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ULTRAVIOLET RADIATION SOURCES USED IN DERMATOLOGY, SEPTEMBER-DE--ETC(U)
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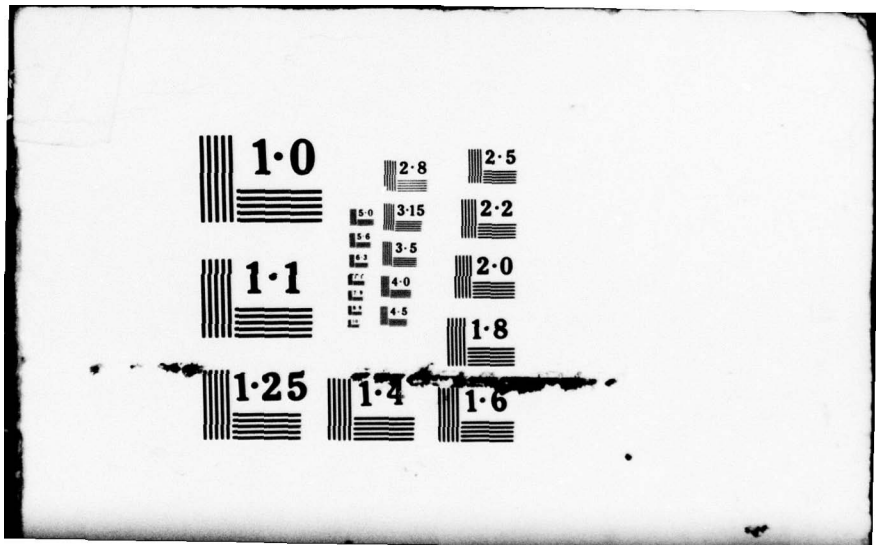
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LEVEL II

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ABERDEEN PROVING GROUND, MD 21010

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(9) NONIONIZING RADIATION PROTECTION SPECIAL STUDY NO. 25-42-0388-79

(6) ULTRAVIOLET RADIATION SOURCES USED IN DERMATOLOGY, SEPTEMBER-DECEMBER 1978.

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(12) 38p.

(10) David H. Sliney

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

A nonionizing radiation protection special study of the ultraviolet(UV) lamps used in dermatology at US Army medical installations was performed by this Agency. Detailed measurements of three characteristics of ultraviolet therapy systems were performed at Fitzsimons Army Medical Center during September 1978. In addition, previous measurements of other small UV lamps and the sun are also provided. The spectra were weighted against the standard erythemal (and hazard) action spectrum to assist users of such UV sources.

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

Mr. Sliney/lr/584-3000

29 MAR 1979

HSE-RL/WP

SUBJECT: Nonionizing Radiation Protection Special Study No. 25-42-0388-79, Ultraviolet Radiation Sources Used in Dermatology, September-December 1978

Commander
US Army Health Services Command
ATTN: HSPA-P
Fort Sam Houston, TX 78234

A summary of the pertinent findings and recommendations of the inclosed report follows:

a. A nonionizing radiation protection special study of ultraviolet (UV) lamps used in dermatology at US Army medical installations was performed by this Agency. Detailed measurements of three characteristics of ultraviolet therapy systems were performed at Fitzsimons Army Medical Center during September 1978. In addition, previous measurements of other small UV lamps and the sun are also provided. The spectra were weighted against the standard erythemal (and hazard) action spectrum to assist users of such UV sources.

b. It is recommended that only authorized, adequately trained personnel operate the equipment; that lamp systems be labeled; that small, inexpensive UV measurement instruments be used to monitor lamp output; and that UV-treatment timers be periodically checked.

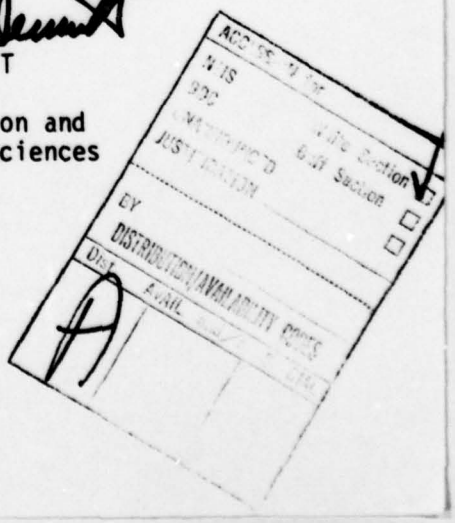
FOR THE COMMANDER:

Frank E. McDermott

FRANK E. McDERMOTT
LTC(P), MSC
Director, Radiation and
Environmental Sciences

1 Incl
as (5 cy)

CF:
HQDA (DASG-PSP)
Cdr, ea MEDCEN/MEDDAC (Dermatology Svc)
Supt, AHS (HSA-IHE)
Cdr, FAMC (PVNTMED Actv)(2 cy)
C, USAEHA-Rgn Div West



DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

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NONIONIZING RADIATION PROTECTION SPECIAL STUDY NO. 25-42-0388-79
ULTRAVIOLET RADIATION SOURCES USED IN DERMATOLOGY
SEPTEMBER-DECEMBER 1978

1. AUTHORITY.

a. AR 40-5, Health and Environment, 25 September 1974.

b. Letter, HSF-PM, Fitzsimons Army Medical Center, 10 August 1978, subject: Measurement of UV Light Output.

2. REFERENCES.

a. AR 40-46, Control of Health Hazards from Lasers and Other High Intensity Optical Sources, 6 February 1974.

b. FM 8-16, Physical Therapy Technician, 24 January 1977.

c. Report, HSE-RL, this Agency, Nonionizing Radiation Protection Special Study No. 42-0305-77, Spectral Irradiance of Several Ultraviolet Sources, July-September 1976 (DDC No. ADA 031276).

d. Technical Guide, HSE-RL, this Agency, Hazard Analysis of Broad-Band Optical Sources, December 1977, Tech Guide 085 (ADA 054-802/4GI).

3. PURPOSE. To evaluate potential health hazards associated with the use of ultraviolet (UV) radiation sources used in dermatology services at US Army hospitals and medical centers and to make recommendations necessary to preclude hazardous exposure of personnel other than the patient under treatment.

4. GENERAL.

a. Background. In accordance with a letter of request (paragraph 1b), several UV sources used for therapeutic purposes at the Dermatology Service, Building T419, Fitzsimons Army Medical Center (FAMC), Denver, CO, were measured on 11 and 15 September 1978. Several diagnostic Wood's Lamps have been measured by the US Army Environmental Hygiene Agency (USAEHA) at other medical facilities during routine surveys. It was determined that a compilation of the UV output characteristics of these sources would be of considerable value to all dermatology services; hence, this study was widened from the consideration of only the FAMC sources. Reasonably accurate information on the radiometric output characteristics would be of value in reducing the risk of unintentional hazardous exposure to such sources. One would expect that the output of other units of the same model would not be significantly different. During the lifetime of any lamp source, one can expect a gradual reduction in UV output with age, the range of this change generally being no more than a factor of two.

b. Instrumentation.

(1) EG&G Model 585 Spectroradiometer System with UV, solar-blind detector head, Serial Number 821, with 2-5-nm bandwidth

(2) Acton Research, Inc., Ultraviolet Hazard Filter

(3) Ultraviolet Products, Inc., Model J-225 Shortwave UV Meter

(4) Ultraviolet Products, Inc., Model J-221 Longwave UV Meter

(5) International Light, Model IL 730 Actinic Ultraviolet Radiometer

c. Exit Briefing. The basic findings of this study and the need for a general study and summary were discussed with COL John L. Aeling, Chief of the FAMC Dermatology Service and Dermatology Consultant to The Surgeon General, and with MAJ Paul B. Thompson, Dermatology Service, FAMC.

d. Radiometric Terms, Units and Abbreviations. A Table of the radiometric terms and units is provided as Appendix A.

5. FINDINGS.

a. Burdick Model 800 Ultraviolet Lamp. This unit is a 115-V, 60-Hz, 410-W mercury lamp system (NSN 6530-00-035-1133) manufactured by the Burdick Corporation, Milton, WI. This unit (Figure 1) is found at many medical centers. Figure 2 provides the ultraviolet spectral irradiance of the system from approximately 200-405 nm at a distance of 28 cm from the cone edge for both linear and semilogarithmic scales. The relative irradiance as a function of distance from the edge of the 4.5-cm-diameter cone is given in Figure 3. The location of the effective "point" source for the purposes of calculating an inverse-square relation of irradiance with distance was found to be 5 cm behind the edge of the cone. A summary of important measurements and calculated values is provided below; complete spectral irradiance values are provided in Appendix B.

Measurement Position: 28 cm from cone edge
Total Irradiance (200-405 nm): 2.30 mW/cm^2
Effective UV Irradiance (AR 40-46): 0.49 mW/cm^2
Permissible Occupational Health Exposure Duration: 6.1 s
Erythemal UV Irradiance (CIE 1936): 0.44 mW/cm^2
Exposure Duration for 25-mW/cm^2 MED: 57 s
Spectral Irradiance at 254 nm: 0.162 mW/cm^2
Spectral Irradiance at 313 nm: 0.385 mW/cm^2
Spectral Irradiance at 366 nm: 0.413 mW/cm^2
Reading* of IL 730 UV Radiometer: 0.45 mW/cm^2
Reading* of UV Products J-225 Shortwave Meter: 0.7 mW/cm^2
Permissible Occupational Exposure Duration to the Direct Beam at 60 cm: 15 s

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* Not considered a calibrated value, but provided for comparison with the other data which are considered to be as accurate as possible(±10 percent).

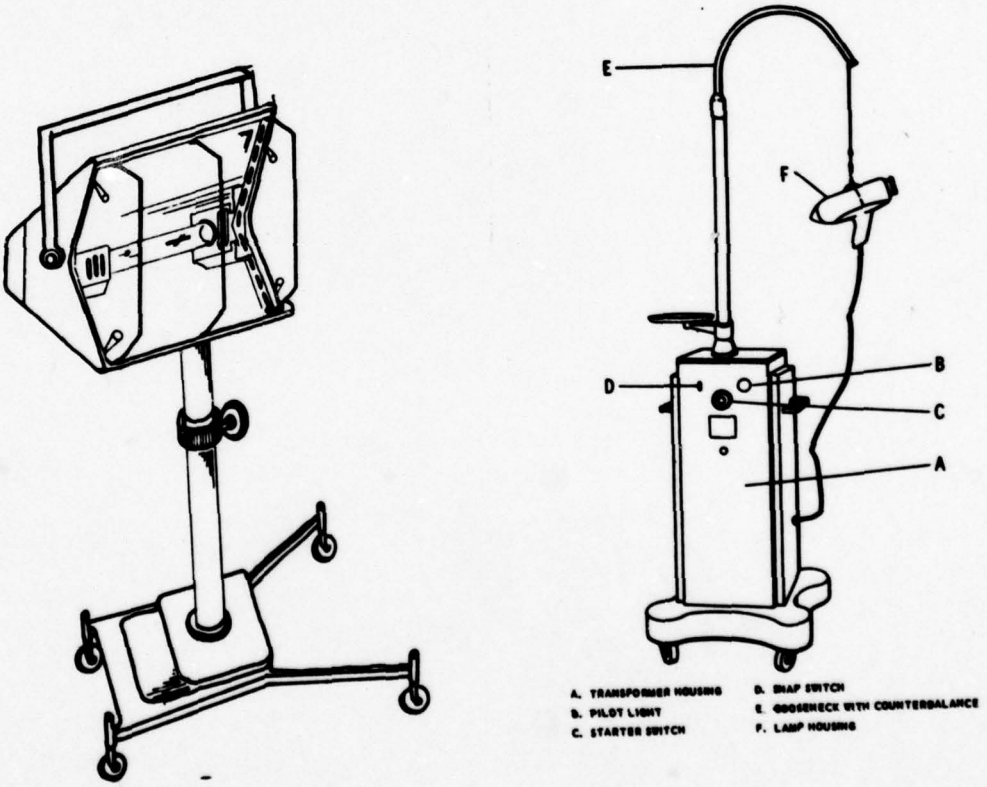

FIGURE 1. Drawings of the Burdick Model 800 (left) and Hanovia Aero-Kromayer (right) Ultraviolet Therapy System.

