For USA

■Cautions when setting up the projector

・Assign a person responsible for the device when using the projector. The person responsible shall be trained by Panasonic before starting to use the projector.

・Installation of the projector shall be performed by a technician trained by Panasonic.

・PT-RQ50K is categorized as Risk Group 3 under IEC 62471-5:2015. (RG3).

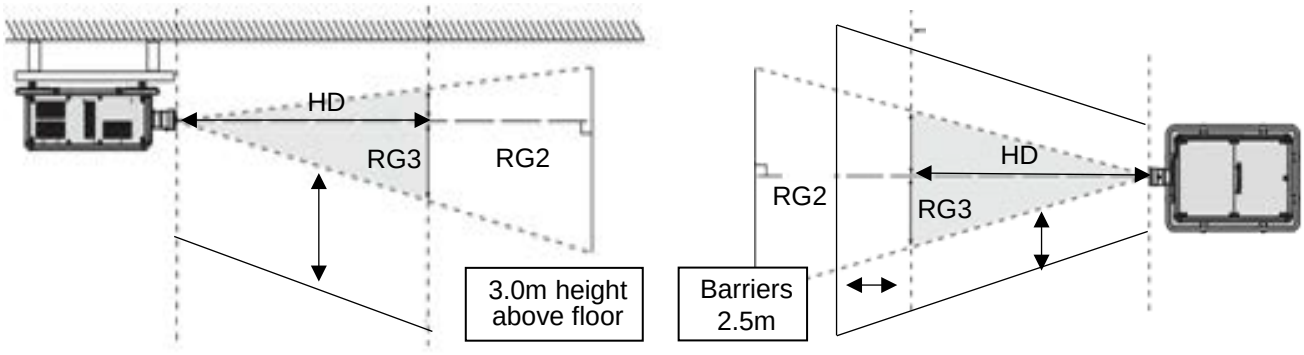
In case of Risk Group 3, there is a possibility of damage to the eyes by direct irradiation when looking into the projection light from inside the Hazard Distance (within the RG3 range). It is considered safe to look into the projected light when beyond the Hazard Distance (within the RG2 range). See figures below.

Definitions

- **Risk Group –** Product groupings that signify possible hazards from the emitted light. Projection and lamp products are assigned to Risk Groups **0, 1 2, or 3** depending on their brightness, and the potential for any eye and skin damage from exposure when in use.
- Hazard Distance - The distance from the projection lens surface where the level of exposure reaches a certain Exposure Limit Value and becomes Risk Group 3. This varies with the lens in use - See table below).
- **Hazard Zone –** A three-dimensional area (pyramid) extending out from the lens that encloses the RG3 area. The Hazard Distance is the height of the pyramid.The base of the pyramid is the image size at that throw distance. (See the shaded areas below, labelled RG3).

・**FDA Guidance (LN57)** - For installations other than cinema theaters, the projector shall be installed at a height vertically above the floor such that the bottom plane of the Hazard Zone shall be no less than 3 meters above the floor. Horizontal clearance to the hazard zone shall be 2.5 meters. (This adds a buffer area around the Hazard Zone).

Any human access horizontally to the Hazard Zone, if applicable, shall be restricted by barriers.



Projection lens Model No.	HD*1
ET-D3QW300	1.8
ET-D3QS400	2.3
ET-D3QT500	3.9
ET-D3QT600	4.1
ET-D3QT700	5.5
ET-D3QT800	8.4

■FDA　Variance application

The model PT-RQ50K is rated Risk Group 3 for all configurations. Owners of RG3 projectors or persons responsible for their use (such as show producers) shall apply for a Variance from the U.S. Food and Drug Administration (FDA) and acquire an Approval letter.

1)　Permanent Installation

FDA Variance application was performed by Panasonic.

The person responsible of the device or usage shall store the original or a copy of the FDA variance approval letter received from Panasonic.　(Refer to page 8 -13)

2) Temporary installation

・The owner of the projector or the persons responsible for their use (such as show producers) shall apply for an FDA Variance and acquire the approval letter.

・The Variance holder who has acquired the FDA variance approval letter must submit the “installation checklist” (required by the FDA) to Panasonic.　（Refer to page 6 - 7）

How to apply for FDA variance:

Fill out Form 3147 and submit it online to the FDA.

