance. If the item has been initially tested under .4(d)(4) after one washing and drying, it shall be labeled with instructions to wash before wearing. Such labels shall be permanent and otherwise in accordance with rules and regulations established by the Federal Trade Commission.

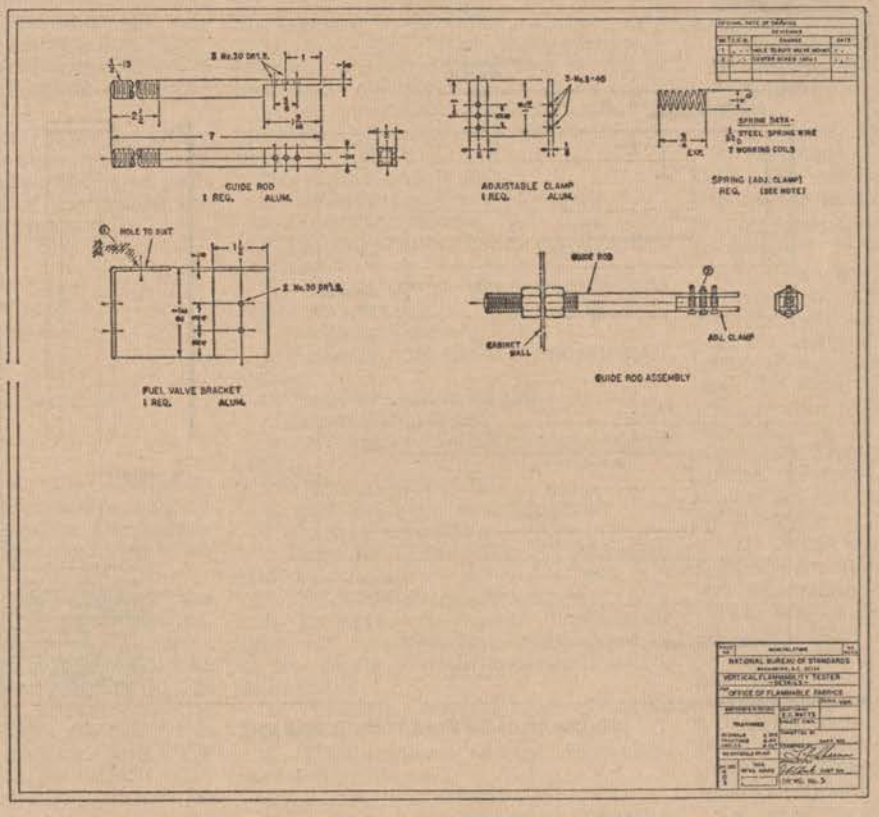
(b) *Temporary Requirement for Noncomplying Items.* Items of noncomplying children's sleepwear which are manufactured during the 12 months following the effective date of the standard shall, prior to introduction into commerce, be prominently, permanently, and conspicuously labeled with the following statement: "Flammable (Does Not Meet U.S. Department of Commerce Standard DOC FF 3–71.) Should not be worn near sources of fire." Such labels should be in accordance with the rules and regulations established by the Federal Trade Commission.