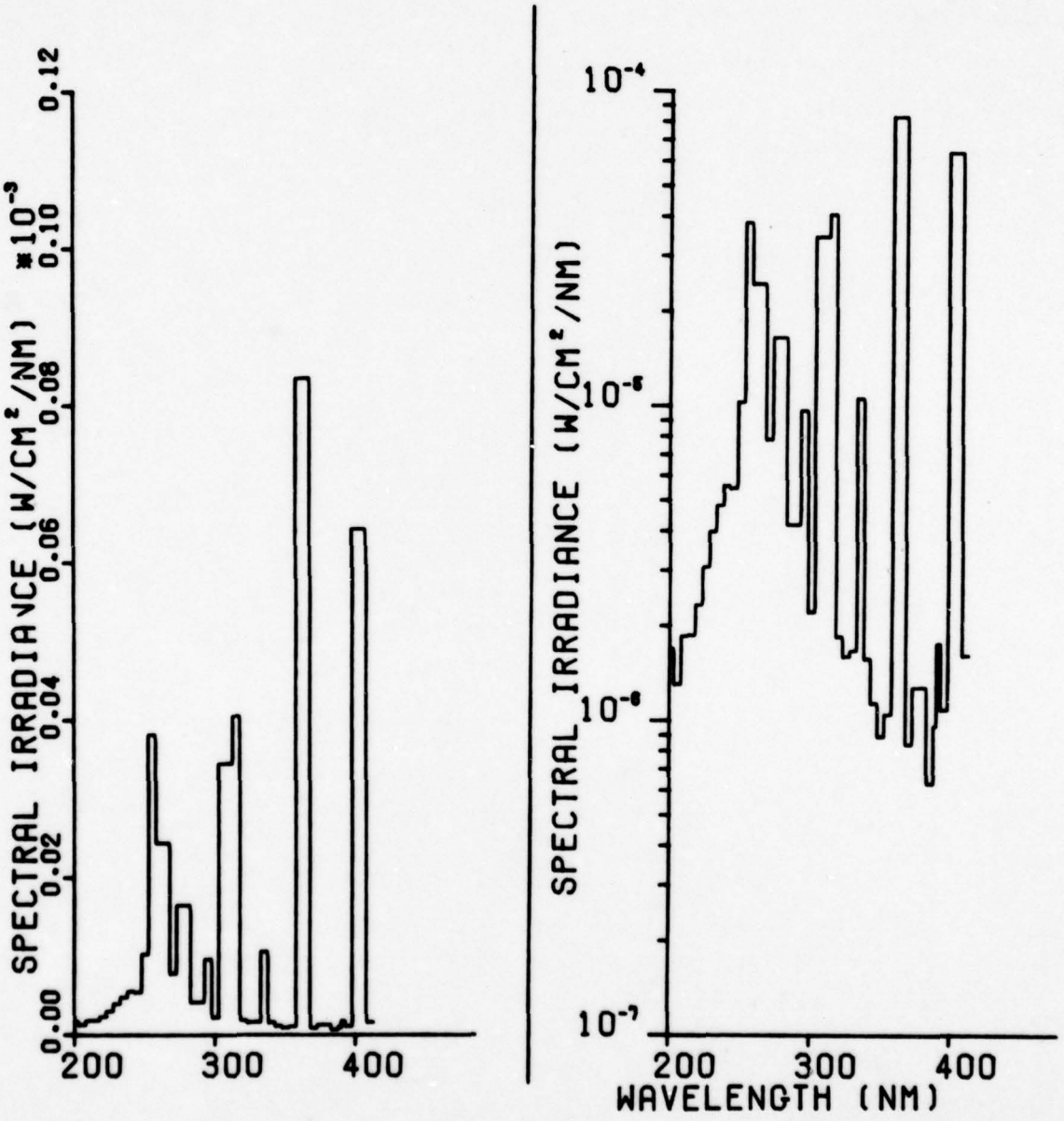

FIGURE 2. Absolute Spectral Irradiance of the Burdick Model 800 UV Lamp at a Distance of 28 cm from the Cone Edge. Note the two Vertical Scales are Different.

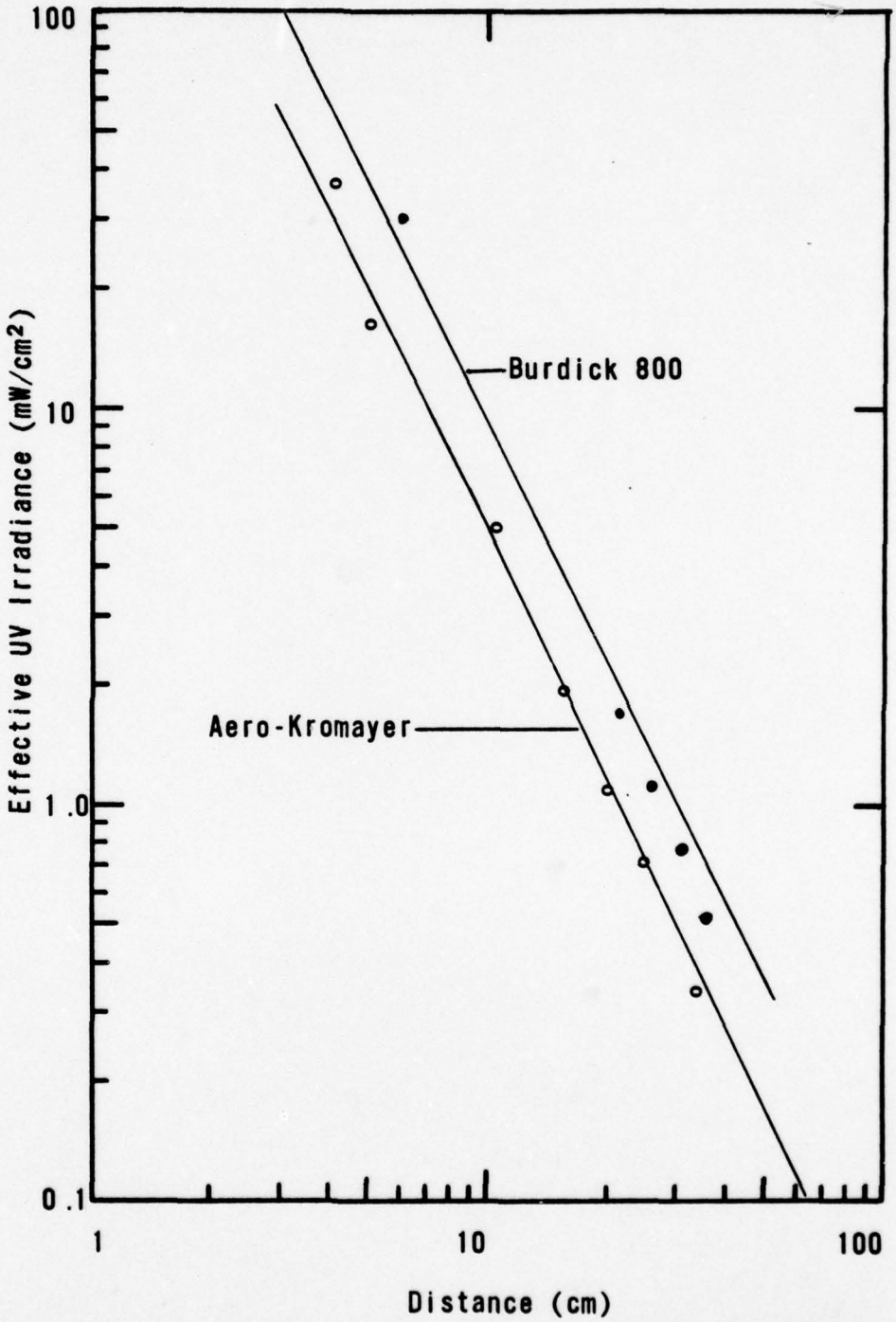

FIGURE 3. Effective UV Irradiance as a Function of Distance for the Burdick 800 and the Aero-Kromayer Treatment Lamps. The zero reference distance was 5 cm behind the cone edge for the Burdick 800 and 4 cm behind the quartz tip for the Aero-Kromayer.

b. Hanovia Aero-Kromayer UV Lamp. This unit, Catalog No. 2221-A (NSN 6530-00-712-8500), is a 115-V, 60-Hz, 260-W system manufactured by Hanovia Chemical and Manufacturing Company, Newark, NJ (Figure 1). Figure 4 provides the spectral irradiance at a distance of 16 cm from the applicator surface for both linear and semilogarithmic scales. The relative irradiance is plotted as a function of distance from the surface of the applicator. The location of the effective "point" source for the purposes of calculating the inverse-square relation of irradiance with distance was found to be 4 cm behind the 4-cm quartz-window applicator tip. Certain principal measurements and calculations are listed below; the complete spectral irradiance values are listed in Appendix B.

Measurement Position: 16 cm from tip (quartz window)
Total Irradiance (200-400 nm): 3.4 mW/cm^2
Effective UV Irradiance (AR 40-46): 0.80 mW/cm^2
Permissible Occupational Health Exposure Duration: 3.7 s
Erythemal UV Irradiance (CIE 1936): 0.66 mW/cm^2
Exposure Duration for 25-mJ/cm^2 MED: 38 s
Spectral Line Irradiance at 254 nm: 0.115 mW/cm^2
Spectral Line Irradiance at 313 nm: 0.367 mW/cm^2
Spectral Line Irradiance at 365 nm: 0.503 mW/cm^2
Reading* of IL 730 UV Radiometer: 0.97 mW/cm^2
Reading* of UV Products J-225 Shortwave Meter: 0.8 mW/cm^2
Permissible Occupational Exposure Duration at 60 cm: 30 s

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* Not considered a calibrated value, but provided for comparison with the other data which are considered to be as accurate as possible (±10 percent).