- Form 3147 can be downloaded from the URL below.
- Submit Form 3147 the FDA thru the “eSubmitter” web page .
- An example is shown on page 3-5.

・FDA Form 3147.
https://www.fda.gov/about-fda/reports-manuals-forms/forms

・FDA eSubmitter page.
https://www.fda.gov/industry/fda-esubmitter

Details of the submission process are described on the site

FDA Variance - Example Entry

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration	APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE	Form Approved: OMB No. 0910-0025 Expiration Date: July 31, 2020 See Page 4 for PRA Statement. DOCKET NUMBER

NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this application in accordance with 21 CFR 1010.4.

INSTRUCTIONS

1. Check all applicable boxes and type or print the requested information.
2. Submit an original and four (4) copies.
3. Mail your application to the Division of Dockets Management (HFA-305), Food and Drug Administration, Rm 1061, 5630 Fishers Lane, Rockville, MD 20852.
4. Enter docket number if assigned.

1. NAME OF COMPANY

2. ADDRESS OF COMPANY *(Include ZIP Code)(If P.O. Box is used, include actual street address also.)*

3. NAME AND TITLE OF RESPONSIBLE PERSON	4.a. TELEPHONE NO. *(Include area code)*
4.b. EMAIL ADDRESS	5. DATE OF SUBMISSION

6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF _____ YEARS FROM THE DATE OF ISSUE. *(In general, the Agency will approve a variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)*

7. **PRODUCT DESCRIPTION AND USE**

a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)

PT-RQ50K

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
- ☐ A laser display device
- ☒ A projector for a laser light show
- ☒ A laser light show
- ☐ Other *(Specify)* _____

c. ☒ PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A
- ☒ Planetarium or other dome projection structure
- ☒ Theater
- ☒ Hotel/motel ballroom or meeting room
- ☒ Store displays
- ☒ Trade show or convention
- ☒ Discotheque or night club
- ☒ Pavilion
- ☒ Indoor arena
- ☒ Outdoor arena
- ☒ Museum
- ☒ Outdoor unenclosed area
- ☒ Other *(Specify)* Lecture hall,presentation area

e. PRODUCT IS INTENDED TO BE USED
- ☒ At only one *(Fixed)* location
- ☒ At a variety of *(Tour)* locations
- ☒ Other *(Specify)* _____

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION
- ☒ More than 15 days
- ☒ More than 5 but not more than 15 days
- ☒ Less than 5 days

g. TOUR IS INTENDED TO RUN FOR
- ☒ More than 6 months
- ☒ 1 - 6 months
- ☒ Less than one month
- ☐ Not applicable *(Not a tour)*
- ☒ Other *(Specify)* _____

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
- ☒ Front screen projections
- ☒ Rear screen projections
- ☒ Holographic displays
- ☐ Multiple reflection/diffraction effects
- ☐ Audience scanning *(Also includes scanning any accessible uncontrolled areas)*
- ☐ Reflections from stationary mirrors or mirrored surfaces *(Beam Matrices)*
- ☐ Stationary irradiation of rotating mirror balls, etc.
- ☐ Scanning irradiation of rotating mirror balls, etc.
- ☐ Fiber optic projections
- ☐ Fog, smoke, or other scattering enhancement effects
- ☐ Other *(Specify)* _____

8. **LASER RADIATION LEVELS**

LASER MEDIUM *(Ar, He-Ne, etc.)*	WAVE LENGTHS *(nm)*	PEAK POWER *(watts)*
N/A	N/A	RG3 LIP

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE

10. REASON FOR REQUESTING VARIANCE
- ☒ Compliance with the limits of 21 CFR 1040.11(c) would restrict the intended use of the product because compliance would limit the output power to the extent that the desired effects would not be sufficiently visible
- ☐ Other or additional explanation *(Specify)* _____

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PSC Publishing Services (301) 443-6740 EF

FDA Variance Example Entry

11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD

- ☒ It is proposed to deviate from the provisions of 21 CFR 1040.11(c) in that the accessible emission level would exceed the accessible emission limits specified in 21 CFR 1040.11(c).
- ☒ It is proposed to deviate from the provisions of 21 CFR 1040.11(c) as follows:

LIP is classified as Laser Class 1 with IEC60825-1:ED.3 with IEC62471-5:Ed.1

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

- ☒ Laser light shows and displays are accepted popular media in entertainment and the arts. Use of power levels in excess of the limits imposed by 21 CFR 1040.11(c) is necessary to achieve the required effects in these media.
- ☐ Other or additional advantages *(describe and explain)*.

