QUALITY CONTROL PRACTICES FOR COMPLIANCE WITH THE FEDERAL MERCURY VAPOR LAMP PERFORMANCE STANDARD

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FORWARD

This guide is intended to help manufacturers of high-intensity mercury vapor discharge lamps to establish adequate quality control and testing programs for compliance with the Federal performance standard for such lamps (21 CFR 1040.30). It is intended as guidance and to define good manufacturing practice in this area. Although specific sampling plans are included in Section 4, other sampling plans could be used as long as they provide equal protection and assurance of compliance.

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1.0 FDA Compliance Policy

The performance standard for high-intensity mercury vapor discharge lamps issued by the Food and Drug Administration to become effective March 7, 1980, requires manufacturer certification of mercury vapor and metal halide lamps. That certification is the manufacturer's assurance to the customers that each lamp complies with all of the applicable requirements of the standard during its useful life.

Certification of self-extinguishing mercury vapor or metal halide lamps will clearly require destructive testing of some lamps. The FDA will be testing samples of such lamps at its Winchester Engineering and Analytical Center laboratory in Winchester, Massachusetts (draft test procedures in Appendix B). Controlled tests will be performed there to determine if lamps which are certified as self-extinguishing do in fact self-extinguish within the required time, 15 minutes, under the appropriate breakage conditions.

Lamps manufactured after the standard becomes effective and prior to September 8, 1981, will be tested to determine if they self-extinguish with complete breakage of the outer envelope. After that date they will be tested with only partial breakage as specified in the standard. Some lamps will undergo life testing to assure that their self-extinguishing mechanism will operate over the useful life of the lamp. Also, at the same time these lamps are tested for performance, their labels will be examined to assure that they comply with the requirements and will remain attached and legible through the useful life of the lamp.

Destructive tests conducted by FDA and manufacturers will involve only small samples of the production lamps. The actual number of lamps which need to be tested in this manner will depend on many factors. These factors include the results of the tests (e.g., how close the cutoff times are to the limits), the specific type of extinguishing device, and any other tests that manufacturers can perform and document which would provide assurance directly or indirectly that the lamps will meet the standard throughout their useful life.

Failure of a single lamp to meet the test for compliance will not necessarily result in a recall by the manufacturer but may require additional analysis and testing. If a lamp fails to comply with the requirements for self-extinguishing lamps, the FDA will attempt to determine the cause of that failure. The manufacturer will probably be contacted and additional lamps from that batch obtained and tested before deciding if a recall of that batch of lamps is needed. If the additional testing indicates other lamps probably do not comply with the standard the FDA may require the manufacturer to recall them.

The extent of any recall will depend on the manufacturer's ability to determine which lamps may be subject to a particular failure. Clearly it is in the manufacturer's best interest to keep complete and accurate records of quality control testing and design a workable lamp tracing system.

Manufacturers should also note that their quality control programs are subject to review by FDA. If a program is found to be inadequate to assure compliance with the standard the FDA may disapprove the manufacturer's testing program (21 CFR 1010.2 (c)). Under Section 360B of the Radiation Control for Health and Safety Act of 1968, it is unlawful for a manufacturer to continue to introduce into commerce lamps certified on the basis of a disapproved testing program. In that case a new or modified testing program would then have to be developed and submitted to the FDA for review. If it is acceptable the disapproval could be rescinded to allow the manufacturer to resume manufacture and certification of lamps.

Disapproval of a testing program does not require that noncompliant products be found first and thus does not automatically require a recall of products. Likewise the finding of a noncompliant lamp by FDA does not automatically mean disapproval of that manufacturer's testing program. Both situations would require further analysis to determine appropriate action.

2.0 Quality Assurance Program

2.1 Elements of a Quality Assurance Program

The adequacy of a specific quality control and testing program must be judged on its own merits and applicability to the product. However, a viable quality control program, in general, should ensure the continued satisfactory performance of a product throughout its useful life. The essential elements of such a program should include the following:

a. Proper organization and administrative procedures to ensure objectivity.

b. Preproduction evaluation and testing of the product including the testing of components and materials obtained from other manufacturers.

c. Evaluation of the product during and after production.

d. Valid measurement techniques, analysis of data and treatment of uncertainties.

e. Establishment of confidence limits and rejection criteria and the procedures for retesting the rejected units if they are recycled back into the production sequence.

f. An audit procedure to randomly select units for retest as a check on the effectiveness of the instituted quality control and testing program.

g. Life and reliability testing procedures which determine whether the product will continue to meet its design specifications during its useful life.

h. A review procedure to assure that any problems discovered in a product during its production life are corrected and that appropriate design changes are made to eliminate them from subsequent units produced.

2.2 Objectivity

Any quality assurance program should be carefully structured and administered to ensure the objectivity of the program. Certain safeguards against personal prejudice and conflicting interests have to be built into the system to avoid biased decisions. For example, a person responsible for maintaining production schedules should not simultaneously be responsible for quality control, because he may be less inclined to reject large numbers of unacceptable units.

2.3 Uniform Procedures

A quality assurance program must be based on standardized methods for the examination or testing of the products. Specific written procedures should be developed and faithfully followed. Data should be recorded in a consistent manner using standardized forms (21 CFR 1002.30). The forms should provide for recording all information relevant to the product such as the identification number of the product, date of test or examination, date of manufacture, sample lot, results of test, names of personnel performing and reviewing the test, identification of test instruments, etc. Records are to be kept for a period of five (5) years (21 CFR 1002.31 (a)).

2.4 Validity of Measurements

A valid program of measurements involves a thorough evaluation and error analysis of the test methods and instruments. A periodic recalibration of measuring instruments against a standard is an important procedure for maintaining a consistent measuring capability.

2.5 Documentation

A complete written documentation of the quality assurance program should be maintained (21 CFR 1002.30 (a)(1)). This should include description of tests and their sequence,description and evaluation of the measurement instrumentation and techniques (including instrument calibration records), the rejection criteria or confidence limits used and the justification for the particular choice of such limits, methods of data analysis, sampling plans, etc. If a sampling technique must be used, it must be documented and rigorously followed.

2.6 Audit Procedures

Adequate audit procedures should be implemented to act as a further check on the continued validity and effectiveness of the quality control program. Random sampling is the only acceptable method in selecting units for audit testing. The audit should be independent of the quality assurance tests.

3.0 PRE-PRODUCTION EVALUATION

The preproduction evaluation and testing should be constructed to include (1) a review of the design to ensure that the design will yield a product in compliance with the performance standard, (2) evaluation of critical components and material obtained from other manufacturers for use in the lamp and (3) engineering and prototype testing and evaluation to confirm that the lamp can be manufactured in compliance with the standard.