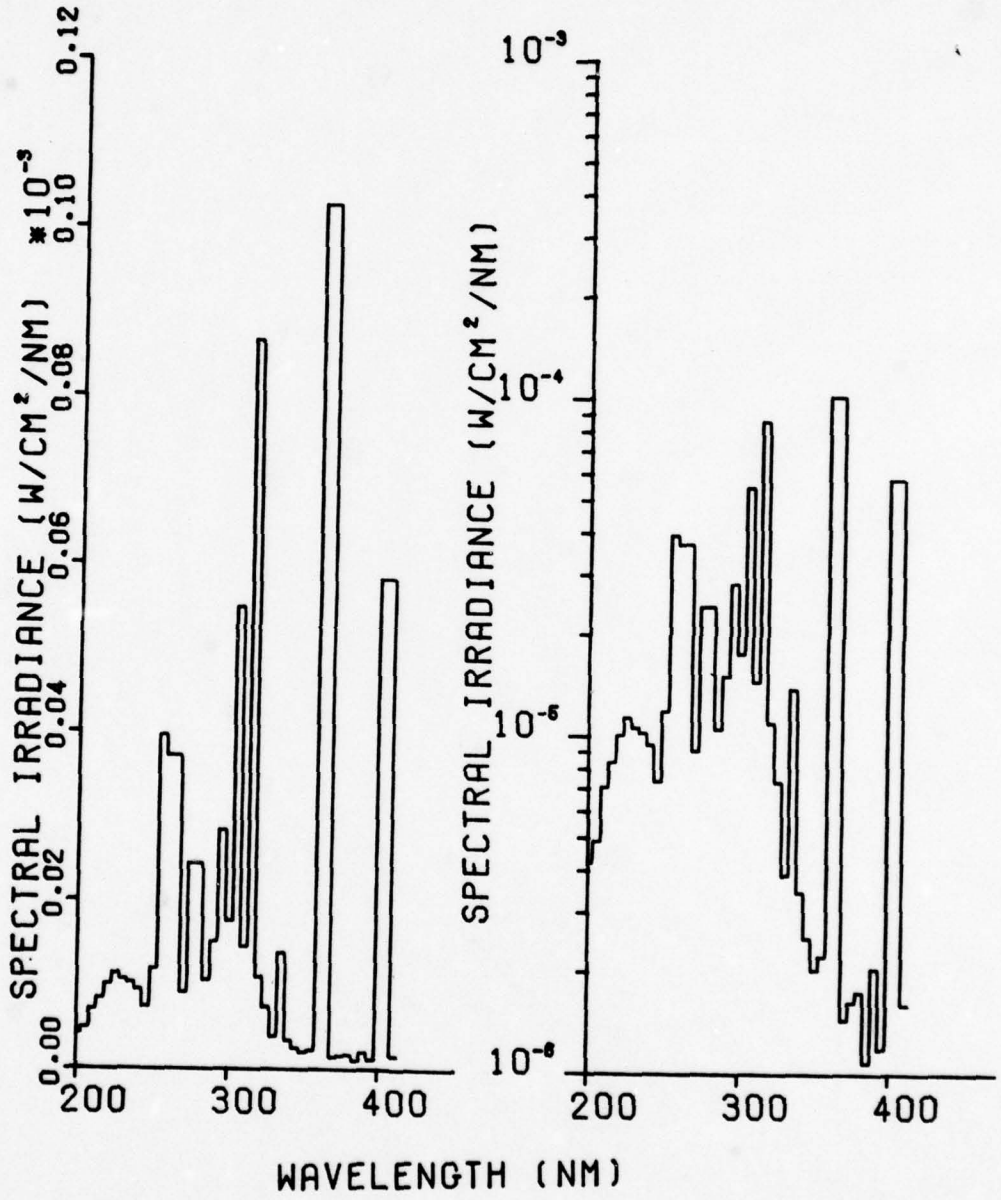

FIGURE 4. Absolute Spectral Irradiance of the Aero-Kromayer UV Lamp at a Distance of 16 cm from the Tip Surface of the Applicator Gun. Note that the two Vertical Scales are Different.

c. Light Box. A light box with vertically oriented fluorescent lamps had been constructed at FAMC and was similar to other units which were found in other Army medical centers. The unit consisted of 28 alternating vertical rows of "black light" F20-BL and F40-BL (UV-A) lamps and type FS-20 and FS-40 sunlamps (UV-B and UV-C). Each vertical row consisted of one 24-inch lamp and one 48-inch lamp, so that a patient 6-foot high standing in the box would be evenly illuminated in the box. Using the small meters (the J-225, J-222 and IL 730), the centerline irradiance appeared to be quite uniform as a function of height. In fact, the cosine-weighted irradiance on any surface facing the nearest array of lamps was rather uniform throughout the box. For example, the actinic UV irradiance when only the FS-40 and FS-20 lamps were operating was typically 0.1 mW/cm^2 at 1 cm from the lamp surface and 0.05 mW/cm^2 at the centerline using the IL 730 instrument. No potentially hazardous levels of UV radiation could leak or be reflected into occupied areas when the light-box door was closed. The FS-20 (20-W) and FS-40 (40-W) sunlamps were manufactured by Westinghouse and the "black light" lamps were Sylvania F40-BL and General Electric F20T12-BL lamps. The lighting fixtures were manufactured by Lithonia Lighting, Conyers, GA, under Issue C-510, 625, 48A, 118-W. Although the numbers of lamps differ at other centers, the types of lamps used are similar. The centerline spectral irradiance measurements (Figures 5 and 6) were made with the EG&G-585 system with the hood removed to provide a wide field-of-view of four vertical rows of lamps, the plane of lamps being approximately 40 cm from the point of measurement. The full view provided by a true cosine-response instrument would have increased the readings by 67 percent. This was determined by placing the IL 730 detector at the diffuser plane of the EG&G behind the filter holder. Hence, one must multiply the reported spectral irradiance readings by 1.67 in order to correctly compare them with the other direct-reading instruments. A summary of the important measurements and calculated values are provided below and a complete list of spectral irradiance values is given in Appendix B.

Value	BL Lamps	FS Lamps
Total Irradiance (200-405 nm)	0.20 mW/cm^2	0.145 mW/cm^2
Effective UV Irradiance (AR 40-46)	6.7×10^{-5} mW/cm^2	0.012 mW/cm^2
Permissible Occupational Health Exposure Duration	>8 hours	250 s
Erythemal UV Irradiance (CIE 1936)	2.7×10^{-4} mW/cm^2	0.025 mW/cm^2
Exposure Duration for 25-mW/cm^2 MED	NA	1000 s (17 min)
Spectral Irradiance at 254 nm	--	0.018 $\mu W/cm^2$
Spectral Irradiance at 313 nm	1.1 $\mu W/cm^2$	8.9 $\mu W/cm^2$
Spectral Irradiance at 365 nm	0.4 $\mu W/cm^2$	1.7 $\mu W/cm^2$
Reading of IL 730 UV Radiometer	NR	0.05 mW/cm^2
Reading of UV Products J-221 Longwave Meter	1.5 mW/cm^2	--

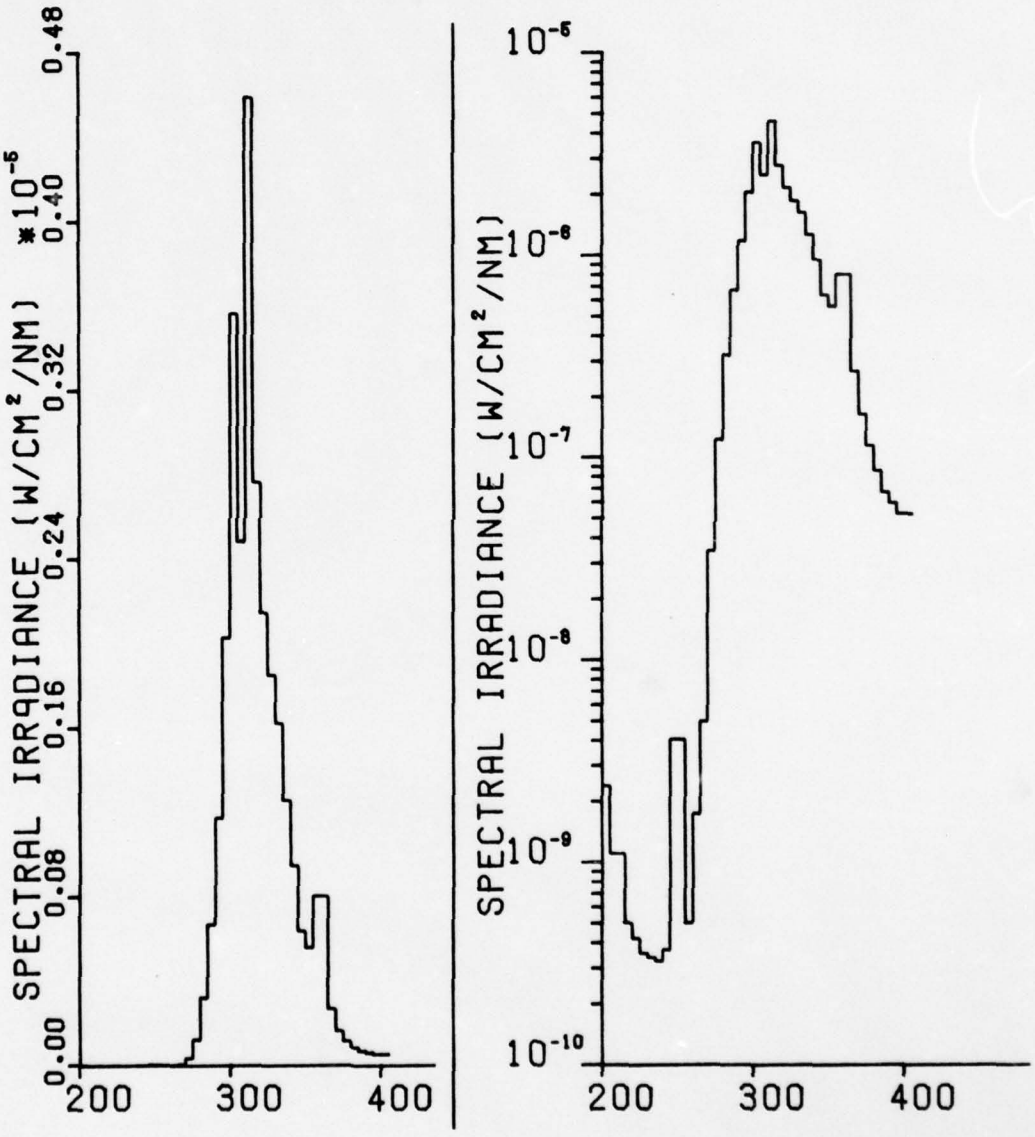

FIGURE 5. Absolute Spectral Irradiance of the FS Sunlamp Array at Light-Box Center-line.