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. *(Check as many boxes as apply. In item 14 "Remarks," justify any boxes not checked, using additional sheets as necessary. State any other means of radiation protection that will be used.)*

a. ☒ All laser products, systems, shows, and projectors will be certified to comply with 21 CFR 1040.10 and the conditions of this variance and will be reported as required by 21 CFR 1002.10 AND 1002.11 using the reporting guides provided for such purpose. These actions will be accomplished prior to any introduction into commerce.

b. ☒ Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or supplements, as applicable, have been submitted.

c. ☒ Scanning, projection, or reflection of laser and collateral radiation *(Light show radiation)* into audience or other accessible uncontrolled areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.

d. ☒ Laser radiation levels in excess of the limits of Class I will not be permitted at any point less than 3.0 meters above any surface upon which persons other than operators, performers, or employees are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted to be. Operators, performers, and employees will not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits specified in 21 CFR 1040.11(c).

e. ☐ Any product which relies on scanning to meet access, exposure, or product class limits will incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.

f. ☒ All laser light shows shall be under the direct and personal control of trained, competent operator(s). The operator(s) will:

(1) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator;

(2) Be located where all beam paths can be directly observed at all times; and

(3) Immediately terminate the emission of light show radiation in the event of any unsafe condition; or, for outdoor shows, upon request by any air traffic control officials.

g. ☒ The maximum laser projector output power will not exceed the level required to obtain the intended effects.

h. ☒ The projection system *(i.e., the projector and all other components used to produce the lighting effects)* will be securely mounted or immobilized to prevent unintended movement or misalignment. Beam masking will be provided as an inherent part of the system design to prevent overfilling of screens, beam stops, targets, etc.

i. ☒ Laser projectors will not be delivered to any other party under an agreement of sale, lease, or loan unless and until the recipient demonstrates that they have a variance in effect at the time of delivery that permits them to produce laser light shows incorporating such projector(s).

j. ☒ In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projectors/systems will provide to parties who purchase, lease, or borrow the equipment, adequate users' instructions for safe installation and operation which explain the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from CDRH prior to introduction into commerce of any laser light shows.

k. ☒ The requirements of 21 CFR 1002.30(a)(1) and (2) will be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show. These procedures will be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and the control of access to radiation areas using the procedures described in the ANSIZ136.1 standard for the safe use of lasers *(Laser Institute of America (LIA), 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826)* or any other equivalent user consensus standard and, where applicable, state or local requirements. Laser radiation areas which can contain radiation levels above the limits specified in 21 CFR 1040.11(c) will be clearly identified by the posting of warning signs and/or restricting access through physical means *(such as pressure switches, photo cells, barriers, guards, etc.)*. These requirements apply to temporary areas *(such as during set up and alignment procedures)* and to final or permanent areas. The variance holder will retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, current procedures, and records relating to each particular show will be with the operator or other responsible individual and will be made available for inspection by FDA and other responsible authorities.

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FDA Variance Example Entry

I. ☒ Advance written notification will be made as early as possible to appropriate federal, state, and local authorities providing show itinerary with dates and locations clearly and completely identified, and a basic description of the proposed effects including a statement of the maximum power output intended. Such notifications will be made, but not necessarily be limited, to:

(1) Information about particular laser shows will be maintained in the records for the show and will be provided upon request to the Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health, Magnetic Resonance Branch, Silver Spring, MD 20993. This information will provide the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and accession numbers clearly referenced, each notice will include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance.

(2) The Federal Aviation Administration (FAA) for any projections into open airspace at any time *(i.e., including set up, alignment, rehearsals, performances, etc.)*. If the FAA objects to any laser effects, the objections will be resolved and any conditions requested by FAA will be adhered to. If these conditions cannot be met, the objectionable effects will be deleted from the show.