3.1 Design Review

Before the manufacture of the lamp begins, its design must be analyzed to ensure that the finished product will comply with the Federal Performance Standard. The requirements of the mercury vapor lamp standard that must be considered in design review include:

a. The lamp must be permanently labeled or marked in such a manner that the manufacturer and month and year of manufacture (all of which may be expressed in code) can be determined on an intact lamp and after the outer envelope of the lamp is broken or removed (21 CFR 1040.30 (c)(1)(ii)). If the dates appear on both the lamp envelope and an internal part of the lamp, be sure that both dates are the same. Labels or marks shall be sufficiently durable to be legible throughout the useful life of the lamp.

b. The outer envelope of the lamp must be clearly marked with the letter "T" or "R" as appropriate (21 CFR 1040.30(d)(2) and (e)(1)). This mark must also appear on another part of the lamp in such a manner that it is visible after the outer envelope is broken or removed. Be sure that the "T" or "R" marks are clearly distinguishable from and will not be confused with other information that may appear on the lamp; e.g., they should not be a part of or be confused with any part of the lamp designation code.

c. The lamp packaging uniquely associated with the lamp (i.e., innermost* lamp packaging) must bear a label or tag which contains the full name and address of the manufacturer, place of manufacture and month and year of manufacture if such a label or tag is not affixed or inscribed on the lamp itself (21 CFR 1040.30(c)(2) and 21 CFR 1010.3(a)). Where the lamp is sold under a name other than the manufacturer, the full name and address of the company under whose name the lamp is sold may be set forth provided sufficient information is provided to the Bureau of Radiological Health to allow the Bureau to identify the manufacturer. The place of manufacture may be expressed in code. However, no specific place

*Note: This has been modified by the Bureau's policy statement of April 25, 1980, which allows the date of manufacture to appear on the outer packaging rather than the intermost packaging until September 7, 1980.

of manufacture identification will be required if the place of manufacture is same as the address of the manufacturer stated on the label or if the manufacturer has only one place of manufacture for high-intensity mercury vapor discharge lamps and has identified that place of manufacture to the Bureau. The month and year of manufacture can not be coded but must appear in full without abreviation as in the following example - Manufactured: March 1980. The month and year of manufacture on the packaging must be the same as that which appears (in a coded or uncoded form) on the lamp. In lieu of providing the full date of manufacture on the lamp packaging, however, the manufacturer may provide on the lamp packaging the key to the lamp date of manufacture code (see BRH policy statement dated February 25, 1980).

d. The lamp packaging uniquely associated with the lamp must also bear a label or tag which contains a statement by the manufacturer certifying that the lamp conforms to the requirements of the Federal performance standard for high-intensity mercury vapor discharge lamps if the certification label or tag is not affixed or inscribed on the lamp itself (21 CFR 1040.30 (c)(2) and 21 CFR 1010.2 (b)). The certification statement can be in any of the following acceptable forms:

> "Complies with DHEW radiation performance standards, 21 CFR Chapter 1, Subchapter J"
>
> "Product complies with applicable DHEW standards under the Radiation Control for Health and Safety Act of 1968."

Other certification statements may be used as long as they are clear and unambiguous.

e. Lamp packaging (21 CFR 1040.30 (b)(3)) for each mercury vapor lamp must clearly and prominently display the letter "T" or "R" and the warning labels for self-extinguishing or non-self-extinguishing lamps as appropriate (21 CFR 1040.30 (d)(3) and (e)(2) respectively).

f. Self-extinguishing mechanisms must be designed to assure that the lamp will comply with the requirements of 21 CFR 1040.30 (d)(1). The following factors should be considered when designing such mechanisms:

> 1. The design cut-off time (i.e., the mechanism) should be designed to function reliabily well within the 15 minute limit following lamp envelope breakage,
>
> 2. Adverse effects of tolerance buildup and production errors on proper functioning of the self-extinguishing mechanism should be minimized, i.e., it should be a "forgiving" design,

3. The ability of indirect (non-destructive) tests to predict and ensure compliance of the completed lamp with the requirements of the standard (i.e., use of non-destructive tests) can reduce the number and cost of destructive tests, and

4. The susceptibility of the self-extinguishing mechanism to degradation in performance because of use or environmental factors.

g. Lamp advertisement for non-self-extinguishing lamps must contain the warning statement required by 21 CFR 1040.30 (e)(3). The statement need not be repeated for each lamp provided it is clear as to which lamps the statement applies. Be sure that the warning statement is contained in all advertisement as defined by 21 CFR 1040.30 (b)(2) and that personnel responsible for advertisement are aware of this requirement.

3.2 Evaluation of Critical Components

Certain components can affect the compliance of mercury vapor lamps. This is particularly true for self-extinguishing lamps. A glass structure or an electrical or mechanical component may be critical for compliance. Tags and labels may also be critical for compliance. Whether such components are fabricated by the manufacturer of the lamp or purchased from a vendor, proper evaluation is essential to determine that the product will comply with the applicable standard after manufacture. The responsibility for product compliance rests with the manufacturer of the final product and not the supplier of components or material. The testing of all critical components is therefore, an important responsibility of the manufacturer. Important aspects of evaluation of these critical components prior to their use in the lamp include:

a. Performance specifications for the critical components should be developed taking both the requirements of the performance standard and a tolerance analysis of the product into consideration. A tolerance analysis is a calculation of the range of performance of a product that can result from variations that can occur in components. Such an analysis should, whenever possible, be experimentally validated.

b. All critical components should be tested to verify that their performance is within the range of specifications required for them by the manufacturer of the final product. Many of the tests of critical components are not possible or feasible after these components have been incorporated into the product except on a destructive testing basis. For example, a tungsten filament used as a fuse in a self-extinguishing mechanism should be checked for proper weight and dimension. Wherever possible, a 100-percent testing of components is recommended. If this is not possible or feasible, sampling procedures having demonstrable statistical validity may be used (see 4.5.1).

c. If at any time the design specifications or materials of any critical components are changed, the design of the entire lamp should be reviewed to ensure that the change does not in any way affect its compliance with the performance standard.

3.3 Engineering and Prototype Testing and Evaluation

Engineering models and prototypes should be tested thoroughly and exhaustively to assure that the lamp can be manufactured in compliance with the performance standard, and that it will remain in compliance under all forseeable conditions during its useful life. This would include adequate transportation tests, tests of performance under expected and adverse environmental conditions, use and abuse testing, and accelerated life tests. Any design changes should be properly documented, tested and evaluated in relation to product compliance.

Sections 4 and 5 of this document should be consulted for more detailed guidance on type of tests, test parameters, test conditions, and testing procedures.

4.0 PRODUCTION TESTING

4.1 Design of the Production Quality Control and Testing Program

After a manufacturer has verified through design review and prototype testing that a product can be manufactured in compliance with the performance standard, he must design and implement a production quality control and testing program that will ensure that each individual lamp manufactured complies with the standard. In designing the production quality control and testing program, it is first necessary to identify the parameters that need to be checked or tested in order to determine compliance with the Federal performance standard. This will depend on whether the lamp is intended to be self-extinguishing (T Type) or non-self-extinguishing (R Type). Both types of lamps require marking and labeling as previously indicated (Part 4.1). In addition, self-extinguishing lamps must comply with the requirement that the lamp extinguish in 15 minutes following complete breakage or removal of the outer envelope and, after September 7, 1981, following breakage or removal of not less than 3 square centimeters of contiguous surface of the outer envelope. All of the above requirements must be checked or tested. In the case of labels or markings such checks or tests consist of merely determining that the correct labels or marks are present and properly affixed to or inscribed on the lamp and/or lamp packaging. Checks and tests for compliance with the self-extinguishing requirements can be of two different types: destructive tests and non-destructive tests.

Destructive tests are tests of the self-extinguishing mechanism requiring breakage of the outer envelope. Non-destructive tests are tests conducted on components and during the manufacturing process which are intended to assure that the self-extinguishing mechanism would operate properly and cause the lamp to extinguish if the outer envelope were broken as prescribed in the standard. Properly designed non-destructive (or indirect) tests can increase compliance confidence levels by improving product quality and help reduce the level of destructive (direct) testing.