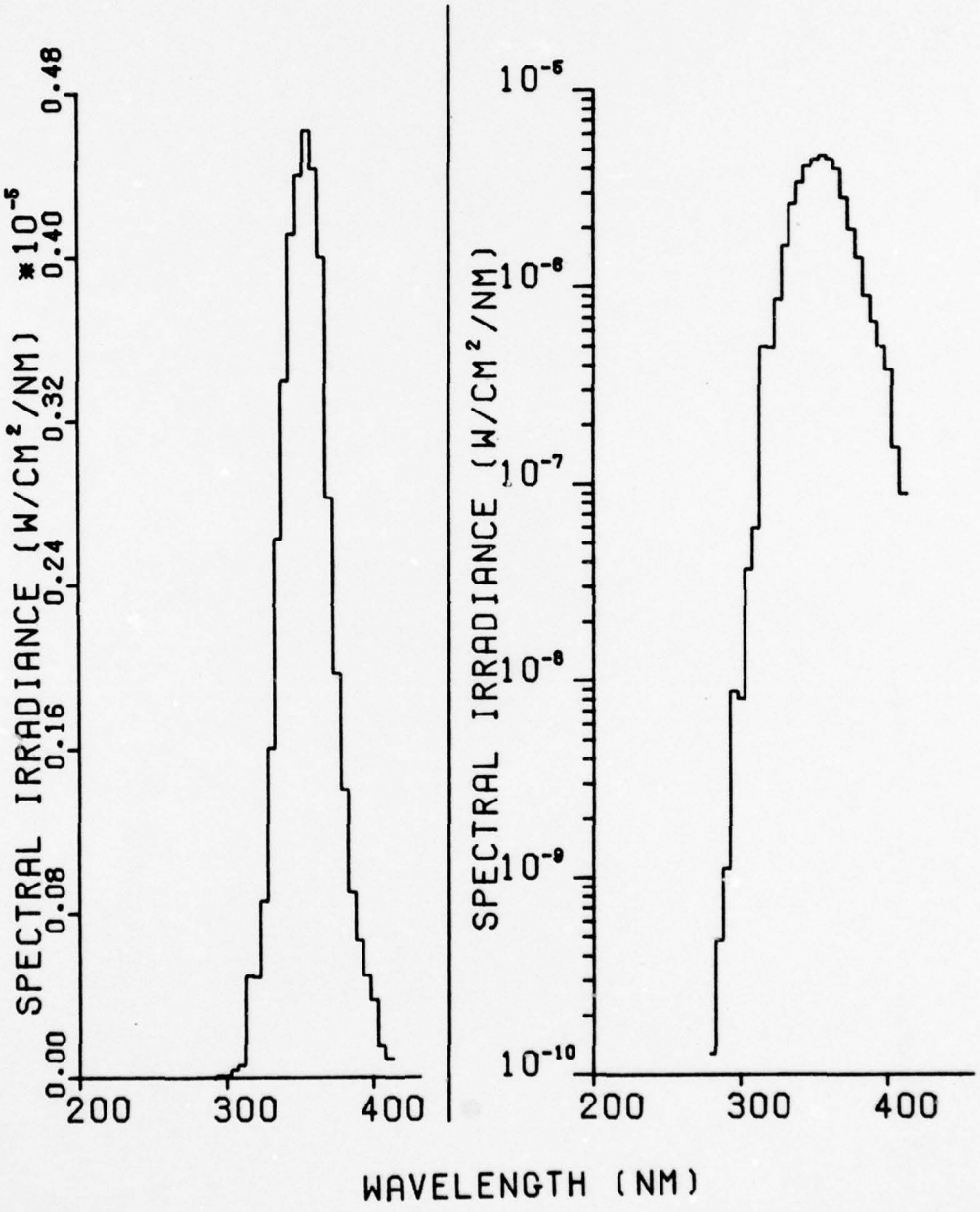

Figure 6. Absolute Spectral Irradiance of the F40-BL Sylvania Black Lamp Array at Light Box Centerline (41 cm).

d. Other Small UV Lamps. There are several other types of small laboratory UV lamps that are occasionally found in dermatology departments. These lamps had previously been measured (paragraph 2c). Some of these types of lamps (those that emit only UV-A) are often termed "Wood's Lamps" when used to excite fluorescence in some diagnostic procedures. The absolute spectral irradiance at 15 cm from the lamp surface for each of five lamps is provided in Figures 7-11 of this report. For each of these lamp spectra, the effective irradiance E (AR 40-46) for occupational exposure is also printed on the spectral plot. Note the clear difference between shortwave (UV-B and UV-C) and longwave (UV-A) lamps.

e. The Solar Spectrum. For comparison with the other spectra, the representative solar spectrum for different zenith angles are provided in Figure 12. Note the dramatic change of spectral irradiance at 300 nm as a function of zenith angle. The zenith angle is the angle measured from zenith (directly overhead) to the center of the solar disk. The total UV-A solar irradiance is 1-3 mW/cm^2 at midday and the effective UV-B irradiance is dependent on the zenith angle of the sun (i.e. time of day and season of the year).

6. DISCUSSION.

a. UV Spectral Bands. For the purposes of discussing the biological effects of UV radiation on the skin and eye, the CIE (International Commission on Illumination) defines three UV spectral bands:

(1) UV-A: 315-320 nm to 380-400 nm (also termed "black light," longwave, or near UV)

(2) UV-B: 280 nm to 315-320 nm (also termed actinic, shortwave, or far UV)

(3) UV-C: 100-280 nm (also termed actinic UV, shortwave or far UV)

Radiation at wavelengths below 180-200 nm is termed "vacuum" UV because it does not propagate through air. These short wavelengths produce ozone in air.

b. UV Radiation Hazards. Although UV-B and UV-C radiation is normally called the "actinic UV," exposure to UV-A is not without hazard and UV photokeratitis and skin erythema can also be produced by UV-A, albeit at levels thousands of times greater than levels of UV-B and UV-C which elicit a response. For these reasons, the eyes of patients being treated and those of the operators should be well protected. Most activities have safety goggles (e.g., plastic eye-cup safety goggles) and those measured by USAEHA all had substantial attenuation in both the near and far UV. Attending physicians and health-care specialists will be at risk of skin and eye injury for all of

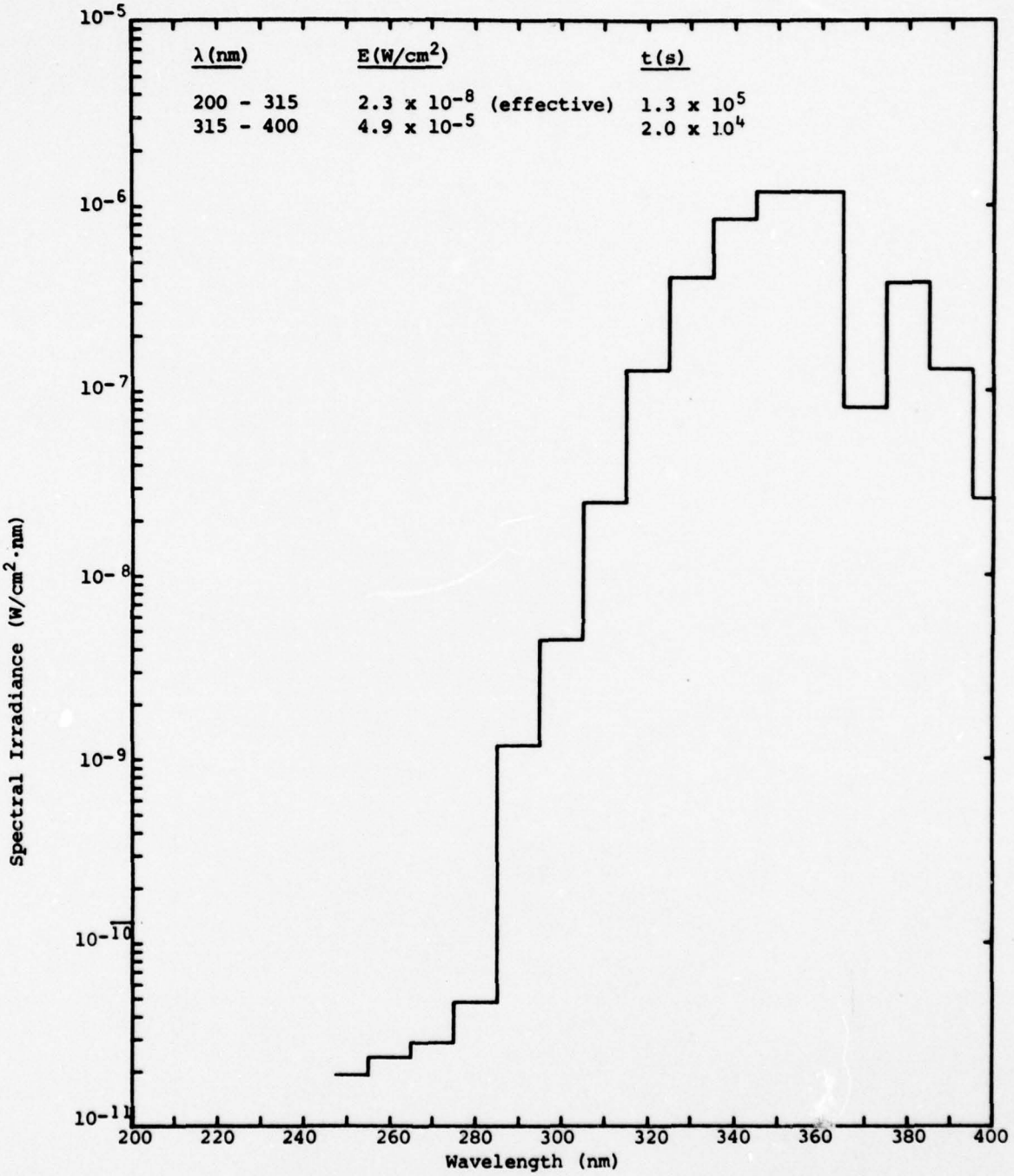

Figure 7. Absolute Spectral Irradiance of the Ultra-Violet Products, Inc., Mineral Light Longwave UVSL25

