



February 24, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville Md. 20852

0449 '06 MAR -3 A10:42

Re: GCP-1B, GCP-1C, GCP-2A and GCP-2B Variance Application for Night Vision Equipment Company (NVEC)

Director,

This is an application for variance from certain emission standards in accordance with Title 21, CFR 1010.4 Subchapter J. The products submitted for variance herein are the GCP-1B, GCP-1C, GCP-2A and GCP-2B laser pointers manufactured by NVEC. The detailed Variance Application is attached for your review.

A Product Report was submitted to the Center for Devices and Radiological Health as required in Title 21, CFR 1002.10 Subchapter J, but that is not part of this Application.

The GCP-1B, 1C, 2A, 2B are field proven applications of infrared technology intended to mark and illuminate items of interest in environments similar to combat, combat training or high security of national interest.

The GCP-1B, 1C, 2A, 2B Pointers project an invisible infrared light which can only be seen with night vision devices. Internal lenses in the GCP-1B, 1C, 2A, 2B focus the infrared light into a narrow beam. Each device incorporates a built-in momentary ON switch that serves the function of both the emission indicator and beam attenuator within the intent of the regulations. This allows the operator to conduct surveillance operations without detection, under the cloak of darkness. Any audible or visible emission indicator could seriously compromise the safety of law enforcement officers in the performance of their duties.

The GCP-1B, 1C, 2A and 2B products contain a normally OFF / momentary ON switch that must be depressed before laser emissions can occur. When this switch is released, the emissions cease. The switch connects two AA batteries through an electronic control circuit to activate the device. This ON/OFF switch is protected by a Safety Cover which must be in the ARMED position before the ON/OFF switch can be activated. In addition, the lens cover must be removed before emissions can be projected. Thus, several intentional steps must occur before emissions can be transmitted from the GCP-1B, 1C, 2A, 2B. The protective Safety Cover also prevents inadvertent activation of the GCP-1B, 1C, 2A, 2B. The remote switch (GCP-2A, 2B) contains a switch that requires strong activation pressure in an indented design to prevent inadvertent activation.

The GCP-1B, 1C, 2A, 2B are the same pointing and illuminating products and are the same device except as shown below;

- o The GCP-1B is hand held and has a maximum power output of 100 mW.
- o The GCP-1C is hand held and has a maximum power output of 175 mW.

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- The GCP-1C has a minimum divergence of 0.3 mR.
- The GCP-2A can be either hand held or weapon mounted (typical operational configuration) and has a maximum power output of 100 mW.
- The GCP-2B can be either hand held or weapon mounted (typical operational configuration) and has a maximum power output of 175 mW.
- The GCP-2A and 2B contain a remote switch feature.

The GCP-1B, 1C are the same product as the GCP-1A (recently granted a FDA variance 2005V-0499), except for the maximum power output listed above. The GCP-2A, 2B are the same product as the GCP-2 (recently granted a FDA variance 2005V-0499), except for the maximum power output listed above.

Each of the GCP-1B, 1C, 2A, 2B contains a variable lens to control the beam width, depending on operational needs (pointing or illuminating) from .5mr to 30°. As the beam moves from a pointer to spot illumination mode, the on-axis position of the beam is maintained. This eliminates off-axis viewing of the beam.

On these products, a laser training safety selector permits reduction of the laser output to eye-safe levels for training and force-on-force maneuvers. Output reduction is achieved via a 180° rotation of the laser training safety selector with a small slot screwdriver. This feature assures safe operation in the training and force-on-force modes.

Without the variances, the GCP-1B, 1C, 2A, 2B will not be able to assist and protect Federal Homeland Security and Law enforcement officers in the conduct of their routine, authorized duties.

The intended use of these products is by government, military and law enforcement agencies in the routine execution of their duties. Night Vision Equipment Company restricts the sale and resale of the GCP-1B, 1C, 2A, 2B laser Pointers to government, military and law enforcement agencies. This variance request is limited to sale of these products to Federal, State, local government and law enforcement agencies and shall not be sold to individual personnel of these agencies or organizations.

We appreciate your consideration in this matter. If you have questions regarding this variance application, please contact me.



Don Grise

Laser Systems Program Manager
Night Vision Equipment Company
2751 N. Mendicino Dr., Prescott Valley, AZ. 86314
928-772-0288
dgrise@nvec.net

Attachments:

Variance Application for the GCP-1B, 1C, 2A, 2B
Operator Manual GCP-1B, 1C, 2A, 2B



Variance Application of Night Vision Equipment Company (NVEC)

This variance application is requested for the NVEC infrared pointing and marking products named GCP-1B, GCP-1C, GCP-2A and GCP-2B.

NVEC responses to CFR Part 21, Subchapter J, Section 1010.4 variance application questions are:

(a) Criteria for variances. (1) Upon application by a manufacturer (including an assembler), the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant a variance from one or more provisions of any performance standard under subchapter J of this chapter for an electronic product subject to such standard when the Director determines that granting such a variance is in keeping with the purposes of the Radiation Control for Health and Safety Act of 1968, and:

(i) The scope of the requested variance is so limited in its applicability as not to justify an amendment to the standard, or

Under this variance, the sale of the GCP-1B, GCP-1C, GCP-2A and GCP-2B will be strictly limited Federal, State, local government and law enforcement agencies and shall not be sold to individual personnel of these agencies or organizations. This very limited applicability will not require amendment to the standard since this product will not be available to the general public under this variance.

(ii) There is not sufficient time for the promulgation of an amendment to the standard.