4.2 Checks for Labels and Markings

Checks should be made of the following labels and markings:

4.2.1 Name of manufacturer on lamp (check marks or labels both inside of the lamp and on the outer envelope).

4.2.2 Month and year of manufacture on lamp (check marks or labels both inside the lamp and on the outer envelope).

4.2.3 The letter "T" or "R", as appropriate, on the outer envelope and on another part of the lamp.

4.2.4 The full name and address of the manufacturer, place of manufacture and month and year of manufacture (or the key to the date code, if it is coded on the lamp) on the innermost lamp packaging.

4.2.5 The letter "T" or "R", as appropriate, on lamp packaging.

4.2.6 The warning statement for "T" type lamps or the warning statement for "R" type lamps, as appropriate, on lamp packaging.

4.3 Component and In-Process Tests

The following types of component and in-process tests should be considered in establishing testing programs for self-extinguishing lamps:

4.3.1 Tests for Mechanical Switches

1. Check of metal parts for proper dimensions, tensile strength, etc.

2. Check of switch contacts for proper surface characteristics, alignment, and contact.

3. Check of switch spring tension to assure that contacts will open.

4. A visual alignment check of switch assembly after outer envelope is installed, if possible.

4.3.2 Tests for Tungsten Filament Fuses

1. Check of incoming tungsten wire for proper weight and dimension.

2. Check of completed tungsten filaments for proper weight, spacing, and number of turns.

3. Check of tungsten filaments to be sure there are no foreign elements present that may cause a short, e.g. fragments of the metal rod on which the filament was wound.

4. Lighting each lamp to check that the light output of each filament appears normal.

The above tests are not all inclusive and some may not be possible or practical for a particular lamp or manufacturing process. The manufacturer should evaluate and adopt other or additional component or in-process tests which might be useful. Such tests may be conducted on a 100% basis or, when appropriate, on a sampling basis.

4.4 Final Product (Destructive) Tests

Tests must be conducted on self-extinguishing lamps after manufacture using statistically valid sampling techniques. Lamps are to be broken as required by 21 CFR 1040.30 (d)(1) while being operated under test conditions prescribed in the standard (21 CFR 1040.30 (f)).

4.4.1 Lamp Breakage Conditions

1. "Each self-extinguishing lamp manufactured after March 7, 1980 shall cease operation within a cumulative operating time not to exceed 15 minutes following complete breakage or removal of the outer envelope (with the exception of fragments extended 50 millimeters or less from the base shell" (21 CFR 1040.30(d)(1)(i)).

The manufacturer must design, fabricate and install apparatus that will efficiently, reliably, and completely break the lamp outer envelope (see 4.4.2). Generally, this can be accomplished by striking the lamp at one or more preselected points with a solid object while the lamp is being operated.

2. "Each self-extinguishing lamp manufactured after September 7, 1981 shall cease operation within a cumulative operating time not to exceed 15 minutes following breakage or removal of at least 3 square centimeters of contiguous surface of the outer envelope" (21 CFR 1040.30 (d)(1)(ii)). It is assumed that after September 7, 1981, the worst case breakage condition will be a single hole exactly 3 square centimeters in area. The manufacturer will have to design, fabricate, and install an apparatus (or develop a method) for efficiently and reliably creating the required hole while the lamp is operating (see 4.4.2). A hole of the required size could be made in the lamp using a drill with a diamond drill bit. A hole could also be produced by heating a small area of the lamp surface and then creating the hole using a punch.

4.4.2 Lamp Test Conditions (21 CFR 1040.30 (f))

1. Lamps should be tested in an enclosure having a volume of not less than 0.227 cubic meters (8 cubic feet). The use of an enclosure is desirable to provide for operator safety and a controlled test environment.

2. Any lamp designed to be operated only in a specific fixture or luminaire that the lamp manufacturer supplies or specifies shall be tested in that fixture or luminaire. All other lamps shall be tested while operating without a reflector or other surrounding material; i.e., the lamp shall be attached only to a bare socket to supply power.

3. The lamp shall be oriented in the test chamber to the orientation indicated or recommended by the manufacturer. If the manufacturer does not recommend a particular orientation or recommends more than one orientation the lamp shall be mounted in the worst case orientation for complianance with the standard.

4. The initial air temperature at the time of lamp start up shall be 25 $\pm$ 5° C. Heating and movement of the air surrounding the lamp shall be that produced by the lamp and ballast alone; i.e., the air temperature and air movement inside the test chamber shall not be artificially controlled or influenced by fans, coolers, heaters, etc.

5. The lamp shall be operated on a reference ballast, which is defined as an "inductive reactor designed to have the operating characteristics as listed in Section 7 in the American National Standards Specifications for High-Intensity Discharge Lamp Reference Ballasts (ANSI C82.51977) or its equivalent."

6. The voltage applied to the reference ballast shall be that recommended or specified for operation of the lamp. After the lamp starts up and its operation stabilizes, the measured current should be within the acceptable current range for the lamp. As long as the current is within the acceptable range, it need not be adjusted, either before or after lamp breakage (even if the lamp current changes significantly after breakage of the outer envelope). If manufacturers wish to maintain a constant lamp current following lamp breakage in order to simulate worst case conditions, the Bureau will not object as long as it can be established that the lamp extinguishing time would never be less than that which would result from testing as indicated above.

7. After the lamp operation has stabilized, the lamp shall be broken in the required manner. The time from the moment of breakage to the time when the lamp ceases operation shall be measured and recorded.

8. After completion of the test the lamp should be examined to make sure that lamp breakage was as specified in the standard (21 CFR 1040.30 (d) (1)(i) or (ii) as appropriate) and that the lamp did not extinguish for any reason other than by operation of the self-extinguishing mechanism.

4.5 Sampling Plans

4.5.1 Sampling Plans for Component and In-process Testing

Component and in-process testing should be conducted on a 100% basis when possible to do so. However, when sampling procedure must be used a statistically valid sampling scheme based on MIL-STD-105D for attributes sampling or MIL-STD-414 for variables sampling or equivalent should be employed. Acceptable quality levels (AQL) and rejection limits should be chosen that are appropriate for the components and processes being controlled.

4.5.2 Sampling Plans for Final Product Testing

Two types of designs for mercury vapor lamp self-extinguishing mechanisms have been developed for compliance with the performance standard for such lamps. One design is a mechanical switch held in the on (closed) position by the outer glass envelope of the lamp. If the entire glass is shattered, the circuit is immediately broken and the lamp goes out. This design will not meet the more stringent standard to go into effect after September 7, 1981, which require the lamp to extinguish in the event that the glass envelope is punctured. The other design is a tungsten filament fuse that should be capable of meeting the more stringent standard because it is based on oxidation and destruction of the tungsten filament that completes the circuit to the light source. In the presence of air, oxidation should occur causing an interruption of the circuit. There is a trade-off with this design, however. The life of the bulb is likely to be related to the length of time it takes the filament to burn out. Thus, if the arc-extinguishing design time is too short the lamp may suffer unacceptable life shortening.

The sampling plans contained in this document are intended only as a convenience for manufacturers. Any plan which provides equivalent protection may be used. Manufacturers are encouraged to adopt equivalent plans which result in reduced sample sizes.