(3) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of state and local law will be satisfied and any objections raised by local authorities will be resolved or the effects deleted. *(A list of federal and state offices is available from the Center for Devices and Radiological Health upon request.)*

14. REMARKS

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.11 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE	16. NAME *(Type or Print)*	17. TITLE

FORM FDA 3147 (8/17) PAGE 3 OF 4 PAGES

Installation checklist for PT-RQ50K installed in USA

Date:	

TRAINING AND DOCUMENTATION PROVIDED TO OPERATOR/OWNER

	Pass/Fail
Training on safe operation and maintenance	
FDA/CDRH installation requirements (Any modifications must be approved)	

Projector information

Projector model	PT-RQ50K
Serial number	

Venue information

Name of Venue	
Room name if applicable	
Address	
Phone	
Email	

SAFETY OFFICER, Person responsible for safety of show and operator :	
Name	
Title	
Phone	
email	

Installer information

Company name	
Name of representative responsible for safety and compliance	

Separation distances confirmed

Hazard Distance is confirmed to be:		m
How high is the lower part of the projected beam above floor level?		m
How wide is the lateral distance between the projected beam from where audience is permitted to stand?		m
No objects intercept the beam path within the HD?		Pass/Fail

Installer's signature:

Return completed forms to tr-laser.support@ml.jp.panasonic.com

FDA Variance Approval Letter (To Panasonic)

U.S. FOOD & DRUG ADMINISTRATION

VIA USPS

August 15, 2019

Ben Botros
Panasonic Corporation Of North America
Two Riverfront Plaza
9th Fl.
Newark, New Jersey 07102

Re: FDA Docket Number: 2019-V-3518
Accession Number: RH19A0184

Dear Mr. Botros:

The Center for Devices and Radiological Health (CDRH) is approving, in accordance with 21 CFR 1010.4(c)(1), the petition of Panasonic Corporation of North America, ("the firm") dated July 11, 2019, for a variance from 21 CFR 1040.11(c) of the performance standard for laser products.

This variance will allow the introduction into commerce of the laser light shows that incorporate Laser Illuminated Projectors (LIPs), described in Section D below, by the laser light show manufacturer.

A. Variance Number

2019-V-3518

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance shall be terminated on December 31, 2020, unless extended by the submission of an annual report, as required by 21 CFR 1002.13. Only upon submission of an annual report, this variance shall be extended for one year at a time, effective December 31 each year.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

DocID 05373.02.00

FDA Variance Approval Letter (To Panasonic)

D. Product(s) for Which Variance is Granted

This variance is granted for the Risk Group 3 (RG3) laser light shows manufactured by the firm that incorporate any of the following certified LIPs: PT-RQ50K projectors manufactuerd by Panasonic.

The firm may incorporate into their laser light shows any LIPs which have been certified and reported by a LIP manufacturer under an approved laser light show variance, except:

1. Projection systems designed or intended to produce visible effects by means of invisible laser emissions, or

2. Projection systems designed for producing effects other than front or rear screen projections.

The firm's laser light shows may be presented in temporary or permanent installations in any type of facility or outdoor space. RG3 LIPs may only be used to create front or rear screen projection effects. RG3 LIPs are not designed or intended for home use.

E. Provisions From Which Variance is Granted

This variance is granted from the portion of 21 CFR 1040.11(c) of the performance standard for laser products which requires that each demonstration laser product shall not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa.

All other provisions of the applicable performance standard(s) remain applicable to the product.

F. Conditions Under Which Variance is Granted

In lieu of the requirement(s) referred to in Item E above, the conditions as specified below in Variance Attachment(s) E shall apply to the laser light shows assembled and produced under this variance.

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Section E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, installation requirements, and by warnings in the user/purchaser information.

This variance action will be posted to the Docket associated with your variance request and made available for public view online at www.regulations.gov. The variance will remain in

DocID 05373.02.00

Page 2

FDA Variance Approval Letter (To Panasonic)

effect until the termination date unless the variance is amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Should you have any questions or comments pertaining to this letter, please contact William Calhoun by email at William.calhoun@fda.hhs.gov or by telephone at (301) 796-2754. In any follow-up correspondence, please clearly reference FDA Variance Number 2019-V-3518 and include a contact email address.

Sincerely,

for Thalia Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

cc: FDA Division of Dockets Management, Docket Number 2019-V-3518

Enclosure: Attachments E

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FDA Variance Approval Letter (To Panasonic)

ATTACHMENT E:

1. This variance is not transferable to any other firm or person and applies only to the specific products identified in the variance.