NA

(2) The issuance of the variance shall be based upon a determination that:

(i) The product utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard, or

NA



(ii) The product performs a function or is intended for a purpose which could not be performed or accomplished if required to meet the applicable standards, and suitable means for assuring radiation safety or protection are provided, or

Variations are sought for the GCP-1B, 1C, 2A, 2B in order that these products may perform their intended function and purpose.

The GCP-1B, 1C, 2A, 2B are field proven applications of infrared technology intended to mark and illuminate items of interest in environments similar to combat, combat training or high level national interest security. Without the variations, the GCP-1B, 1C, 2A, 2B will not be able to perform these functions, which will assist and protect Federal, State, local government and law enforcement agency officers in the conduct of their authorized duties.

The GCP-1B, 1C, 2A, 2B contain features such as a power safety switch cover, lens cover, as well as an eye safe laser training mode and selector which are suitable means to assure radiation safety during intended use.

(iii) One or more requirements of the applicable standard are not appropriate, and suitable means for assuring radiation safety or protection are provided.

NA

(b) Applications for variances. If you are submitting an application for variances or for amendments or extensions thereof, you must submit an original and two copies to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(1) The application for variance shall include the following information:

(i) A description of the product and its intended use.

The GCP-1B, 1C, 2A, 2B are field proven applications of infrared technology intended to mark and illuminate items of interest in environments similar to combat, combat training or high level national interest security.

The GCP-1B, 1C, 2A, 2B are the same device except that:

- The GCP-1B is hand held and has a maximum power output of 100 mW.
- The GCP-1C is hand held and has a maximum power output of 175 mW.
- The GCP-1C has a minimum divergence of 0.3 mR.
- The GCP-2A can be either hand held or weapon mounted (typical operational configuration) and has a maximum power output of 100 mW.
- The GCP-2B can be either hand held or weapon mounted (typical operational configuration) and has a maximum power output of 175 mW.



The GCP-1B, 1C are the same product as the GCP-1A (recently granted a FDA variance 2005V-0499), except for the maximum power output listed above. The GCP-2A, 2B are the same product as the GCP-2 (recently granted a FDA variance 2005V-0499), except for the maximum power output listed above.

Each of the GCP-1B, 1C, 2A, 2B contains a variable lens to control the beam width, depending on operational needs (pointing or illuminating) from .5mr to 30°. As the beam moves from a pointer to spot illumination mode, the on-axis position of the beam is maintained. This eliminates off-axis viewing of the beam.

(ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

The GCP-1B, 1C, 2A, 2B are designed and manufactured in order to mark and illuminate items of interest in environments similar to combat or combat training. Modification of the current designs to meet applicable standards would result in the products having the potential to:

1. Reveal an officers' surveillance position, endangering the officers' lives.
2. Delay an officers' speed of operation in a potentially life-threatening situation, endangering the agents' or officers' lives.
3. Significantly reduce the effectiveness of these products, increasing the risk for the officer to the exposure to unrecognized threats to his or her life.

(iii) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard.

The GCP-1B, 1C, 2A, 2B proposed deviations from the requirements of the applicable standard are as follows:

- a. These products will not include the key control, required per 1040.10(f)(4)
- b. These products will include a normally off / momentary on switch that provides a tactile emission indicator for the operator, but it will not include the emission indicator delay required per 1040.10(f)(5)
- c. The products will not include the remote interlock connector, required per 1040.10(f)(3)
- d. The GCP-2A, 2B each contain a remote fire switch which is indented and requires strong pressure to activate, providing a tactile emission indicator for the operator, but it will not include the emission indicator delay required per 1040.10(f)(5).



(iv) A description of the advantages to be derived from such deviation .

The GCP-1B, 1C, 2A, 2B will enable officers perform covert marking, surveillance and identification functions. Variances requested from the standard will provide sufficient product function (power, speed and flexibility of operation) so as to protect officers as they perform their job functions in environments similar to combat and combat training.

(v) An explanation of how alternate or suitable means of radiation protection will be provided.

Under this variance, the GCP-1B, 1C, 2A, 2B are to be sold only to Federal, State, local government and law enforcement agencies and shall not be sold to individual personnel of these agencies or organizations.

These products are each to be provided with:

1. A clearly marked eye safe laser training safety selector.
2. Fixed beam orientation design that projects all laser power downrange in the defined beam pattern only.
3. Safety cover for the power switch to eliminate inadvertent activation.
4. Lens cover to eliminate inadvertent emissions when not in use.
5. Soft carrying case which will eliminate accidental radiation emissions when the unit is stored.
6. The Operator Manual (GCP-1B, 1C, 2A, 2B, attached) contain the appropriate laser safety warnings and recommendations for training.

These features require the operator to take several intentional steps before fully empowering the laser (either local - or remote for GCP-2A, 2B only - operation), providing suitable protection from inadvertent exposure to fully powered laser emissions.

For remote switch operation (GCP-2A, 2B), the remote fire switch is indented and requires strong pressure to activate, providing suitable protection from inadvertent exposure to fully powered laser emissions, while maintaining the operational features to safeguard the lives of the officers.

(vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture.

March 1, 2005 to March 1, 2010.

(vii) In the case of prototype or experimental equipment, the proposed location of each unit.

GCP-1B, 1C, 2A, 2B are currently in production mode and not in prototype or the experimental stage.



(viii) Such other information required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

NVEC will provide additional information as required by the Director to assist in evaluation and action upon this application.

(ix) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

NA

(x) [Reserved]

(xi) If the electronic product is used in a clinical investigation involving human subjects, is subject to the requirements for institutional review set forth in part 56 of this chapter, and is subject to the requirements for informed consent set forth in part 50 of this chapter, the investigation shall be conducted in compliance with such requirements.

NA

2) The application for amendment or extension of a variance shall include the following information:

This application is only for the initial variance request.