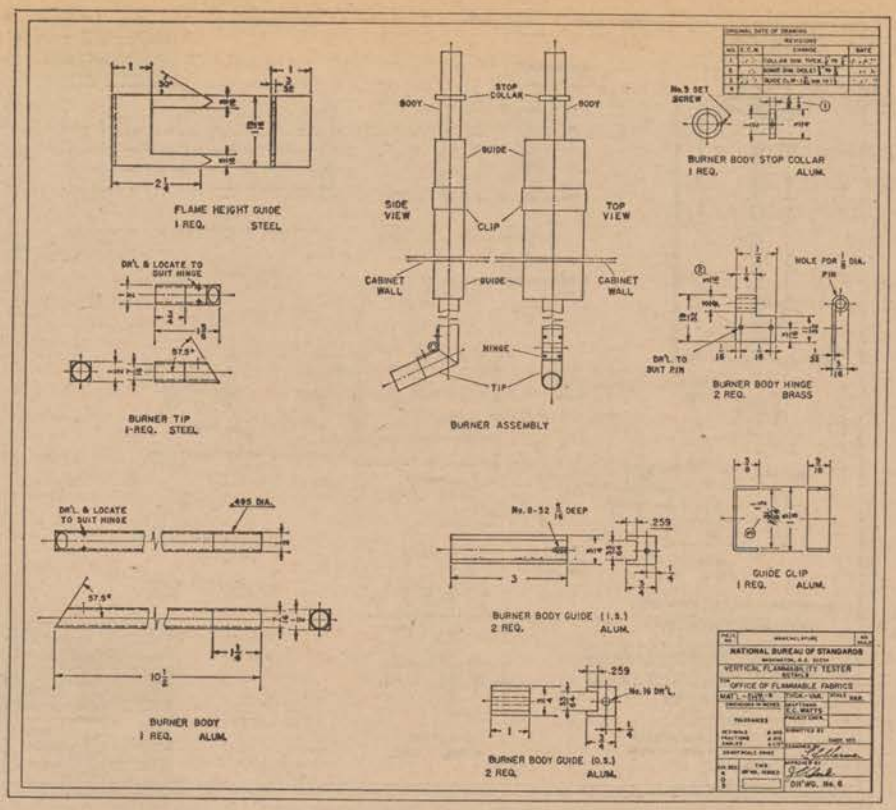


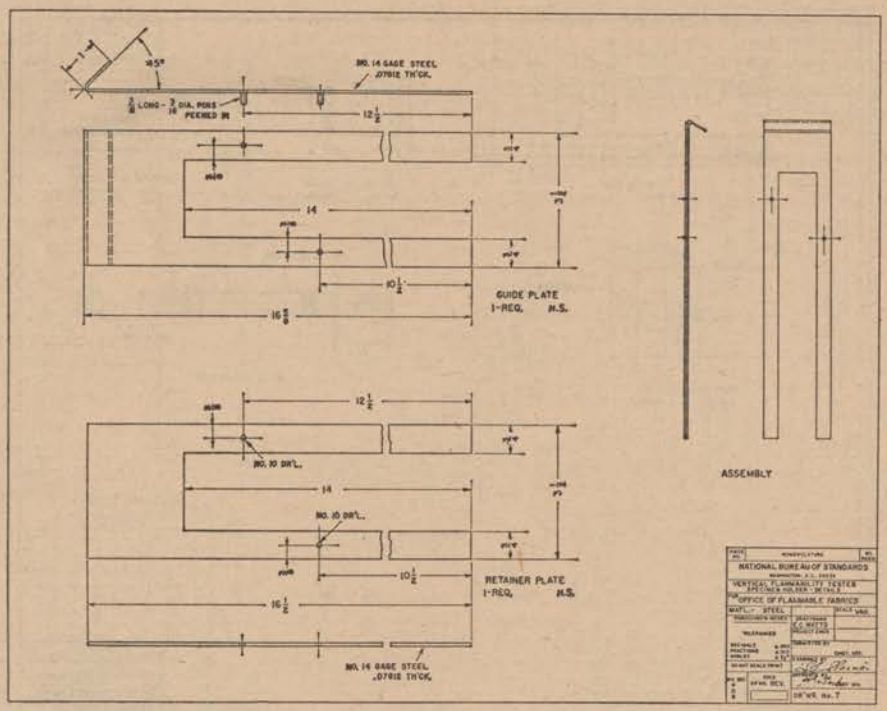

FRONT VIEW
(DOOR REMOVED)
COLLAR STOP
HANGER
GUIDE ROD
SPECIMEN HOLDER
NOTE - HOLDER MUST HANG TO LEFT OF HANGER AS SHOWN
FLAME HEIGHT GUIDE
(INSTALL WITH DOUBLE SIDED TAPE OR SUITABLE SCREWS)
BURNER
FUEL LINE TO FUEL VALVE
BURNER GUIDE
NATIONAL BUREAU OF STANDARDS
OFFICE OF FLAMMABLE FABRICS