4.5.2.1 Sampling by Attributes

Since all lamps, especially those using mechanical switches, can be classified as being defective or not defective, depending upon whether the lamp stays on or goes out when the outer envelope is broken, they conform to the process monitoring procedures of sampling by attributes described in MIL-STD-105D. The tungsten filament fuse lamps, however, can take advantage of the smaller sample sizes associated with variables sampling described in the next section. It is the

intent of the Bureau of Radiological Health that the attributes inspection procedures conform to the procedures given in MIL-STD-105D or their equivalent and include additional restrictions specific to this problem. While it is an ideal that no lamps produced should fail to comply with the standard, the Bureau of Radiological Health believes that a testing program is adequate if it ensures that, on the average, not more than 1 lamp per 1,000 produced will fail to comply. Under the guidance of the referenced sampling plans, the Bureau recognizes that such an acceptable quality level (AQL) will result in the destruction for testing purposes of a large fraction of the lamps produced for any reasonable lot size. It is clear that large sampling fractions would constitute an unacceptable burden on the manufacturer and the public because of the prohibitive per unit costs of testing.

Therefore, the Bureau of Radiological Health proposes that the lot-by-lot AQL not exceed 1% for product sampling and that the lots not be accepted if one reject is found in any sample. This will have the effect of decreasing the AQL as lot sizes (and, therefore, sample sizes) are increased. Lower lot quality protection can be tolerated in small lots but not in larger lots. However, the long term average percent defective must not exceed 0.1%. Sampling plans based on MIL-STD-105D and this guidance are included in Appendix A.

4.5.2.2 Sampling by Variables for Tungsten Filament Fuses

Since tungsten filament fuses will always oxidize and interrupt lamp operation in a finite time, lamps using such fuses can be tested by variables sampling inspection. The variable that would be measured is self-extinguishing time. Variables sampling has the advantage that sample sizes can be significantly reduced. Variables sampling plans set forth in MIL-STD-414 or later volume as modified by this guidance are included in Appendix A. All restrictions set forth in MIL-STD-414 should be followed in addition to those modifications stated here. The variables sampling plan contained in Appendix A is based on the assumption that the measured parameter is normally distributed. Should the normality assumption not be satisfied, it is possible to base an inspection by variables plan on any well-behaved probability distribution. Such sampling plans will be considered on a case-by-case basis. In any case, the sampling plan should assure that, on the average, not more than one lamp per 1,000 produced will fail to comply.

5.0 RELIABILITY TESTS

Product reliability is the probability of a product performing its intended function over its intended life and under the operating conditions encountered. The primary product reliability concern of mercury vapor lamp manufacturers has been lamp useful life. The mercury vapor lamp performance standard adds a new concern, the ability of self-extinguishing devices to function reliably during the useful life of the lamp. Reliability of the self-extinguishing mechanism must be carefully considered in lamp design and must be proven through engineering evaluation and prototype and production testing.

For mechanical switches, processes that may decrease reliability include those that cause switch contact welding, metal fatigue, and decreased tensile strength. Although lamps with filament fuses are expected to self-extinguish without fail, there may be aging processes that could lengthen the self-extinguishing time; e.g., the current may not increase as much when the lamp is broken after lamp aging as it would if broken when new.

Life and reliability testing is routinely conducted by mercury vapor lamp manufacturers to assure that lamps will meet rated life specifications. Tests of the self-extinguishing mechanism can readily be added to the life test protocols. The conditions under which lamps are operated should simulate, to the degree possible, actual use and environmental conditions. Each life test should be conducted for a period of lamp operation equal to the rated life of the lamp and, preferably longer.

At the end of the test, lamps that are still operating should be removed from their life test fixtures and the self-extinguishing mechanism tested under the conditions described in item 5.4.2 of this guide.

The possibility of using accelerated life testing methods should be investigated. Valid accelerated life tests can shorten considerably the length of time that each lamp must be operated, thereby making test results available much sooner. However, manufacturers are cautioned to ensure that accelerated life tests, when used, will not give false or misleading results.

6.0 QUALITY AUDITS

A quality control program can be only as good as the people who are conducting that program. Even the most carefully planned and technically and statistically valid quality control procedures will not assure compliance with the mercruy vapor lamp performance standard if those procedures are not properly implemented and followed faithfully. To ensure the effectiveness of the quality control program it should be monitored using accepted quality audit techniques.

The three elements of a quality audit are procedures audits, product audits, and organizational and personnel evaluations.

6.1 Procedures Audits

Frequent audits should be conducted to verify that the quality control plan is followed. This includes ensuring that (1) all required checks and tests are performed, (2) there is no deviation from estabilished test procedures, (3) samples are taken in accordance with the sampling plan, (4) all required statistical calculations are properly made and correctly used in determining sampling levels, (5) lot rejection limits and reaction plans are rigorously complied with, and (6) full and complete quality control and testing records are generated and maintained.

The results of procedure audits are a measure of managerial control and can indicate areas requiring better instruction and closer supervision.

6.2 Product Audits

A product audit is an independent evaluation of a relatively small number of products. Its purpose is not to control quality but to determine the effectiveness of the quality control system.

Completed lamps that are audited may be taken at the end of the production line or from warehoused stock. In-process audits could also be made of components and sub-assemblies when relavant quality characteristics can be evaluated during the production process. However, a particular characteristic should only be audited following the completion of the quality control procedure related to control of that characteristic. For example, if a date code tag inside the lamp is checked by quality control during lamp assembly, the presence of that tag could be audited at some point in production after that quality control check is made.

Audits should cover all applicable requirements of the performance standard including marks and labels as well as proper functioning of the self-extinguishing mechanism. Audit results should be analyzed to identify specific areas that call for further investigation of design, processing, control methods, procedures, or personnel performance. Corrective actions shall be applied where the results of the analysis dictate.

6.3 Organizational and Personnel Evaluations

The results of the quality audit should be used to access the adequacy and performance of organizational units and personnel. Audit results may uncover underlying weaknesses in organization or managerial structure or they may indicate need for additional training or instruction for personnel or even need for disciplinary action.

APPENDIX A

SAMPLING PLANS

A.1 Sampling by Attributes

The manufacturer will determine the lot size and choose the appropriate letter code from Appendix A, Table I. Then the appropriate sample size and rejection limit will be read from Appendix A, Table II (normal inspection) and the sample results will be obtained. The lot will be rejected if the number of tested lamps that fail to extinguish equal or exceed the rejection limit. If a lot is rejected tightened inspection shall be instituted following the sampling plan specified in Table III and shall remain in effect until five (5) consecutive lots have been considered acceptable, at which time normal inspection may be reinstituted. When normal inspection is in effect, reduced inspection may be instituted following the sample plan specified in Table IV provided the preceding 10 lots have been on normal inspection and the process average has not exceeded one (1) defective lamp per 1000. If less than 1000 samples have been taken and none have been rejected, it can be assumed that the process average has not exceeded 1 defective per 1000. When reduced inspection is in effect, tightened inspection shall be instituted following lot rejection if the process average exceeds one defect per 1000 lamps. If the process average does not exceed one defective per 1000, normal inspection shall be instituted following lot rejection when reduced inspection is in effect.

There should be no compromise of the process average percent defectives being less than 1 per 1000. The method of allowing a lot rejection rule based on a larger AQL is merely a convenient instrument to allow an inspection process that does not impose a prohibitive burden on the manufacturer. These requirements, which exceed those given in MIL-STD-105D, are imposed to ensure that the Bureau acceptance level is not compromised.