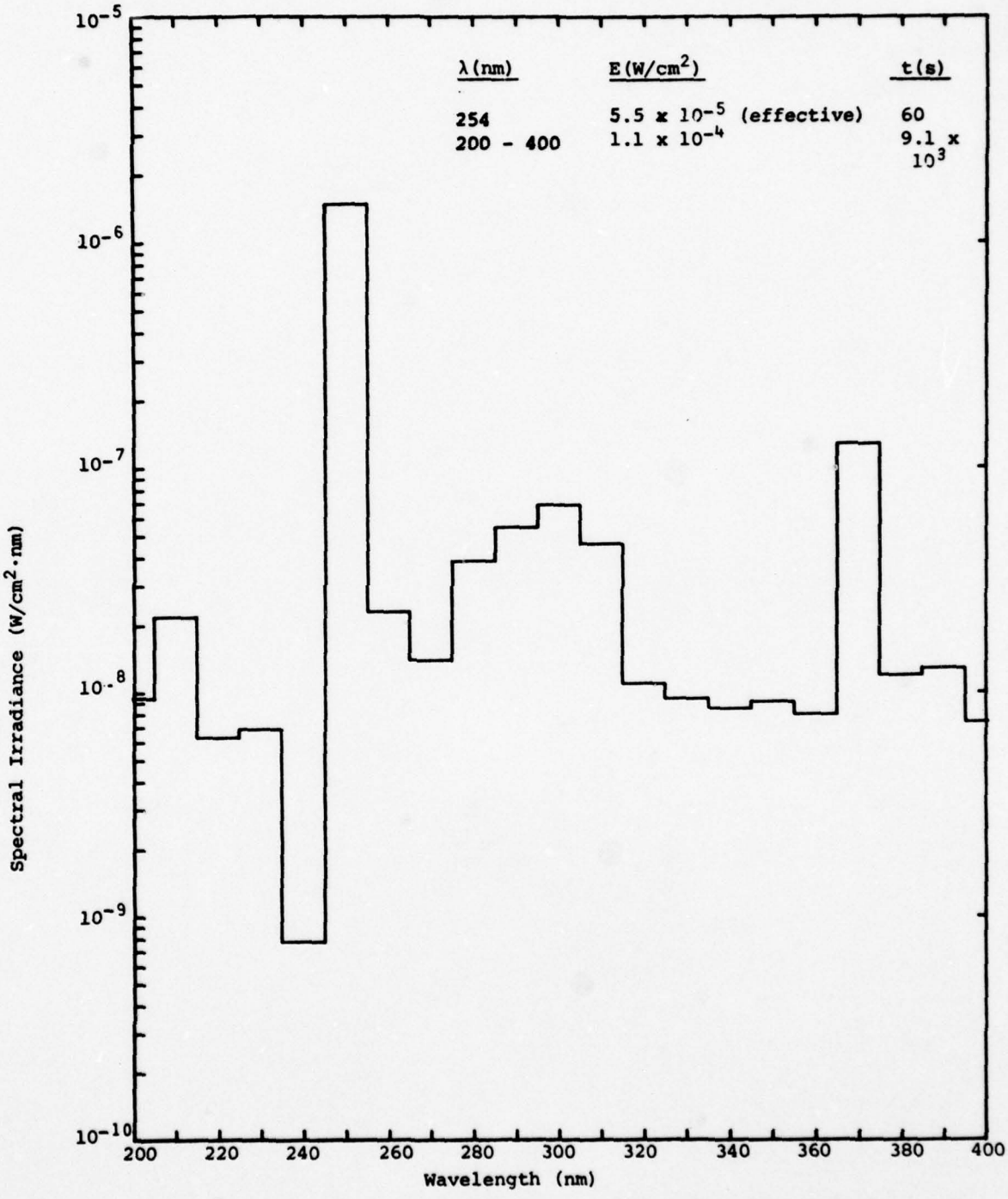

Figure 8. Absolute Spectral Irradiance of the Ultra-Violet Products, Inc., Mineral Light Shortwave UVSL25

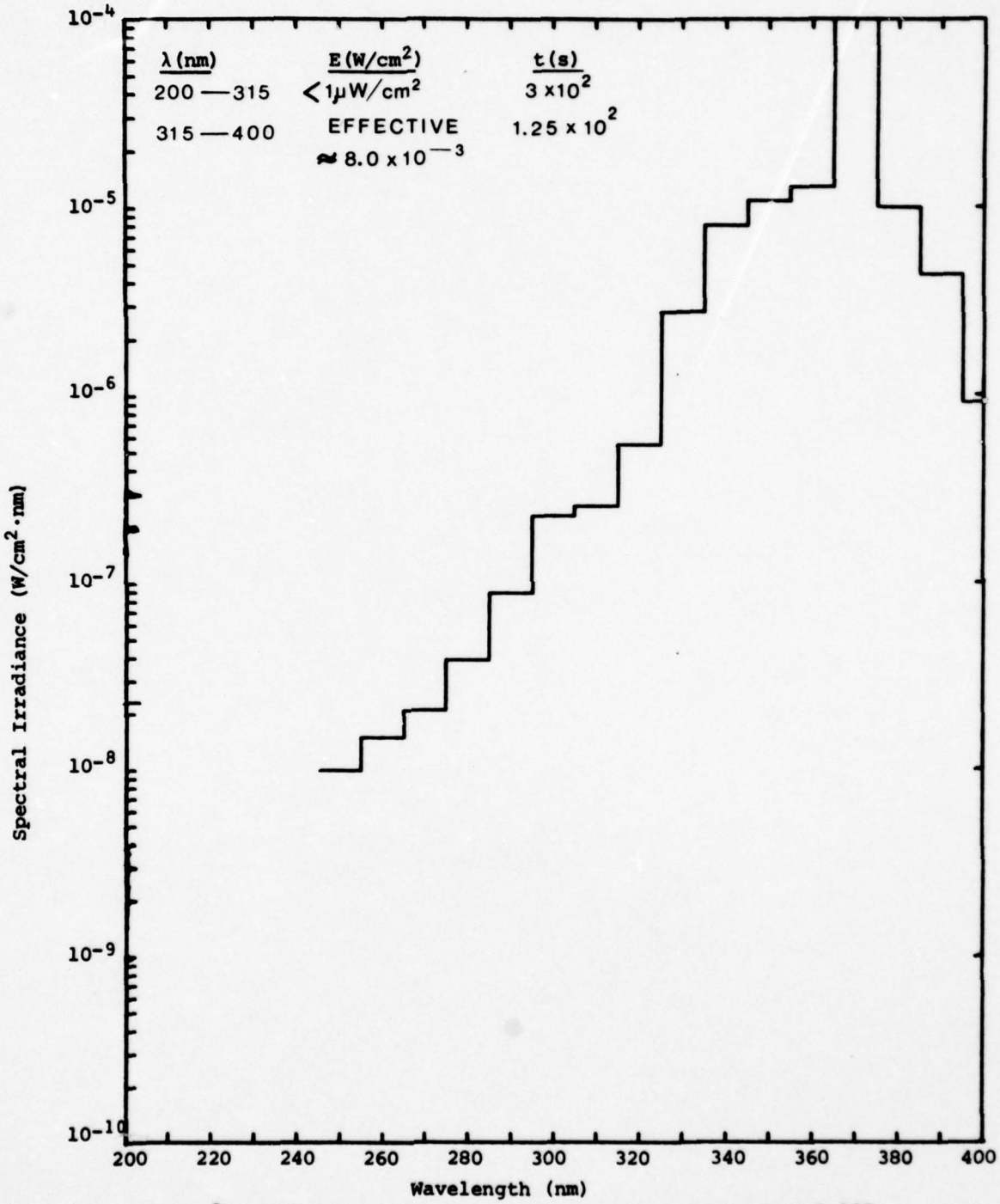

Figure 9. Absolute Spectral Irradiance of Blak-Ray Model B-100 Made by Ultra-Violet Products, Inc., Lamp is H44GS-108

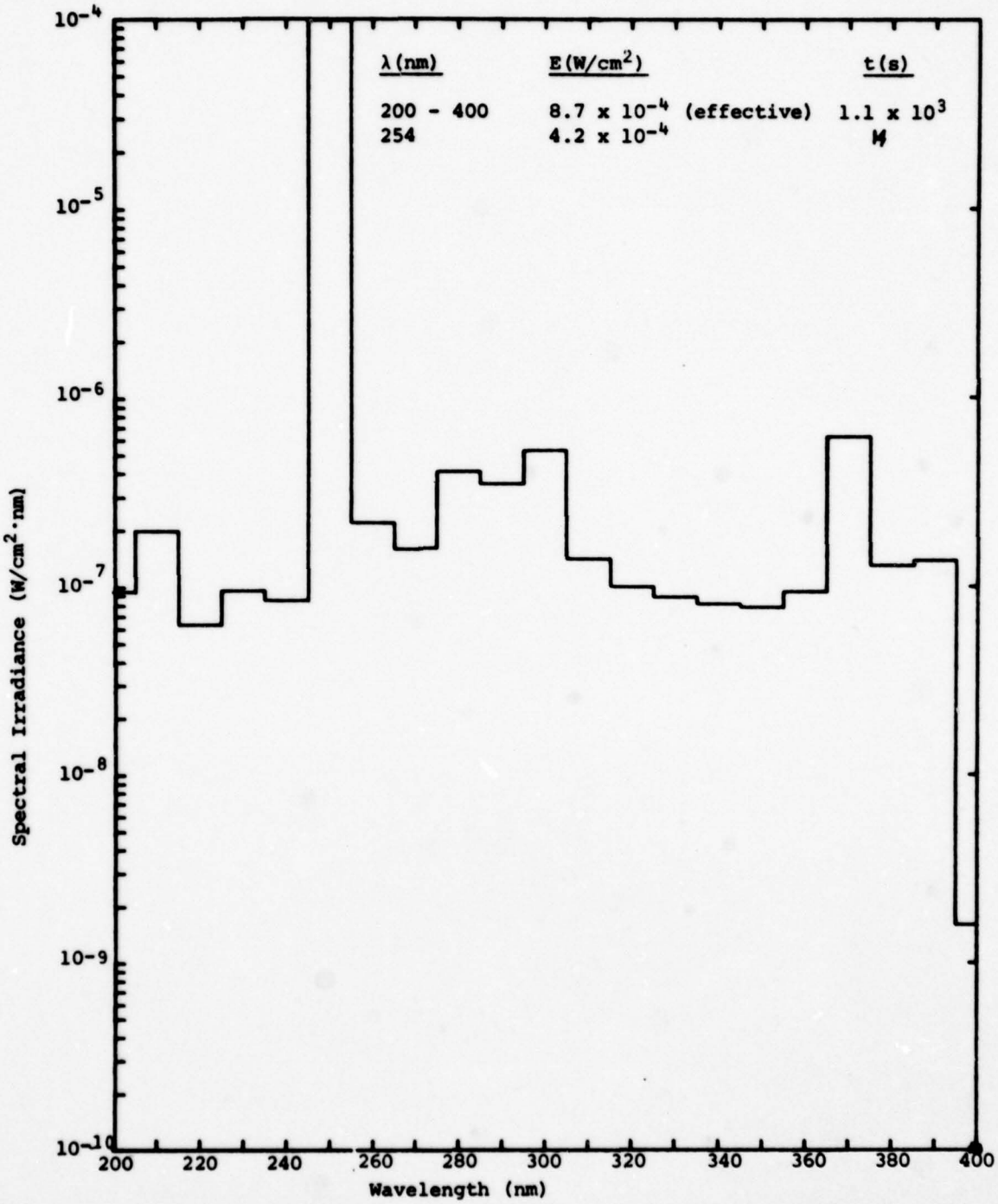

Figure 10. Absolute Spectral Irradiance of the Mineral Light Model R52. This Fixture is Manufactured by Ultra-Violet Products, Inc. Note: Spectrum Emitted by Longwave Side No Different from Shortwave.