NOTES:
1- WHEN USING SCREWS OR RIVETS COUNTERSINK WHERE NECESSARY
2- SPOT WELDING MAY BE SUBSTITUTED FOR SCREWS OR RIVETS, IF SPOT WELDING IS USED OMIT DRILL HOLES
BACK
LEFT SIDE
RIGHT SIDE
DOOR
BOTTOM
COVER PLATE
TOP
NATIONAL BUREAU OF STANDARDS
OFFICE OF FLAMMABLE FABRICS


DOOR GLASS PANEL GUIDE (VERT.)
2 REQ. ALUM.
DOOR GLASS PANEL GUIDE (HORZ.)
2 REQ. ALUM.
VENT DEFLECTING SHIELD
2 REQ. STEEL
HANGER
1 REQ. STEEL
HANGER COLLAR STOP
1 REQ. STEEL
DOOR LATCH
1 REQ. ALUM.
TOP COVER SPACER
4 REQ. STEEL
LATCH RETAINER
1 REQ. ALUM.
CABINET LEG
4 REQ. STEEL
NATIONAL BUREAU OF STANDARDS
VERTICAL FLAMMABILITY TESTER
DETAILS
OFFICE OF FLAMMABLE FABRICS


GUIDE ROD
1 REQ. ALUM.
ADJUSTABLE CLAMP
1 REQ. ALUM.
SPRING (ADJ. CLAMP)
REQ. (SEE NOTE)
FUEL VALVE BRACKET
1 REQ. ALUM.
GUIDE ROD ASSEMBLY
NATIONAL BUREAU OF STANDARDS
VERTICAL FLAMMABILITY TESTER
DETAILS
OFFICE OF FLAMMABLE FABRICS





[FR Doc.72-11252 Filed 7-20-72;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

OVER-THE-COUNTER INTERNAL ANALGESIC AND ANTIRHEUMATIC DRUG PRODUCTS

Safety and Efficacy Review; Request for Data and Information

The FDA is undertaking a review of all over-the-counter (OTC) drug products currently marketed in the United States, to determine that these OTC products are safe and effective for their labeled indications. This review will utilize expert panels working with FDA personnel.

A notice outlining procedures for this review was published in the FEDERAL REGISTER of May 11, 1972 (37 F.R. 9464).

To facilitate this review and a determination as to whether an OTC drug for human use is generally recognized as safe and effective and not misbranded under its recommended conditions of use, and to provide all interested persons an opportunity to present for the consideration of the reviewing experts the best data and information available to support the stated claims for these internal analgesic, including antirheumatic drug products, the administration invites submission of data, published and unpublished, and other information pertinent to all active ingredients utilized in internal analgesic, including antirheumatic drug products.

FDA is aware that the following active ingredients are used in such products and has conducted a literature search on each of them. The results of the search are available to interested persons.

Aspirin.
Phenacetin.
Caffeine.
Acetaminophen.
Salicylamide.
Calcium Carbaspirin.
Sodium Salicylate.
Potassium Salicylate.
Magnesium Salicylate.
Choline Salicylate.
Carbethyl Salicylate.

Interested persons are also invited to submit data on any other active ingredients for internal analgesic and antirheumatic drugs which they may wish to be considered.

To be considered, eight copies of the data and/or views must be submitted, preferably bound, indexed, and on standard-sized paper (approximately 8½ x 11 inches). All submissions must be in the format described in paragraph (B) below; except that data on aspirin is too voluminous to be included under the full format. Therefore, for aspirin only, an abbreviated submission should be made as follows:

(A) OTC Drug Review Information for Aspirin. I. Label(s) and all labeling (preferably mounted and filed with the other data—facsimile labeling is acceptable in lieu of actual container labeling).

II. A statement setting forth the quantities of active ingredients of the drug.

III. All animal data relevant to potential teratogenicity; all animal data relevant to chronic toxicity.

A. Controlled studies.

B. Partially controlled or uncontrolled studies.

IV. Human safety data relevant to special claims for safety, e.g., lack of gastric irritation or lack of gastrointestinal blood loss.