2. All laser products, systems, shows, and projectors shall be certified to comply with applicable requirements of 21 CFR 1040.10 and the conditions of this variance and be reported as required by 21 CFR 1002.10 and 1002.11 using the reporting guides provided for such purpose. These actions shall be accomplished prior to any introduction into commerce.

3. The annual report required by 21 CFR 1002.13 shall be submitted by September 1st of the current year as a condition for renewal of this variance effective December 31st following the due date of the annual report. The annual report shall also include a list identifying all laser illuminated projectors (LIPs) used in shows by your firm during the reported year. The list shall include manufacturer, model designation, and accession number under which each projector was reported. [Note, firms granted a new variance after June 30th do not have an annual report required in the year of issuance, but will have an annual report required in subsequent years.]

4. Effects other than front or rear screen projections shall not be performed. Any additional effects require the submission of a variance amendment request (in accordance with 21 CFR 1010.4) and the filing of product reports or supplements as applicable.

5. LIPs distributed under this variance shall be installed by the LIP manufacturer or by a trained, manufacturer-authorized installer. Show installations must be performed in accordance with the LIP manufacturer's instructions. If not installed by the manufacturer or by a manufacturer-authorized installer, the LIP shall not be transferred to any other party until the recipient has demonstrated that they have a variance, as required, in effect that permits them to manufacture certified laser light shows incorporating these LIPs. If a variance is required, a notation of the recipient's variance number and its effective date, as applicable, shall be entered by the firm and retained in the records of compliance test results required by 21 CFR 1002.30.

6. A Hazard Zone is the region of space where the projection light from the LIP exceeds the Emission Limits for RG2. For installations other than in cinema theaters, the LIP shall be installed at a height vertically above the floor such that the bottom plane of the Hazard Zone shall be no lower than 3 meters above the floor. Horizontal clearance to the hazard zone shall be 2.5 meters. Cinema theater installations shall locate the Hazard Zone no lower than 2.5 meter above the floor and shall provide no less than 1 meter of horizontal clearance. Any human access horizontally to the Hazard Zone, if applicable, shall be restricted by barriers. If human access is possible in an unsupervised environment, the horizontal or vertical clearances shall be increased to prevent exposure to the RG3 hazard zone.

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FDA Variance Approval Letter (To Panasonic)

In areas where audience access is restricted, LIP Hazard Zones shall be clearly identified by the posting of warning signs and/or restricted through physical means (such as pressure switches, photocells, barriers, guards, etc.). These requirements apply to temporary areas (such as during setup and alignment procedures) and to final or permanent areas.

7. For firm-operated, temporary RG3 LIP installations, including those for customer or trade show demonstrations, the firm shall assure that:

   (a) The LIP(s) are located so that all propagating beam paths within the Hazard Zone, and the audience, can be directly observed at all times;

   (b) Communication is maintained with other personnel if assisting in surveillance of the LIP projection;

   (c) In the event of any unsafe condition, LIP projection light is immediately terminated.

   (d) One or more readily accessible controls to immediately terminate LIP projection light is provided.

8. The projection system shall be securely mounted or immobilized to prevent unintended movement or misalignment.

9. The requirements of 21 CFR 1002.30(a)(1) and (2) shall be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show. These procedures shall be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and any emergency shutdown requirements, and the control of access to radiation areas using the procedures described in the ANSI Z136.1:2007 Standard For The Safe Use of Lasers (available from The Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, Florida 32826) or any other equivalent user consensus standard and, where applicable, State or local requirements.

10. The variance holder shall retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance approval letter shall be with the operator or other responsible individual. The variance application, variance approval letter, and if applicable, the most recent annual report, CDRH acknowledgment of receipt for the annual report, current procedures, and records relating to each particular show shall be made available for inspection by FDA and other responsible authorities.

11. For temporary installations, the firm or person to whom this variance is issued shall maintain complete records of all show itineraries with dates, locations, operator name, and contact information clearly and completely identified. Records shall contain the specific equipment used and a basic description of proposed effects These records shall be available to the Food and Drug Administration upon request.

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FDA Variance Approval Letter (To Panasonic)

12. The LIP shall be installed in accordance with any applicable state or local regulations pertaining to operation of laser Class IIIb, Class IV or Risk Group 3 projector systems for public use. It is the joint responsibility of the firm and the installation owner, or manager, to determine whether there are applicable state or local statures and/or regulatory requirements, and if so, to meet those requirements prior to beginning to operate the LIP.