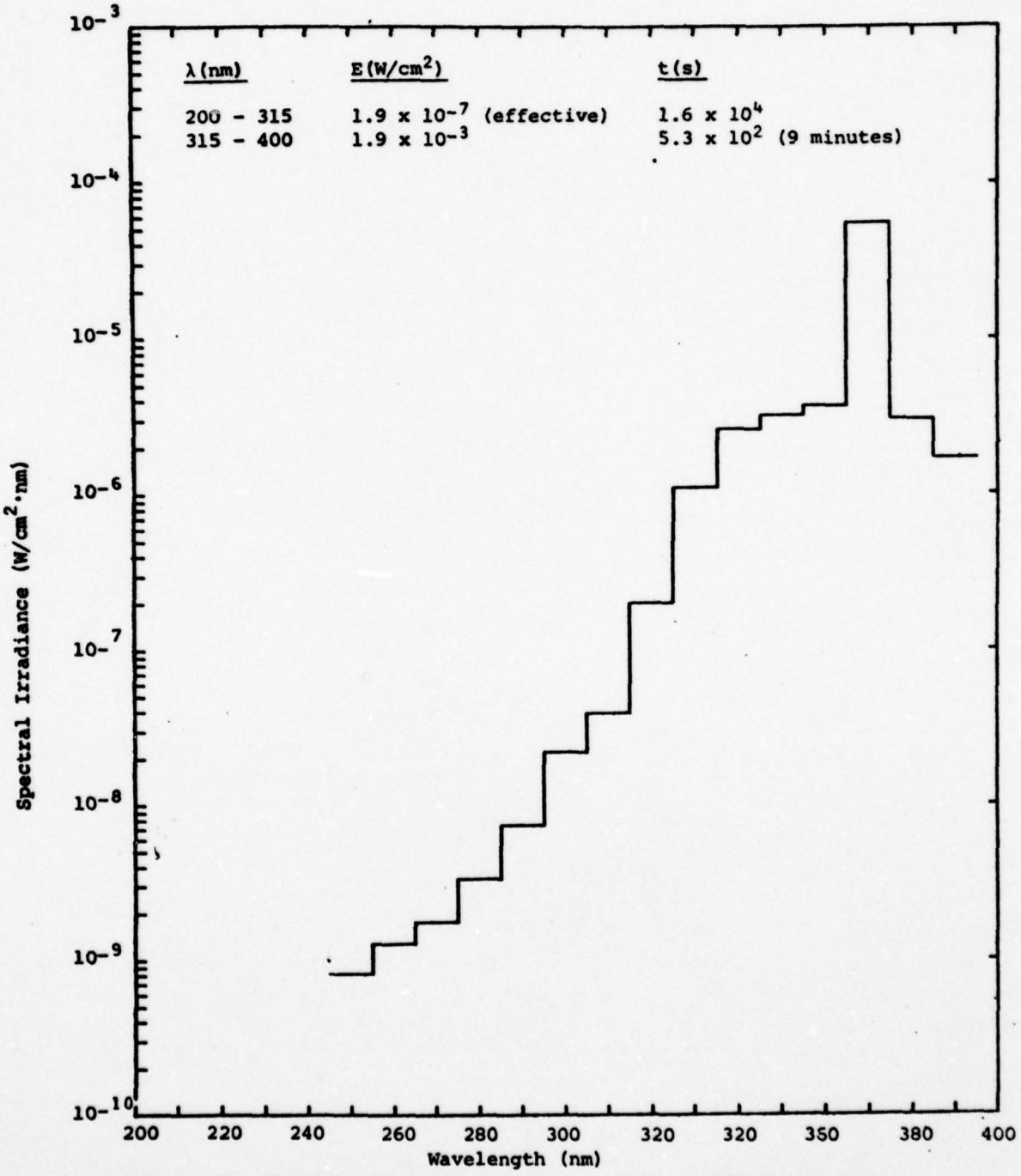

Figure 11. Absolute Spectral Irradiance of the B-100 Spectroline Manufactured by BLACKLIGHT Eastern Corp.

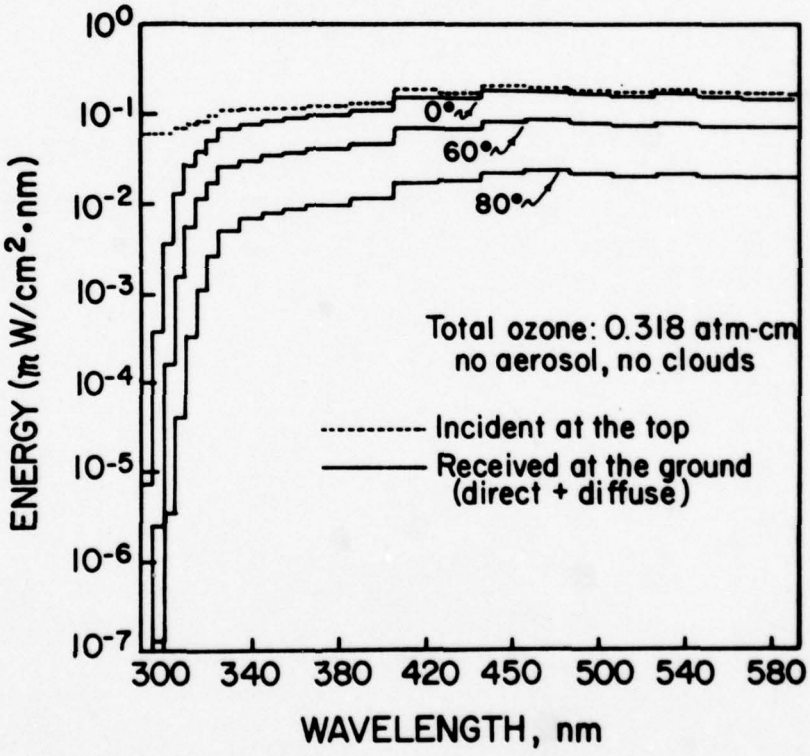

FIGURE 12. Solar Spectral Irradiance at the Earth's Surface for Sun at Zenith and at Zenith Angles of 60° and 80°. Note the Dramatic Reduction of Solar UV-B as the Sun Drops from Zenith.

the sources studied which emit UV-B and UV-C radiation unless precautions are taken to stay out of the UV beam from these lamps. Accidents have occurred when equipment was operated for the first time by personnel unfamiliar with proper procedures and characteristic treatment times.

c. UV Measurements. The spectral irradiance measurements presented in this report were made with instrumentation believed to be calibrated to ±10 percent. However, a greater uncertainty exists due to possible geometrical errors. For instance, measurements made at a distance of 15 cm from a source could really have been at a distance of 15±1 cm. The field-of-view and cosine response of the instrumentation has some variation from the ideal. Taking all of these factors into account, the measured values are believed to be within ±20 percent. Because of the enormous variation in skin sensitivity, the ±20-percent uncertainty is not of any great concern. Additionally, lamp outputs decrease with time, and are affected by line voltage variations and temperature of the lamp. All measurements were performed with fully-heated lamps. It is hoped that the users of the data in this report will proceed with caution prior to actual application to the treatment with these sources. Hopefully, the relative values will permit a physician to shift from one source to another with a proper estimate of relative treatment times and potential hazards. One can probably assume that a specific model UV source that appears to be operating normally will not have an output varying by more than a factor of 50 percent from the values reported herein. The three small, direct-reading instruments used to provide comparison readings were reasonably consistant and could be used as monitors to record relative changes in lamp output.

d. High Intensity Light Boxes. The light box at FAMC did not have as many UV-A lamps as are now used in psoralen-UV-A (PUVA) therapy (a treatment technique not in use at FAMC). If all of the lamp fixtures had UV-A lamps, the dose rate (irradiance) would be doubled, but the box would still not be truly a high-intensity light box requiring higher ventilation rates. For future reference, Appendix C provides guidance for the design of such boxes.

7. CONCLUSIONS. The output of present UV sources used for skin treatment and for certain diagnostic procedures vary widely. The physician or other health specialist using such equipment will be able to safely use such equipment if proper information on radiometric output characteristics and safe standing operating procedures are developed and followed. The use of small, relatively inexpensive UV instruments such as the "Blak Ray" J-221 and J-225 monitors can provide an indication of relative change in lamp output as well as an approximate value of irradiance.

8. RECOMMENDATIONS.

a. Permit only authorized users who are adequately informed of the UV hazards to operate UV therapy lamps [paragraph 5-38b(5), AR 40-5].

b. Label lamp fixtures as to "UV-A" or "UV-B/UV-C" so that improper installation of the more hazardous UV-B/UV-C lamps into UV-A fixtures does not result in hazardous exposure [paragraph 1-5d(1), AR 40-46].

c. Consider the procurement of two small UV-meters such as the UV Products Co. Blak-Ray Shortwave (J-225) and Longwave (J-221) Meters or the Solar Ultraviolet Co. Sunburn Meter to permit routine monitoring of both UV-B/UV-C and UV-A sources. Use of such instruments could improve the reproducibility of results and, hopefully, preclude unintentional overexposure of the operator and patient following the installation of new lamps [paragraph 5-38b(4), AR 40-5].

d. Label UV therapy equipment with the following label [paragraph 1-5d(1), AR 40-46].

e. Periodically check timers to assure their proper operation [paragraph 5-38b(4), AR 40-5].

f. Warn personnel not to substitute sunglasses or other untested eyewear for special UV protective goggles supplied by the lamp manufacturer [paragraph 1-5d(3), AR 40-46].

David H. Sliney

DAVID H. SLINEY
Chief, Laser Branch
Laser Microwave Division

APPROVED:

Gary W. Gaston

GARY W. GASTON
MAJ, MSC
Chief, Laser Microwave Division

APPENDIX A

USEFUL CIE RADIOMETRIC AND PHOTOMETRIC TERMS AND UNITS[1, 2]