A. Controlled studies.

B. Pertinent marketing experiences regarding safety.

V. Data relevant to increased efficacy of greater than usual dosages, prolonged action, increased absorption, or other special claims which manufacturers believe justified in respect to their formulations of aspirin.

A. Controlled studies.

B. Partially controlled or uncontrolled studies.

VI. For the material requested above, if the submission is by a manufacturer, a statement signed by the person responsible for such submission, that to the best of his knowledge it includes all unfavorable information, as well as, any favorable information available to him pertinent to an evaluation of the safety, effectiveness, and labeling of such an aspirin product.

(B) OTC Drug Review Information for all Other Ingredients. I. Label(s) and all labeling (preferably mounted and filed with the other data—facsimile labeling is acceptable in lieu of actual container labeling).

II. A statement setting forth the quantities of active ingredients of the drug.

III. Animal safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

IV. Human safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination as to the safety of the finished drug product.

5. Pertinent medical and scientific literature.

V. Efficacy data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination on the efficacy of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination on the efficacy of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports.

4. Pertinent marketing experiences that may influence a determination on the efficacy of the finished drug product.

5. Pertinent medical and scientific literature.

VI. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the drug and its ingredients and the scientific basis (or lack thereof) for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

VII. If the submission is by a manufacturer, a statement signed by the person responsible for such submission, that to the best of his knowledge it includes all unfavorable information, as well as, any favorable information available to him pertinent to an evaluation of the safety, effectiveness, and labeling of such a product, including information derived from investigations, consumer complaints, commercial marketing, or published literature.

In order to avoid duplication, interested persons should not in their submissions include published literature listed in the FDA literature search. An abstract of all such literature will be

provided to the panel. Upon request the panel will be provided with the complete article. Interested persons may, of course, refer to such literature in their submissions by citation.

Submissions or requests for copies of the FDA literature search should be forwarded to:

Food and Drug Administration, Bureau of Drugs, OTC Drug Products Evaluation Staff (BD–109), 5600 Fishers Lane, Rockville, Maryland 20852.

Submission of data must be within 60 days from date of this publication. (Federal Food, Drug, and Cosmetic Act, sec. 701; 21 U.S.C. 371.)

Dated: July 18, 1972.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.72–11323 Filed 7–20–72;8:52 am]

Public Health Service

HYPERTENSION INFORMATION AND EDUCATION ADVISORY COMMITTEE

Notice of Meeting

Pursuant to Executive Order No. 11671, notice is hereby given of the following meeting:

Date	Time (a.m.)	Location of conference room
July 24, 1972	10	Room 10, Bldg. 31, National Institutes of Health.
and		
July 25, 1972	9	Room 5131, HEW Bldg.
	11	Snow room, HEW Bldg.

This meeting shall be open to the public pursuant to section 13 of Executive Order 11671.

Name of person from whom rosters of committee members may be obtained: Dr. Theodore Cooper, NHLI.

Dated: July 19, 1972.

ROBERT Q. MARSTON,
Director, NIH.

[FR Doc.72–11324 Filed 7–19–72;10:18 am]

Office of the Secretary

ADVISORY COMMITTEE ON OLDER AMERICANS

Committee Meeting Announcement

HEW Advisory Committee on Older Americans will held a regular meeting on July 27, 9 a.m. to 4 p.m., Hotel Washington, 15th and Pennsylvania Avenue NW., Washington, D.C. The committee will review the status of the pending Older Americans Act amendments and the Social Security amendments and the implementation of the Nutrition Program for the Elderly. The Subcommittees on Social Services and on Health will report on their beginning activities in preparing recommendations on social services and long-term care systems for the elderly. Meeting open to public observation.

CLEONICE TAVANI,
Staff Director.

JULY 17, 1972.