A.2 Sampling by Variables

The Bureau requires that the percent defectives shall be less than 1 in 1,000 which implies that the percent of self-extinguishing times that exceed the standard value of 15 minutes shall be less than 0.1%. If we let "μ" be the theoretical but unknown mean self-extinguishing time and "s" be the sample standard deviation of the self-extinguishing times, then we require

$$\Pr\left[\frac{15-\mu}{s} \geq k\right] \leq 0.001 \qquad (1)$$

where k is the standard normal value corresponding to a probability of 1 in 1,000 (0.001). The manufacturer should furnish data to support the use of the normal distribution function for testing purposes. If this normality assumption is acceptable, then k = 3.1 and we can solve for μ, the mean self-extinguishing time.

$$\mu = 15 - 3.1s \qquad (2)$$

The manufacturer may use one of a number of procedures to ensure that the percent defectives is less than 1 in 1000. For sufficiently large lot sizes the manufacturer may use the 15 minutes for the upper specification limit (U) and an AQL of 0.1%. This is the most direct method to ensure the desired quality. Alternatively, a lower in-factory rejection limit can be established based on a higher AQL. This method allows some flexibility of sample size particularly for the smaller lot sizes. The main objective under either method is to maintain the process average at a level to ensure the percent defectives being less than 1 in 1000. For example if an AQL of 1% is chosen, then the upper specification limit should be set such that the self-extinguishing times of not more than 1 in 100 bulbs (0.01) would exceed that specification, therefore

$$\Pr\left[\frac{U-\mu}{s} \geq m\right] \leq 0.01 \qquad (3)$$

where "U" is the upper specification limit and "m" is the standard normal value corresponding to a probability of 0.01. Thus m = 2.32 and

$$\frac{U-\mu}{s} = 2.32 \qquad (4)$$

Therefore,

$$U = \mu + 2.32s = 15 - 3.1s + 2.32s$$

$$U = 15 - 0.78s \qquad (5)$$

Therefore, if the theoretical mean (μ) of the self-extinguishing times and the standard deviation (s) of the self-extinguishing times of the samples is such that $\mu + 3.1s < 15$ and the self-extinguishing time specification limit (U) is equal to or less than 15- 0.78s, lots should be accepted and not rejected, since the process average of lamps that exceed a self-extinguishing time of 15 minutes would not be greater than 1 in 1,000.

The sampling plan discussed below is based on the preceding technique and use of an AQL of 1% with variability unknown. MIL-STD-414 should be consulted for plans using other AQL's. The manufacturer will determine the lot size and choose the appropriate sample letter code from Appendix A, Table V. Then the appropriate sample size will be read from Appendix A, Table VI (AQL 1%) and the sample results will be obtained. To determine lot acceptance or rejection the following quantity is calculated:

$$Q_u = \frac{U - \bar{x}}{s} \qquad (6)$$

where $\bar{x}$ is the sample mean self-extinguishing time. That value is compared with the value of K for normal inspection taken from Appendix A, Table VI. If Q_u is equal to or greater than K, the lot is accepted. The standard deviation should be estimated by the following calculation:

$$s = \sqrt{\frac{\sum x^2 - (\sum x)^2/n}{n-1}} \qquad (7)$$

where n is the sample size and x is the individual lamp extinguishing time.

Tightened inspection shall be instituted when the estimated process average computed from the preceding ten (10) lots is greater than the AQL (1.00 percent). Tightened inspection is also required when the number of lots with estimates of percent defective above the AQL from the preceding 5, 10 or 15 lots is greater than the given value of "T" in Appendix A, Table VIII, and the process average from these lots exceeds the AQL. Normal inspection may be reinstated if the estimated process average of lots under tightened inspection is equal to or less than the AQL.

Reduced inspection may be instituted provided (1) the preceding ten lots (or other designated number of lots) have been under normal inspection and none have been rejected; (2) the estimated percent defective for each of the preceding 5, 10 or 15 lots is less than the applicable lower limit shown in Appendix A, Table IX or, for certain sampling plans, the estimated lot percent defective is equal to zero for a specified number of consecutive lots (see Table IX); and (3) production is at a steady rate. However, normal inspection shall be reinstated if a lot is rejected, the estimated process average is greater than the AQL, or production becomes irregular or delayed.

The estimated process average referenced above is the arithmetic mean of the estimated lot percent defectives computed from the appropriate number of lots. The estimated lot percent defective is to be determined from Appendix A, Table X for any particular value of Q_u (quantity in the extreme left hand column) (see equation (6)) and sample size.

Table I

Sample Size Code Letter for
Sampling by Attributes

Lot or batch size	Sample Code Letter
2 to 150	F
151 to 280	G
281 to 500	H
501 to 1200	J
1201 to 3200	K

(Adapted from MIL-STD 105D, Table 1)

Table II

Normal Inspection by Attributes

Sample Size Code	Sample Size	% of Lot	AQL (%)	Number of Defects	
				Accept	Reject
F	13	8.7-100	1	0	1
G	20	7-13	0.65	0	1
H	32	6.4-11	0.40	0	1
J	50	4.2-10	0.25	0	1
K	80	2.5-6.6	0.15	0	1

Adapted from MIL-STD 105D, Table II-A)

Table III

Tightened Inspection by Attributes

Sample Size Code	Sample Size	% of Lot	AQL (%)	Number of Defects	
				Accept	Reject
F	20	13.4-100	1	0	1
G	32	11.4-21	0.65	0	1
H	50	10 -18	0.40	0	1
J	80	6.7-16	0.25	0	1
K	125	3.9-10	0.15	0	1

(Adapted from MIL-STD 105D, Table II-B)

Table IV

Reduced Inspection by Attributes

Sample Size Code	Sample Size	% of Lot	AQL (%)	Number of Defects	
				Accept	Reject
F	5	3.3-100	1	0	1
G	8	2.8-5.2	0.65	0	1
H	13	2.6-4.6	0.40	0	1
J	20	1.7-4.0	0.25	0	1
K	32	1.0-2.7	0.15	0	1

(Adapted from MIL-STD 105D, Table II-C)

Table V

Sample Size Code Letter for
Sampling by Variables

Lot Size	Code Letter	Lot Size	Code Letter
3 - 25	C	801 - 1,300	K
26 - 40	D	1,301 - 3,200	L
41 - 65	E	3,200 - 8,000	M
66 - 110	F	8,001 - 22,000	N
111 - 180	G	22,001 - 110,000	O
181 - 300	H	110,001 - 550,000	P
301 - 500	I	550,001 - over	Q
501 - 800	J		

(Adapted from MIL-STD 414, Table A-2)

Table VI

Normal and Tightened Inspection by Variables
Variability Unknown - AQL 1%

Sample size Code Letter	Sample Size	K value Normal Inspection	K value Tightened Inspection
C	4	1.45	-
D	5	1.53	1.65
E	7	1.62	1.75
F	10	1.72	1.84
G	15	1.79	1.91
H	20	1.82	1.96
I	25	1.85	1.98
J	30	1.86	2.00
K	35	1.89	2.03
L	40	1.89	2.03
M	50	1.93	2.08
N	75	1.98	2.12
O	100	2.00	2.14
P	150	2.03	2.18
Q	200	2.04	2.18

(Adapted from MIL-STD 414, Table B-1)

Table VII

Reduced Inspection by Variables
Variability Unknown - AQL 1%

Sample Size Code Letter	Sample Size	K Value
C	4	1.34
D	4	1.34
E	4	1.34
F	4	1.34
G	5	1.40
H	7	1.50
I	10	1.58
J	10	1.58
K	15	1.65
L	20	1.69
M	20	1.69
N	25	1.72
O	30	1.73
P	50	1.80
Q	75	1.84

(Adapted from MIL-STD 414, Table B-2)