RADIOMETRIC				PHOTOMETRIC			
Term	Symbol	Defining Equation	SI Unit and Abbreviation	Term	Symbol	Defining Equation	SI Units and Abbreviation
Radiant Energy	Q_e		Joule (J)	Quantity of Light	Q_v	$Q_v = \int \Phi_v dt$	lumen-second (lm·s) (talbot)
Radiant Energy Density	W_e	$W_e = \frac{dQ_e}{dV}$	Joule per cubic meter ($J \cdot m^{-3}$)	Luminous Energy Density	W_v	$W_v = \frac{dQ_v}{dV}$	talbot per square meter ($lm \cdot s \cdot m^{-3}$)
Radiant Power (Radiant Flux)	Φ_e, P	$\Phi_e = \frac{dQ_e}{dt}$	Watt (W)	Luminous Flux	Φ_v	$\Phi_v = 680 \int \frac{d\Phi_e}{d\lambda} V(\lambda)\, d\lambda$	lumen (lm)
Radiant Exitance	M_e	$M_e = \frac{d\Phi_e}{dA} = \int L_e \cdot \cos\theta \cdot d\Omega$	Watt per square meter ($W \cdot m^{-2}$)	Luminous Exitance	M_v	$M_v = \frac{d\Phi_v}{dA} = \int L_v \cdot \cos\theta \cdot d\Omega$	lumen per square meter $lm \cdot m^{-2}$
Irradiance or Radiant Flux Density (Dose Rate in Photobiology)	E_e	$E_e = \frac{d\Phi_e}{dA}$	Watt per square meter ($W \cdot m^{-2}$)	Illuminance (luminous flux density)	E_v	$E_v = \frac{d\Phi_v}{dA}$	lumen per square meter ($lm \cdot m^{-2}$) lux (lx)
Radiant Intensity	I_e	$I_e = \frac{d\Phi_e}{d\Omega}$	Watt per steradian ($W \cdot sr^{-1}$)	Luminous Intensity (candlepower)	I_v	$I_v = \frac{d\Phi_v}{dr}$	lumen per steradian ($lm \cdot sr$) or candela (cd)
Radiance	L_e	$L_e = \frac{d^2\Phi_e}{d\Omega \cdot dA \cdot \cos\theta}$ [5]	Watt per steradian and per square meter ($W \cdot sr^{-1} \cdot m^{-2}$)	Luminance	L_v	$L_v = \frac{d^2\Phi_e}{dr \cdot dA \cdot \cos\theta}$ [5]	candela per square meter ($cd \cdot m^{-1}$)
Radiant Exposure (Dose in Photobiology)	H_e	$H_e = \frac{dQ_e}{dA}$	Joule per square meter ($J \cdot m^{-2}$)	Light Exposure	H_v	$H_v = \frac{dQ_v}{dA} = \int E_v dt$	lux-second ($lx \cdot s$)
				Luminous Efficacy (of radiation)	K	$K = \frac{\Phi_v}{\Phi_e}$	lumen per watt ($lm \cdot W^{-1}$)
				Luminous Efficiency (of a broad band radiation)	V(*)	$V(*) = \frac{K}{K_m} = \frac{K}{680}$	unitless
Radiant Efficiency [3] (of a source)	η_e	$\eta_e = \frac{P}{P_i}$	unitless	Luminous Efficacy [3] (of a source)	η_v	$\eta_v = \frac{\Phi_v}{P_i}$	lumen per watt ($lm \cdot W^{-1}$)
Optical Density [4]	D_e	$D_e = -\log_{10} \tau_e$	unitless	Optical Density [4]	D_v	$D_v = -\log_{10} \tau_v$	unitless
				Retinal Illuminance in Trolands	E_t	$E_t = \frac{L_v}{S_p}$	troland (td) = luminance in $cd \cdot m^{-2}$ times pupil area in mm^2

1. The units may be altered to refer to narrow spectral bands in which case the term is preceded by the word *spectral*, and the unit is then per wavelength interval and the symbol has a subscript λ. For example, spectral irradiance H_λ has units of $W \cdot m^{-2} \cdot m^{-1}$ or more often, $W \cdot cm^{-2} \cdot nm^{-1}$.

2. While the meter is the preferred unit of length, the centimeter is still the most commonly used unit of length for many of the above terms and the nm or um are most commonly used to express wavelength.

3. P_i is electrical input power in watts.

4. τ is the transmission

5. At the source $L = \frac{dI}{dA \cdot \cos\theta}$ and at a receptor $L = \frac{dE}{d\Omega}$

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APPENDIX B

SPECTRAL IRRADIANCE OF FOUR ULTRAVIOLET PHOTOTHERAPY LAMPS

Wavelength (nm)	Burdick Spectral Irradiance $\mu W/(cm^2 \cdot nm)$	Kromayer Spectral Irradiance $\mu W/(cm^2 \cdot nm)$	FS Spectral Irradiance $\mu W/(cm^2 \cdot nm)$	BL Spectral Irradiance $\mu W/(cm^2 \cdot nm)$
200	1.69	4.23		
205	1.30	4.89		
210	1.85	7.09		
215	1.87	8.40		
220	2.33	10.1		
225	3.07	11.4		
230	3.97	10.6		
235	4.81	10.3		
240	5.56	9.47	0.00033	
245	5.45	7.39	0.00037	
250	5.68	11.9	0.00040	
255	5.91	16.7	0.00044	
260	5.26	7.47	0.00050	
265	6.23	8.10	0.00172	
270	7.80	9.08	0.00496	
275	6.55	12.1	0.0343	
280	3.44	11.2	0.121	0.00013
285	1.44	10.6	0.320	0.00048
290	1.60	15.1	0.668	0.00111
295	1.79	14.8	1.17	0.00309
300	2.21	17.6	2.03	0.00811
305	2.27	19.9	2.32	0.0227
310	2.17	14.5	2.48	0.0594
315	2.09	13.1	2.81	0.281
320	1.84	11.0	2.77	0.489
325	1.60	7.36	2.15	0.859
330	1.67	3.88	1.85	1.60
335	1.63	3.69	1.63	2.63
340	1.57	3.46	1.26	3.40
345	1.14	2.53	0.950	4.11

SPECTRAL IRRADIANCE OF FOUR ULTRAVIOLET PHOTOTHERAPY LAMPS (CONT.)

Wavelength (nm)	Burdick Spectral Irradiance $\mu W/(cm^2 \cdot nm)$	Kromayer Spectral Irradiance $\mu W/(cm^2 \cdot nm)$	FS Spectral Irradiance $\mu W/(cm^2 \cdot nm)$	BL Spectral Irradiance $\mu W/(cm^2 \cdot nm)$
350	0.892	2.04	0.640	4.39
355	1.05	2.24	0.559	4.62
360	0.916	2.05	0.458	4.43
365	0.880	1.70	0.362	4.00
370	0.840	1.45	0.267	2.82
375	0.656	1.64	0.164	1.97
380	0.648	1.75	0.114	1.40
385	0.631	1.08	0.0856	0.901
390	0.963	1.08	0.0670	0.670
395	1.08	1.19	0.0595	0.497
400	1.24	1.31	0.0524	0.380
405	1.40	1.46		0.154
410	1.61	1.61		0.0893

Individual Spectral Lines

Wavelength (nm)	Line Irradiance $\mu W/cm^2$	Line Irradiance $\mu W/cm^2$	Line Irradiance $\mu W/cm^2$	Line Irradiance $\mu W/cm^2$
248	23.0			
254	162	115	0.0183	
265	957	146		
280	49.8	61.2		
290	27.4			
297	78.9	67.8		0.0286
303	161	175	6.23	0.0699
313	385	367	8.9	1.074
336	44.9	50.9		
365	413	503	1.73	
380	3.11			
392		4.89		
405	189	171		

APPENDIX C

Risks Associated With Use Of UV-A Irradiators Being Used In Treating Psoriasis and Other Conditions

Prepared by the Photobiology Committee
of the Illuminating Engineering Society

E. D. Bickford, Chairman

D. S. Berger
R. Corth, Ph.D.
*C. L. Crouch, P.E.
*F. Daniels, Jr., M.D.
J. W. Griffith
*S. K. Guth, Ph.D.
W. T. Ham, Ph.D.
*P. C. Hughes, Ph.D.
D. D. Job, Ph.D.
*A. L. Lewis, O.D.
*I. Matelsky
R. M. Neer, M.D.
W. H. Parr, Ph.D.
J. A. Parrish, M.D.
*J. W. Sausville, Ph.D.
D. H. Sliney
*L. Thorington

*Advisory

Illuminating Engineering Society of North America
345 East 47th Street, New York, NY 10017

Approved by the IES Board of Directors
June 16, 1978

The efficacy of psoralen-UV-A therapy for treatment of psoriasis has now been well documented. For reports on the early work the reader is referred to papers by Parrish, J.A., et. al.[1] and by Wolff, et. al.[2] This work has been extended to include a 16 center clinical trial which was recently completed and submitted to the Food and Drug Administration (FDA) for granting of marketing approval.[3]

UV-A irradiators* currently being sold for use in treatment of psoriasis may increase the risks to the patients. Despite the fact that UV-A is only used in combination with a drug which is regulated by the FDA, the UV-A irradiators themselves are for all practical purposes, un-regulated. It is the concern of this committee that risks to patients are unnecessarily increased as a result. We would like to call attention to some of the potential problem areas and suggest areas in which enforceable performance standards might be adopted. Our comments can be categorized into two areas according to whether they deal primarily with physical design of irradiation units or control of parameters affecting the photobiological action.

PHYSICAL DESIGN CONSIDERATIONS

There are four areas of concern in the physical design of phototherapy units for treatment of psoriasis and similarly treated diseases. They are as follows:

*UV-A irradiators in current use consist of an array of special fluorescent lamps with phosphors which emit radiation primarily in the range of 320-380nm.

1. Electrical hazards. For full body treatment a patient is typically standing or lying down with little or no clothing on. Elevated temperatures (often over 100°F) cause perspiration which enhances the possibility of low resistance pathways for current leaks. Even without perspiration, the skin can be exposed to the unit surface which in turn houses lamps and ballasts which carry large amounts of current. The potential for electrocution is substantial without proper circuit design and insulation barriers. If the patient were to urinate or vomit, the hazard would be increased. In addition to the hazards to the patient, there are potential hazards to the operator and to service personnel. Changing lamps, turning on units, etc., can be a hazard if units are not grounded properly and if ground fault protectors are not included in the design. There is also the possibility of a fire breaking out due to circuit overloads, wire shorting, and flammable material being used.

2. Protection from lamp breakage. There have been incidents in which a patient was standing in a unit being treated and was overcome by a combination of postural hypotension, the unfamiliar surroundings, high temperatures, etc., and fainted.[4] These could have been serious accidents had not these particular units had special sleeves around the individual fluorescent lamps so that the glass was contained. The use of screen wire between lamps and patient appears to us to offer limited protection because even the finest practical grid could allow glass to protrude through. A finer grid would cut out considerable energy. There are, at present, no requirements for providing adequate hand-holds for patients in stand-up units. Due to the incidence of fainting mentioned above, lack of a means for the patient to balance

or hold himself up could lead to an increased incidence of patients breaking lamps and seriously cutting themselves.

3. Temperature and Ventilation. There has been a recent study of cardiac stress placed on people being treated for psoriasis in UV-A irradiators.[4] It was concluded that the combination of high heat over a prolonged duration and standing relatively immobile could over-tax the heart. This would suggest the need for warnings to physicians in the product literature so that they would monitor patients' reactions to the treatment. It would also suggest that UV-A irradiators should provide adequate ventilation. Most of the concerns mentioned in this category could be met by having units subject to UL approval and to conformance with Good Manufacturing Practices for Medical Devices. (To be issued in the Federal Register) The Code of Federal Regulations section dealing with Medical Devices is Title 21, Subchapter H.

4. Passage and Observation. It should be easy for the patients to open the unit and let themselves out. A further safety feature would be that if a patient were to faint and fall against the door, it would not only open but the lamps would go out. This should not only protect against an accidental over-exposure; but, should also stop the clock so that when treatment was re-started, the exposure time remaining for a full treatment would be known exactly. An observation window of non-UV transmitting material should be provided so the patient's reaction to treatment could be easily monitored. The non-UV transmitting character of the window should prevent unnecessary exposure of clinical personnel.

PHOTOBIOLOGICAL CONCERNS

1. Eye protection. During UV-A treatment, psoralen is at its highest level in the body. It has been shown that psoralen is taken up by the lens of the eye.[5]

At very high UV-A and psoralen doses, cataracts have been caused in certain animal species.[6-8] Thus, even though no problems have been seen in clinical studies it would appear prudent to require, through labelling, the use of appropriate goggles. This was a part of the clinical protocol but is not currently mandated. Exposures to UV-A from sunlight out-of-doors during the approximately eight to twelve hours the drug remains in the body could also be a hazard if one were in intense sunlight for many hours. This risk can be minimized by alerting physicians who administer the drug to tell patients to stay out of sunlight for 12 hours from the time of drug ingestion. Since many light sources emit UV-A, appropriate eye protection from UV-A should also be prescribed for constant wear for the 12 hours after ingestion of the drug.

