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FR/FRVLBR NOTIFIED
✓ No comments made
___ Comments attached
___ Excisions/Revisions
___ Firm has not requested further notice
[illegible] 8/16/84

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

September 29, 1977

Mr. Richard J. Allen
Environmental Design Consultants, Inc.
2830 Victory Parkway
Cincinnati, Ohio 45206

Dear Mr. Allen:

This letter is in response to your correspondence of August 30, 1977 and your conversation of September 23, 1977 with Mr. Alan H. Schoem of this office concerning the coverage of "lead (Xray) glass" under the standard for architectural glazing materials, 16 CFR 1201. Section 1201.1(b) of the standard provides that the standard applies only to "glazing materials and architectural products incorporating glazing materials that are produced or distributed for sale to or for the personal use, consumption or enjoyment of consumers in or around a temporary household or residence or in recreational, school, public, or other buildings or parts thereof." The Consumer Product Safety Act (CPSA) defines the term "consumer product" which delimits the Commission's jurisdiction in a similar manner.

You advised Mr. Schoem in your September 23 telephone conversation that the lead (Xray) glass that is the subject of your letter is installed in a "special procedure room" so that hospital personnel can view a patient undergoing radiation treatment. You further advised that the glass is for the sole use of hospital personnel and that there is no need for the glass other than to allow hospital personnel to view a patient. The glass serves to protect hospital personnel from being exposed to radiation.

In view of this information, it is the view of the Office of the General Counsel that the use of the lead (Xray) glass as described in your letter and telephone

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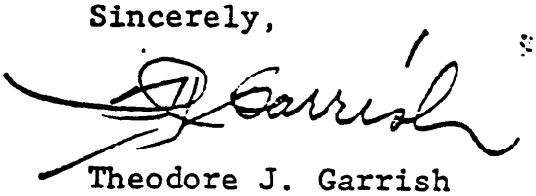
conversation would not in this particular instance be a consumer product because it is not sold to or used or enjoyed by consumers. Accordingly, in our view, it would not be subject to the standard for architectural glazing materials.

In addition, the CPSA excludes from Commission jurisdiction medical devices as defined in the Federal Food, Drug, and Cosmetic Act. In our view, lead (Xray) glass whose purpose is to protect hospital personnel from exposure to radiation, may be a medical device. If so, on that basis it would also not be a consumer product within the Commission's jurisdiction. We have asked the Food and Drug Administration for an opinion on whether lead Xray glass is a medical device.

Sincerely,



Theodore J. Garrish
General Counsel.

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KZF
ENVIRONMENTAL DESIGN CONSULTANTS INC
ARCHITECTS • ENGINEERS • PLANNERS • SURVEYORS
2830 Victory Parkway, Cincinnati, Ohio. 45206 (513)281-7723

August 30, 1977

The General Consel's Office
Consumer Protection Safety Commission
Washington, D.C. 20207

Att: Mr. David Smeltzer

Re: Lead (Xray) Glass Meeting Safety Standards for Architectural Glazing
Project: Bethesda Hospital - Oak, Cincinnati, Ohio

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CONSUMER PRODUCT SAFETY COMMISSION ENFORCEMENT

Dear Sir:

We are petitioning for an immediate exemption from the Safety Standard for Architectural Glazing materials issued by the Consumer Products Safety Commission which became law July 6, 1977. In particular we are petitioning for a variance to the requirement that glass installed in doors must be safety glass or in windows which occur within 48 inches of any adjacent door frame. (Please refer to the attached drawings for the conditions as proposed).

Specifically, we are petitioning for a variance to the requirement to permit the use of lead (Xray) glass in lieu of safety glass in this particular application. First of all there is, at this time, no lead (Xray) glass manufactured that will meet the CPSC code requirements of safety glass. In addition, all lead (Xray) glass is foreign made and the manufacturers are unaware of this law and have made no provisions to meet the requirement of this code.

The local glass supplier tells us that lead (Xray) glass - if laminated to safety glass cannot be certified to meet the CPSC standards. In addition, there is no guarantee that the quality of the lead shielding is maintained. And at this time it is not possible to temper lead (Xray) glass.

The area in which the lead (Xray) glass will be installed in the Hospital is not a public area but a highly supervised special procedure room. The patient is always escorted by an attendant and strapped to the procedures table and is attended to 100% of the time by the Doctor and his technicians. Therefore, the chances for accidental breakage of glass by a semi-conscious person is zero.