Table VIII

Values of T for Tightened Inspection

Sample Size Code Letter	Number of Lots 5	10	15	Sample Size Code Letter	Number of Lots 5	10	15
C	2	3	5	K	4	7	10
D	3	4	6	L	4	7	10
E	3	5	7	M	4	7	10
F	4	6	8	N	4	8	11
G	4	7	9	O	4	8	11
H	4	7	9	P	4	8	11
I	4	7	10	Q	4	8	11
J	4	7	10	-	-	-	--

(Adapted from MIL-STD 414, Table B-6)

Table IX

Limits of Estimated Lot Percent Defective for Reduced Inspection

Sample Size Code Letter	Number of Lots 5	10	15	Sample Size Code Letter	Number of Lots 5	10	15
C	(45)*	(45)*	(45)*	K	.483	.940	1.00
D	(25)*	(25)*	(25)*	L	.525	.961	1.00
E	(11)*	(11)*	(11)*	M	.587	.989	1.00
F	.003	.317	.81	N	.681	1.00	1.00
G	.136	.643	1.00	O	.733	1.00	1.00
H	.266	.785	1.00	P	.799	1.00	1.00
I	.360	.863	1.00	Q	.830	1.00	1.00
J	.431	.909	1.00	-	-	-	-

* The estimated lot percent defective must be zero for the number of consecutive lots indicated in parenthesis.

(Adapted from MIL-STD 414, Table B-7)

TABLE XI

Table for Estimating the Lot Percent Defective Using Standard Deviation Method[1]

Q_u	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
0	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00
.1	47.24	46.67	46.44	46.46	46.56	46.58	46.66	46.06	46.66	46.66	46.64	46.64	46.63	46.63	46.62	46.62
.2	44.46	43.33	42.98	42.84	42.80	42.86	42.19	42.16	42.13	42.13	42.13	42.11	42.13	42.09	42.06	42.06
.3	41.63	40.00	39.27	38.97	38.80	38.64	38.57	38.52	38.51	38.50	38.48	38.47	38.45	38.34	38.33	38.33
.31	41.30	39.67	39.04	38.90	38.83	38.08	37.99	37.98	37.93	37.91	37.90	37.89	37.87	37.84	37.84	37.84
.32	41.06	39.33	38.67	38.54	37.86	37.68	37.63	37.56	37.53	37.54	37.53	37.51	37.49	37.44	37.44	37.44
.33	40.77	39.00	38.33	37.75	37.49	37.31	37.26	37.20	37.18	37.16	37.13	37.13	37.11	37.10	37.09	37.08
.34	40.49	38.67	37.97	37.63	37.13	36.94	36.87	36.83	36.80	36.78	36.77	36.75	36.73	36.72	36.71	36.71
.35	40.20	38.33	37.63	37.06	36.75	36.57	36.49	36.43	36.43	36.41	36.40	36.38	36.36	36.33	36.33	36.33
.36	39.91	38.00	37.28	36.68	36.38	36.20	36.12	36.08	36.08	36.04	36.03	36.01	35.99	35.97	35.96	35.96
.37	39.62	37.67	36.93	36.33	36.03	35.83	35.75	35.73	35.68	35.66	35.65	35.63	35.61	35.60	35.59	35.58
.38	39.33	37.33	36.58	35.98	35.65	35.46	35.38	35.34	35.31	35.29	35.28	35.26	35.24	35.23	35.22	35.21
.39	39.03	37.00	36.23	35.63	35.28	35.10	35.01	34.97	34.94	34.93	34.91	34.89	34.87	34.86	34.85	34.84
.40	38.74	36.67	35.88	35.28	34.90	34.73	34.63	34.60	34.58	34.56	34.54	34.53	34.50	34.49	34.48	34.47
.41	38.43	36.33	35.54	34.90	34.52	34.37	34.28	34.24	34.21	34.19	34.18	34.16	34.13	34.12	34.11	34.10
.42	38.13	36.00	35.19	34.53	34.21	34.00	33.92	33.87	33.85	33.83	33.81	33.79	33.77	33.76	33.74	33.74
.43	37.83	35.67	34.83	34.19	33.85	33.64	33.56	33.51	33.48	33.46	33.45	33.43	33.40	33.39	33.38	33.37
.44	37.54	35.33	34.50	33.84	33.49	33.28	33.20	33.15	33.12	33.10	33.09	33.07	33.04	33.03	33.03	33.01
.45	37.26	35.00	34.16	33.49	33.13	32.92	32.84	32.79	32.76	32.74	32.73	32.71	32.68	32.67	32.66	32.65
.46	36.96	34.67	33.83	33.15	32.78	32.57	32.48	32.43	32.40	32.38	32.37	32.35	32.33	32.31	32.30	32.29
.47	36.66	34.33	33.47	32.78	32.42	32.21	32.12	32.07	32.04	32.02	32.01	31.99	31.96	31.95	31.94	31.93
.48	36.33	34.00	33.12	32.42	32.07	31.85	31.77	31.72	31.69	31.67	31.65	31.63	31.61	31.60	31.59	31.58
.49	36.08	33.67	32.79	32.08	31.72	31.50	31.41	31.36	31.33	31.31	31.30	31.28	31.25	31.24	31.23	31.22
.50	35.79	33.33	32.44	31.74	31.37	31.15	31.06	31.01	30.98	30.96	30.94	30.93	30.90	30.89	30.87	30.87
.51	35.44	33.00	32.10	31.39	31.02	30.80	30.71	30.66	30.63	30.60	30.59	30.57	30.54	30.53	30.52	30.51
.52	35.13	32.67	31.76	31.04	30.67	30.45	30.36	30.31	30.28	30.26	30.25	30.23	30.20	30.19	30.17	30.17
.53	34.82	32.33	31.42	30.70	30.32	30.10	30.01	29.96	29.93	29.91	29.90	29.88	29.85	29.84	29.83	29.82
.54	34.51	32.00	31.08	30.36	29.98	29.76	29.67	29.62	29.59	29.57	29.55	29.53	29.51	29.49	29.48	29.48
.55	34.20	31.67	30.74	30.01	29.64	29.41	29.32	29.27	29.24	29.22	29.21	29.19	29.16	29.15	29.14	29.13
.56	33.88	31.33	30.40	29.67	29.29	29.07	28.98	28.93	28.90	28.88	28.87	28.85	28.82	28.81	28.79	28.79
.57	33.57	31.00	30.06	29.33	28.95	28.73	28.64	28.59	28.56	28.54	28.53	28.51	28.48	28.47	28.45	28.45
.58	33.25	30.67	29.73	28.99	28.61	28.39	28.30	28.25	28.22	28.20	28.19	28.17	28.14	28.13	28.12	28.11
.59	32.93	30.33	29.39	28.66	28.28	28.06	27.96	27.92	27.89	27.87	27.85	27.83	27.81	27.79	27.78	27.77
.60	32.61	30.00	29.05	28.33	27.94	27.72	27.63	27.58	27.55	27.53	27.52	27.50	27.47	27.46	27.45	27.44
.61	32.28	29.67	28.72	27.98	27.60	27.39	27.30	27.25	27.22	27.20	27.18	27.16	27.13	27.12	27.11	27.11
.62	31.96	29.33	28.39	27.65	27.27	27.05	26.96	26.92	26.89	26.87	26.85	26.83	26.81	26.80	26.78	26.78
.63	31.63	29.00	28.06	27.32	26.94	26.72	26.63	26.59	26.56	26.54	26.52	26.50	26.48	26.47	26.45	26.45
.64	31.30	28.67	27.72	26.97	26.61	26.39	26.31	26.26	26.23	26.21	26.20	26.18	26.15	26.14	26.13	26.12
.65	30.97	28.33	27.39	26.66	26.28	26.07	25.98	25.93	25.90	25.88	25.87	25.85	25.82	25.81	25.80	25.80
.66	30.63	28.00	27.06	26.33	25.96	25.74	25.66	25.61	25.58	25.56	25.55	25.53	25.51	25.49	25.48	25.48
.67	30.30	27.67	26.73	26.00	25.63	25.42	25.33	25.29	25.26	25.24	25.23	25.21	25.19	25.17	25.16	25.16
.68	29.96	27.33	26.40	25.68	25.31	25.10	25.01	24.97	24.94	24.92	24.91	24.89	24.87	24.86	24.84	24.84
.69	29.61	27.00	26.07	25.35	24.99	24.78	24.70	24.65	24.63	24.60	24.59	24.57	24.55	24.54	24.53	24.52

[1]Values tabulated are read to percent.