2. Control of UV-A Dose. Standard practice for therapeutic doses calls for administration of doses just below those required to produce erythema. This level varies with skin type, previous solar exposure history, and previous treatment history. Depending on the practitioner, the initial dose may be a judgment based on experience or may be based on trial exposures to small areas. It is not our intent to comment on that judgment; rather it is to point out that, due to the nature of the device, the dose the dermatologist thinks is being given and the actual dose delivered to the patient may be considerably different unless adequate care is taken. To err on either side is to be avoided. To err on the low side means the patient has endured a treatment with little benefit, and thus the total number of treatments and total energy to clear may increase. To err on the high side can lead to burns ranging from mild to severe with possible induction of more serious long term effects.

Dose Sensitivity. To speak of "low" or "high" doses is not very meaningful. It has been reported from clinical studies that a 30% increase in UV-A dose (J/cm^2) causes a change from +1 to +2 erythema.[1] Since a +1 erythema response is used as the upper limit to exposure, this means that all sources of variability should be controlled so as to obtain an accuracy in dose irradiance to within ± 15%.

Radiometry. Measuring techniques using the meter should be specified such that the readings are representative of the *in situ* irradiance on the patient's body. The reference point should be approximately waist high which would represent in most cases a maximum exposure for irraidators using fluorescent lamps. An acceptable radiometer should meet certain minimum criteria.

•The meter itself should be designed so that no meter malfunction would cause a falsely low reading (excluding a zero reading which would be indicative of malfunction). A means should be provided for checking meter accuracy.

•The metering system must respond only to the ultraviolet band of interest and calibration must be for the UV-A irradiance of the specific source spectral power distribution. In addition, the spectral sensitivity of the metering system should be supplied.

•The detector must be corrected to cosine spatial response.

•The meter must be manufacturer certified for an error not exceeding ± 7.5%. For a discussion of practical tolerances on UV measurements see the paper from the National Bureau of Standards.[9]

A protocol for avoiding common system errors should be specified such as cleaning the detector face, etc. A rapid simple means of translating the radiometric readings into exposure times should be available to all practitioners.

Source Spectrum. Another factor in proper phototheraputic dosimetry is the specification of the source spectral power distribution (SPD), which should be supplied.

Hidden errors can occur if the source SPD is not matched to the radiometer spectral sensitivity. Also, ideally the source should emit radiation all within the wavelength bands defined by the in vivo action spectrum. The action spectrum is the therapeutic response of the psoriatic to various narrow bands or combinations thereof of light. This information, however, is not available. What we have instead is the action spectrum for erythema; the absorption spectra for the psoralen; and clinical results showing efficacy and safety of a particular source. The 16 center clinical trial data was obtained using a source having its peak emission at 355 nm and about 90% of the emission in the band from 320-380 nm.[10] Since both the risks and the benefits have been determined with this source, it should logically be considered as the reference source for determining proper doses for subsequent clinical use. The safety and efficiacy of different sources should be verified experimentally before approval.

Radiometer Spectral Sensitivity. In the 16 center clinical trial studies, a radiometer was manufactured which had its spectral sensitivity curve tailored to the spectral output of the lamps used. The resulting readings were internally weighted to give a direct indication of milliwatts/cm^2 of UV-A (radiation from 320-400 nm). If either a lamp with a different SPD were used or a meter with a different spectral response were used, the dose recorded could vary considerably. For a discussion of the pitfalls in measuring energy from lamps of different spectral power distributions (SPD) and/or different meter sensititivites see the National Research Council's Report of the Committee on Phototherapy in the Newborn.[11] Unless there are requirements for matching the lamp SPD to the meter sensitivity, the potential error in estimating "clinical dose" could be several fold.

Irradiance Uniformity. Another aspect of the dosage problem is the question of uniformity of dose over the body surface. In some units on the market, there can be more than a two-fold differential in light irradiance depending on placement of one's body in a unit. Exposures of the head and feet areas often are particularly difficult to control. This is aggravated by the fact that light output is diminished at the ends of fluorescent lamps. By appropriate design of the units this vertical non-uniformity can be reduced to 30-40%. The horizontal uniformity in irradiance is a function of the number of lamps, the reflectors, reflecting surfaces, and general geometry. It is possible to design a stand-up unit in which the patient will receive approximately the same radiation on all sides whether he stands in the center or not. This uniformity of better than 20% contrasts sharply with the possible alternative approach of using single or few high intensity lamps. A procedure for checking uniformity should be specified by the unit manufacturer. Uniformity should be checked periodically.

Exposure Times. Yet another aspect of the dose question is the time to achieve that dose. Within the range of times offered by current fluorescent lamp systems, it seems that the shorter the exposure time the better, While biological effects would be expected to be the same due to reciprocity, (for shorter exposures proportionatly higher irradiance will give an equivalent response) the patient discomfort would be expected to be reduced with shorter exposures.

Besides accidents or cardiac over-exertion, there is another reason for keeping treatment times short. This is the variable sensitivity of the patient with time. The light treatment is normally given during the time at which the drug level in the affected tissue is highest (2-3 hours after ingestion). The period of nearly constant maximal sensitivity only lasts on the order of 1 hour after

which sensitivity decreases. If exposures are very long, there will be diminishing returns. Scheduling errors could accentuate this problem of knowing the effective dose being given.

UV-B Exposure. While we are not aware of any instance in which a source is used that contains excessive short wave ultraviolet (280 to 320 nm), it is possible for this to occur. This is especially likely to occur in dermatology clinics which also use UV-B for therapy. UV-B alone can burn patients.* UV-B at exposure times typical for psoralen UV-A therapy, could produce disastrous results. Aside from severe burns, there is the possibility of induction of cancer.[12] Even if a lamp had no UV-B, there is the possibility of causing unnecessary heat load on the patient independent of any specific photobiological responses. Thus, we consider it essential that lamps to be used in the clinical setting be clearly identified as to their intended purpose. Any lamp approved for use would have to be tested for UV-B emission.

CONCLUSIONS

In conclusion, there are a number of risks involved in providing phototherapy for the psoralen-sensitized patient. These include hazards from the design of the device itself such as electrocution and fire; and hazards associated with not having control of the UV-A dose. We feel that the risks we have identified can be minimized by promulgation of enforceable Standards of Performance and we would urge that appropriate action be taken in the near future. Our concerns have been communicated to the Food and Drug Administration.

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*We recognize that there may be some overlap between UV-A and UV-B in interaction with psoralens. The concern here is largely with UV radiation which does not interact with psoralen.

BIBLIOGRAPHY

1. Parrish, H.A., Fitzpatrick, T.B., Tanenbaum, L. and Pathak, M.A. "Photochemotherapy of Psoriasis with Oral Methoxsalen and Longwave Ultraviolet Light." New England Journal of Medicine 291: 1207-1222, 1974.

2. Wolff, K., T.B. Fitzpatrick, J.A. Parrish, F. Gschnait, N. Gilchrest, H. Honigsmann, M.A. Pathak, and L. Tanenbaum. "Photochemotherapy for Psoriasis with Orally Administred Methoxsalen." Arch. Dermatology 112: 943-950, 1976.

3. Melski, J.W., L. Tanenbaum, J.A. Parrish, T.B. Fitzpatrick, H.L. Bleich, et. al. "Oral Methoxsalen Photochemotherapy for the Treatment of Psoriasis." J. Investigative Dermatology 68: 328-335, 1977.

4. Rhodes, A., R. Ciagone, M. Audley. "Cardiovascular Response to PUVA Therapy." Clinical Research 25: 286a, April 1977.

5. Lerman, S. "A method for detecting 8-Methoxypsoralen in Ocular Lens." Science 197: 1287, 1977

6. Cloud, T.M. R. Hakim, A.C. Griffin. "Photosensitization of the Eye with Methoxaalen: I. Acute Effects." Arch. Opthalmol. 64: 346-352, 1960.

7. Cloud, T.M. R. Hakin, and A.C. Griffin. "Photosensitization of the Eye with Methoxsalen: II. Chronic Effects." Arch. Opthalmol. 66: 689-694, 1961.

8. Freeman, R.G. and D. Troll. "Photosensitization of the Eye by 8-Methoxypsoralen." J. Invest. Dermatol. 53: 449-453, 1969

9. Ambler, E. "Ultraviolet Radiation: Problems and Issues." Dimensions/NBS, Sept. 1977, pp. 3-6.

10. Levin, R.E. and J.A. Parrish. "Phototherapy of Vitiligo." Lighting Design & Application March 1975, pp. 35-43.

11. _____, "Final Report of the Committee on Phototherapy in the Newborn." National Research Council, National Academy of Sciences, Washington D.C., 1974.

12. Hakin, R.E., Griffin, A.C. J.M. Knox. "Erythema and Tumor Formation in Methoxsalen Treated Mice Exposed to Fluorescent Light." Arch Dermatol 82: 572-577, 1960.

ABSTRACT

RISKS ASSOCIATED WITH USE OF UV-A IRRADIATIORS BEING USED IN TREATING PSORIASIS AND OTHER CONDITIONS.

Position Paper by the Photobiology Committee of the Illuminating Engineering Society of North America.

The IES Photobiology Committee has reviewed current practices of irradiating psoralen-sensitized patients with ultraviolet light in the 320-400 nm region (UV-A). This regime is currently being used for treating psoriasis and other skin diseases. We have concluded that in the absence of any effective regulations or controls there are a number of potential hazards associated with the use of UV-A irradiators. These may be summarized as follows: Physical design considerations include electrical hazards, injury from lamp breakage, inadequate temperature and ventilation control, and extended or erroneous exposure due to lack of interlocks between doors, timers, and lamp switches.

Concerns dealing with photobiology specifically include the following: There should be special eye protection mandated. Dosimetry should be carefully specified so that the attending physician can give reproducible doses for clinically similar conditions and so that there will be minimal risk of patient over-dose. This means maintaining over-all tolerances to within ± 15%. In order to do this, the radiometer must be specially designed so it measures only the UV-A and the source-radiometer combination used in the actual unit is referenced to the source and procedure used in the 16 center clinical trials as reported by Melski, et, al. ("Oral methoxsalen photochemotherapy for treatment of psoriasis: A cooperative clinical trial." J. Investigative Dermatol. 68; 328-335, 1977.)

Certain standards for uniformity of irradiance should be adopted to insure reasonable uniformity of exposure to various parts of the patient's body. Exposure times and amount of UV-B (wavelengths between 280 and 320 nanometers) also needs to be controlled to minimize risks to patients. It is concluded that there are numerous aspects to the proper administration of a controlled dose of long wave ultraviolet radiation (UV-A). Only by adoption of proper regulations and controls can risks to patients and attending personnel be minimized.