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KZF

Finally, strict application of the new code will delay the finishing of the special procedure rooms and this of course will delay the revenue that this room can generate for the Hospital. In addition, researching or providing something other than lead (Xray) glass as already contracted will increase the construction costs.

This is not an appeal in an attempt to circumvent the purposes and intents of the Consumer Products Safety Commission Standards. However, in this particular instance we feel an appeal is justified and that an exemption to this requirement should be granted as soon as possible.

If you require any additional information please do not hesitate to call me.

Very truly yours,

KZF, INC.

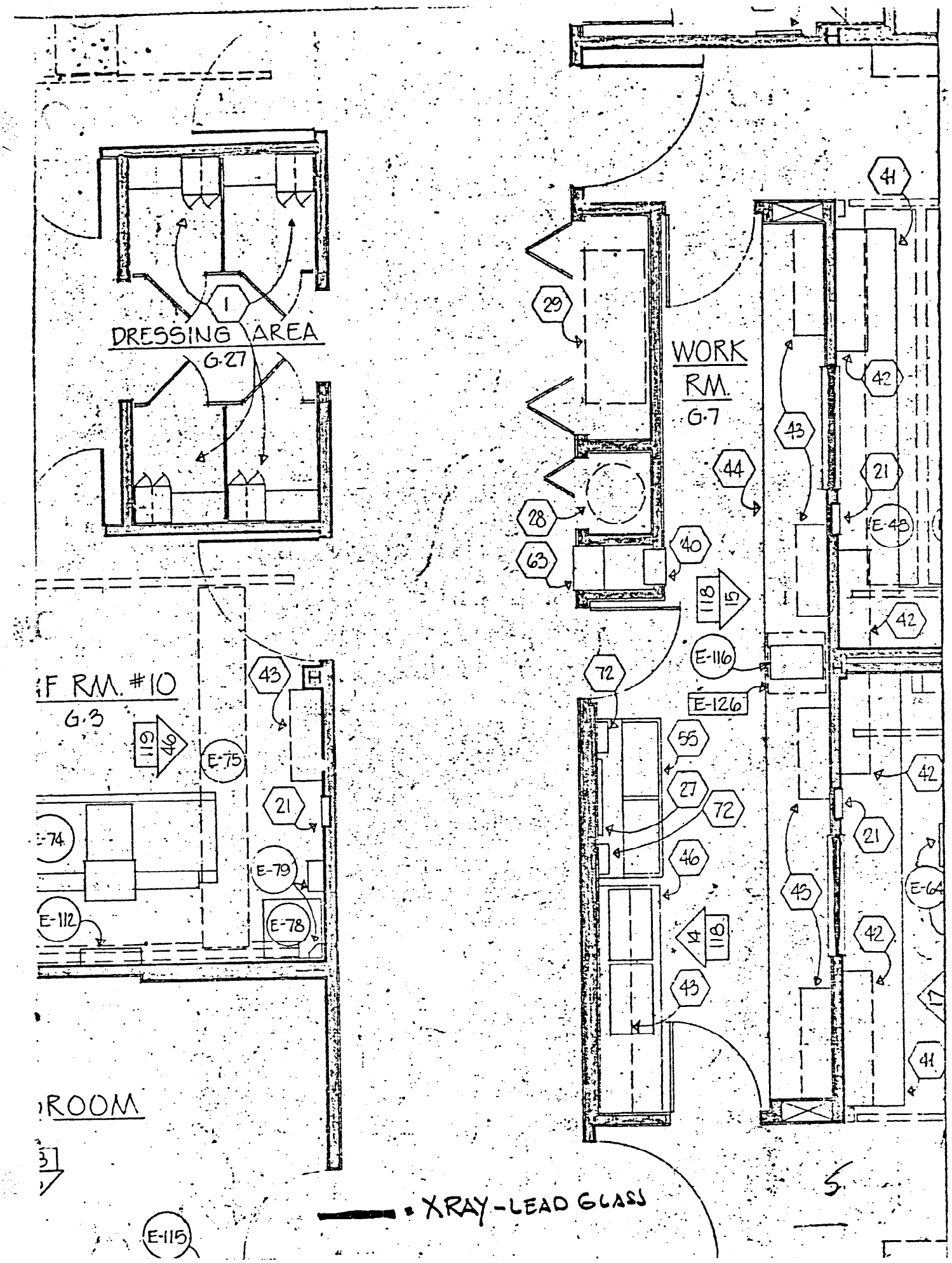
Richard J. Allen

Richard J. Allen

Enclosure

cc: Mr. Harry Jettke
Mr. Greg Rhoads

RJA/jp


DRESSING AREA
G-27
WORK RM.
G-7
F RM. #10
G-3
ROOM
E-115
E-116
E-126
E-75
E-74
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E-43
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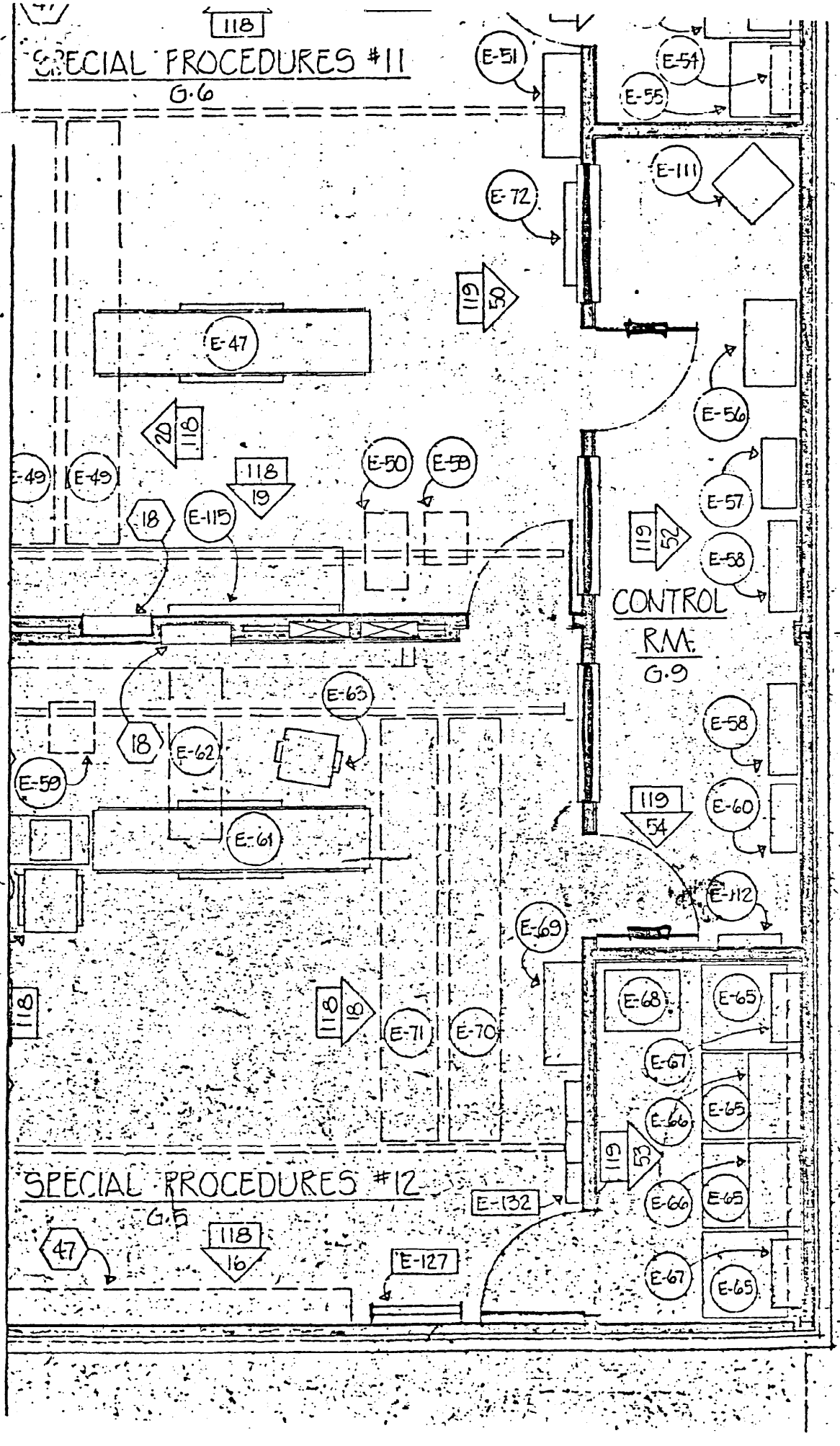
XRAY-LEAD GLASS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SPECIAL PROCEDURES #11
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CONTROL
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SPECIAL PROCEDURES #12
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