Q_u	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
.70	29.27	26.67	25.74	25.03	24.67	24.46	24.36	24.33	24.31	24.29	24.28	24.26	24.24	24.23	24.22	24.21
.71	28.92	26.33	25.41	24.71	24.33	24.13	24.06	24.02	23.99	23.98	23.96	23.94	23.93	23.91	23.90	23.90
.72	28.57	26.00	25.09	24.39	24.03	23.82	23.75	23.71	23.68	23.67	25.65	23.64	23.61	23.60	23.59	23.59
.73	28.22	25.67	24.76	24.07	23.72	23.52	23.44	23.40	23.37	23.36	23.34	23.33	23.31	23.30	23.29	23.28
.74	27.86	25.33	24.44	23.75	23.41	23.21	23.13	23.09	23.07	23.06	23.04	23.03	23.00	22.99	22.98	22.98
.75	27.50	25.00	24.11	23.44	23.10	22.90	22.83	22.79	22.76	22.75	22.73	22.72	22.70	22.69	22.68	22.67
.76	27.13	24.67	23.79	23.13	22.79	22.60	22.53	22.48	22.46	22.44	22.43	22.42	22.40	22.39	22.38	22.37
.77	26.77	24.33	23.47	22.81	22.48	22.30	22.22	22.18	22.16	22.14	22.13	22.12	22.10	22.09	22.08	22.08
.78	26.39	24.00	23.13	22.50	22.18	21.99	21.92	21.89	21.86	21.85	21.84	21.83	21.80	21.79	21.78	21.78
.79	26.02	23.67	22.80	22.19	21.87	21.70	21.63	21.59	21.57	21.55	21.54	21.53	21.51	21.51	21.50	21.49
.80	25.64	23.33	22.51	21.88	21.57	21.40	21.33	21.29	21.27	21.26	21.25	21.23	21.22	21.21	21.20	21.20
.81	25.25	23.00	22.19	21.58	21.27	21.10	21.04	21.00	20.98	20.97	20.96	20.94	20.93	20.93	20.91	20.91
.82	24.86	22.67	21.87	21.27	20.96	20.81	20.75	20.71	20.69	20.68	20.67	20.65	20.64	20.63	20.62	20.62
.83	24.47	22.33	21.54	20.97	20.68	20.52	20.46	20.43	20.40	20.39	20.38	20.37	20.35	20.35	20.34	20.34
.84	24.09	22.00	21.24	20.67	20.39	20.23	20.17	20.14	20.13	20.12	20.10	20.09	20.07	20.06	20.06	20.06
.85	23.67	21.67	20.93	20.37	20.10	19.94	19.89	19.86	19.84	19.83	19.82	19.80	19.79	19.78	19.78	19.77
.86	23.26	21.33	20.62	20.07	19.81	19.66	19.60	19.57	19.56	19.54	19.53	19.51	19.51	19.51	19.50	19.50
.87	22.84	21.00	20.31	19.78	19.52	19.38	19.32	19.30	19.28	19.27	19.26	19.25	19.24	19.24	19.23	19.22
.88	22.42	20.67	20.00	19.48	19.23	19.10	19.04	19.03	19.00	18.99	18.98	18.96	18.96	18.96	18.93	18.93
.89	21.99	20.33	19.69	19.19	18.95	18.82	18.77	18.74	18.73	18.72	18.71	18.70	18.69	18.68	18.64	18.64
.90	21.53	20.00	19.36	18.90	18.67	18.54	18.50	18.47	18.46	18.45	18.44	18.43	18.42	18.42	18.41	18.41
.91	21.11	19.67	19.07	18.61	18.39	18.27	18.22	18.20	18.19	18.18	18.17	18.17	18.16	18.15	18.15	18.15
.92	20.66	19.33	18.77	18.33	18.11	18.00	17.96	17.94	17.92	17.92	17.91	17.90	17.89	17.89	17.88	17.88
.93	20.20	19.00	18.46	18.04	17.84	17.73	17.69	17.67	17.66	17.65	17.65	17.64	17.63	17.63	17.62	17.62
.94	19.74	18.67	18.16	17.76	17.57	17.46	17.43	17.41	17.40	17.39	17.39	17.38	17.37	17.37	17.36	17.36
.95	19.25	18.33	17.86	17.48	17.29	17.20	17.17	17.15	17.14	17.13	17.13	17.12	17.11	17.11	17.11	17.11
.96	18.76	18.00	17.54	17.20	17.03	16.94	16.91	16.89	16.88	16.88	16.87	16.87	16.86	16.86	16.86	16.85
.97	18.25	17.67	17.23	16.92	16.76	16.68	16.65	16.63	16.63	16.62	16.62	16.62	16.61	16.61	16.60	16.60
.98	17.74	17.33	16.94	16.63	16.49	16.42	16.39	16.38	16.37	16.37	16.36	16.36	16.36	16.36	16.36	16.36
.99	17.21	17.00	16.64	16.37	16.22	16.16	16.14	16.13	16.13	16.12	16.12	16.12	16.12	16.11	16.11	16.11
1.00	16.67	16.67	16.34	16.10	15.97	15.91	15.89	15.88	15.86	15.87	15.87	15.87	15.87	15.87	15.87	15.87
1.01	16.11	16.33	16.07	15.83	15.72	15.66	15.64	15.63	15.63	15.63	15.63	15.63	15.63	15.63	15.63	15.63
1.02	15.53	16.00	15.78	15.56	15.46	15.41	15.40	15.39	15.39	15.39	15.39	15.39	15.39	15.39	15.39	15.39
1.03	14.93	15.67	15.48	15.30	15.21	15.17	15.15	15.15	15.15	15.15	15.15	15.15	15.15	15.15	15.15	15.15
1.04	14.31	15.33	15.19	15.03	14.96	14.92	14.91	14.91	14.91	14.91	14.91	14.91	14.91	14.91	14.91	14.91
1.05	13.66	15.00	14.91	14.77	14.71	14.68	14.67	14.67	14.67	14.67	14.68	14.68	14.68	14.68	14.68	14.68
1.06	12.98	14.67	14.62	14.51	14.46	14.44	14.44	14.44	14.44	14.44	14.44	14.44	14.45	14.45	14.45	14.45
1.07	12.27	14.33	14.33	14.26	14.22	14.20	14.20	14.21	14.21	14.21	14.22	14.22	14.22	14.22	14.22	14.23
1.08	11.51	14.00	14.08	14.00	13.97	13.97	13.97	13.98	13.98	13.98	13.98	13.98	13.99	14.00	14.00	14.01
1.09	10.71	13.67	13.76	13.73	13.73	13.74	13.74	13.75	13.75	13.76	13.76	13.77	13.77	13.77	13.78	13.78