[FR Doc.72–11268 Filed 7–20–72;8:49 am]

ADVISORY COMMITTEE ON OLDER AMERICANS

Subcommittee Meeting Announcement

HEW Advisory Committee on Older Americans, Health Subcommittee will hold their first meeting on July 26, 9 a.m. to 4 p.m., HEW South Building, Room 3065, 330 Independence Avenue, Washington, D.C. The committee will review HEW health-related activities for the chronic care needs of the elderly as a basis for making recommendations for future long-term care systems. Meeting open to public observation.

CLEONICE TAVANI,
Staff Director.

JULY 17, 1972.

[FR Doc.72–11267 Filed 7–20–72;8:49 am]

SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE

Notice of Meeting of Consumer Issues Advisory Panel

The Secretary's Commission on Medical Malpractice Consumer Issues Advisory Panel created to provide technical assistance to the Commission on medical malpractice consumer issues will meet July 24, 1972, at 8:30 a.m., in Room 5116 of the New Executive Office Building, 726 Jackson Place NW., Washington, DC. The panel will discuss the doctrine of implied consent from the viewpoint of the consumer and patient. The meeting will be open to the public.

Dated: July 18, 1972.

ELI P. BERNZWEIG,
Executive Director.

[FR Doc.72–11269 Filed 7–20–72;8:49 am]

SECRETARY'S ADVISORY COMMITTEE ON AUTOMATED PERSONAL DATA SYSTEMS

Notice of Meeting

In accordance with the provisions of Executive Order No. 11676, dated June 5, 1972, announcement is made of the public meeting of the Secretary's Advisory Committee on Automated Personal Data Systems, to be held beginning at 9 a.m. on Monday, July 24, 1972, and continuing through Wednesday, July 26, 1972. The Committee will meet at Stone House, (Building 16), National Institutes of Health, Bethesda, Md.

(1) *Purposes.* The Committee was appointed to advise and assist the Department of Health, Education, and Welfare in the preparation of analyses and recommendations which the Secretary determines will help the Department to take initiative in seeking to assure that the use of automated data systems will be managed to maximize their benefits and minimize their potential for harmful consequences.

(2) *Membership.* The Committee is chaired by Frances Grommers, M.D., and is composed of the following: Layman Allen, Juan Anglero, Stanley Aronoff, William Bagley, Philip Burgess, Gertrude Cox, Patricia Cross, Gerald Davey, Taylor DeWeese, Guy Dobbs, Robert Gallati, Florence Gaynor, John Gentile, Jane Hardaway, James Impara, Patricia Lanphere, Arthur Miller, Don Muchmore, Jane Noreen, Roy Siemiller, Ruth Silver, Sheila Smythe, Willis Ware, and Joseph Weizenbaum.

(3) *Activities.* This will be the fourth meeting of the Committee. As at prior meetings, representatives of governmental and private agencies and institutions appear and present to the Committee information on various aspects of specific data systems and discuss issues relating to the use of such systems and their impact on privacy, confidentiality, and due process.

(4) *Agenda.* The agenda for the July 24, 25, and 26 meeting will include presentations of evidence regarding the following automated personal data systems:

New York State Identification and Intelligence System.
Vocational Rehabilitation Case Service Report System.
Maryland Psychiatric Case Register.
National Cancer Survey.
Medical X-Ray Examination System.
National Surveillance Network.

In addition, the Committee will receive a presentation from the National Center for Health Statistics.

It is suggested that those desiring more specific information on the meeting first call the Office of the Executive Director at 963–3003.

DAVID B. H. MARTIN,
Executive Director.

JULY 18, 1972.

[FR Doc.72–11294 Filed 7–20–72;8:49 am]

ATOMIC ENERGY COMMISSION

[Docket No. 50–309]

MAINE YANKEEE ATOMIC POWER CO.

Notice of Availability of Final Environmental Statement for Maine Yankee Atomic Power Station

Pursuant to the National Environmental Policy Act of 1969 and the Atomic Energy Commission's regulations in Appendix D to 10 CFR Part 50, notice is hereby given that the "Final Environmental Statement Related to the Opera-