TABLE XI -Continued

Table for Estimating the Lot Percent Defective Using Standard Deviation Method

Q_U	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
1.10	9.84	13.33	13.46	13.49	13.50	13.51	13.52	13.52	13.53	13.54	13.54	13.54	13.55	13.55	13.56	13.56
1.11	8.89	13.00	13.20	13.25	13.26	13.28	13.29	13.30	13.31	13.31	13.32	13.33	13.33	13.34	13.34	13.34
1.12	7.82	12.67	12.93	13.00	13.03	13.05	13.07	13.08	13.09	13.10	13.10	13.11	13.12	13.12	13.13	13.13
1.13	6.60	12.33	12.63	12.73	12.80	12.83	12.85	12.86	12.87	12.88	12.89	12.89	12.90	12.91	12.91	12.92
1.14	5.08	12.00	12.27	12.31	12.37	12.41	12.43	12.45	12.46	12.47	12.47	12.48	12.49	12.70	12.70	12.70
1.15	0.39	11.67	12.10	12.27	12.34	12.39	12.42	12.44	12.45	12.46	12.46	12.47	12.48	12.49	12.49	12.50
1.16	0.00	11.33	11.83	12.03	12.12	12.18	12.21	12.23	12.24	12.25	12.25	12.26	12.28	12.28	12.29	12.29
1.17	0.00	11.00	11.54	11.79	11.90	11.96	12.00	12.02	12.03	12.04	12.05	12.06	12.07	12.08	12.08	12.09
1.18	0.00	10.67	11.29	11.54	11.68	11.75	11.79	11.81	11.83	11.84	11.84	11.85	11.87	11.88	11.88	11.89
1.19	0.00	10.33	11.03	11.33	11.46	11.54	11.58	11.61	11.62	11.63	11.64	11.65	11.67	11.68	11.69	11.69
1.20	0.00	10.00	10.76	11.10	11.24	11.34	11.38	11.41	11.42	11.43	11.44	11.46	11.47	11.48	11.49	11.49
1.21	0.00	9.67	10.50	10.87	11.03	11.13	11.18	11.21	11.22	11.24	11.25	11.26	11.28	11.29	11.30	11.30
1.22	0.00	9.33	10.23	10.63	10.82	10.93	10.98	11.01	11.03	11.04	11.05	11.07	11.09	11.09	11.10	11.11
1.23	0.00	9.00	9.97	10.40	10.61	10.73	10.78	10.81	10.84	10.85	10.86	10.88	10.90	10.91	10.91	10.92
1.24	0.00	8.67	9.72	10.20	10.41	10.53	10.59	10.62	10.64	10.66	10.67	10.69	10.71	10.72	10.73	10.73
1.25	0.00	8.33	9.46	9.99	10.21	10.34	10.40	10.43	10.46	10.48	10.48	10.50	10.53	10.53	10.54	10.55
1.26	0.00	8.00	9.21	9.77	10.00	10.13	10.21	10.25	10.27	10.29	10.30	10.32	10.34	10.35	10.36	10.37
1.27	0.00	7.67	8.96	9.55	9.81	9.96	10.02	10.06	10.09	10.10	10.12	10.13	10.16	10.17	10.18	10.19
1.28	0.00	7.33	8.71	9.34	9.61	9.77	9.84	9.88	9.90	9.92	9.94	9.96	9.99	10.00	10.01	
1.29	0.00	7.00	8.46	9.13	9.42	9.58	9.65	9.70	9.72	9.74	9.76	9.78	9.80	9.82	9.83	9.83
1.30	0.00	6.67	8.21	8.93	9.22	9.40	9.48	9.52	9.55	9.57	9.58	9.60	9.63	9.64	9.65	9.66
1.31	0.00	6.33	7.97	8.72	9.03	9.22	9.30	9.34	9.37	9.39	9.41	9.43	9.46	9.47	9.48	9.49
1.32	0.00	6.00	7.72	8.52	8.83	9.04	9.12	9.17	9.20	9.22	9.24	9.26	9.29	9.30	9.31	9.32
1.33	0.00	5.67	7.49	8.32	8.66	8.86	8.93	9.00	9.03	9.06	9.07	9.09	9.12	9.13	9.13	9.15
1.34	0.00	5.33	7.25	8.12	8.48	8.69	8.78	8.83	8.86	8.88	8.90	8.92	8.95	8.97	8.98	8.99
1.35	0.00	5.00	7.02	7.93	8.30	8.52	8.61	8.66	8.69	8.72	8.74	8.76	8.79	8.81	8.82	8.83
1.36	0.00	4.67	6.79	7.73	8.12	8.35	8.44	8.50	8.53	8.55	8.57	8.60	8.63	8.65	8.66	8.67
1.37	0.00	4.33	6.56	7.54	7.95	8.18	8.28	8.33	8.37	8.39	8.41	8.44	8.47	8.49	8.50	8.51
1.38	0.00	4.00	6.33	7.35	7.77	8.01	8.12	8.17	8.21	8.24	8.25	8.28	8.31	8.33	8.35	8.35
1.39	0.00	3.67	6.10	7.17	7.60	7.85	7.96	8.01	8.06	8.08	8.10	8.12	8.16	8.18	8.19	8.20
1.40	0.00	3.33	5.88	6.98	7.44	7.68	7.80	7.86	7.90	7.92	7.94	7.97	8.01	8.02	8.04	8.05
1.41	0.00	3.00	5.66	6.80	7.27	7.52	7.64	7.70	7.74	7.77	7.79	7.82	7.86	7.87	7.89	7.90
1.42	0.00	2.67	5.44	6.62	7.10	7.37	7.49	7.55	7.59	7.62	7.64	7.67	7.71	7.73	7.74	7.75
1.43	0.00	2.33	5.23	6.45	6.94	7.22	7.34	7.40	7.44	7.47	7.50	7.53	7.56	7.58	7.60	7.61
1.44	0.00	2.00	5.01	6.27	6.78	7.07	7.19	7.26	7.30	7.33	7.35	7.38	7.42	7.44	7.46	7.47
1.45	0.00	1.67	4.81	6.10	6.63	6.92	7.06	7.13	7.17	7.19	7.21	7.24	7.28	7.30	7.31	7.33
1.46	0.00	1.33	4.60	5.93	6.47	6.77	6.90	6.97	7.01	7.04	7.07	7.10	7.14	7.16	7.18	7.19
1.47	0.00	1.00	4.39	5.77	6.32	6.63	6.79	6.83	6.87	6.90	6.93	6.96	7.00	7.02	7.04	7.05
1.48	0.00	.67	4.19	5.60	6.17	6.48	6.63	6.69	6.73	6.77	6.79	6.83	6.86	6.88	6.90	6.91
1.49	0.00	.33	3.99	5.44	6.02	6.34	6.48	6.55	6.60	6.63	6.65	6.69	6.73	6.75	6.77	6.78

Q_U	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
1.50	0.00	0.00	3.20	3.28	3.87	4.20	4.34	4.41	4.46	4.50	4.53	4.58	4.60	4.62	4.64	4.65
1.51	0.00	0.00	3.01	3.13	3.73	4.06	4.20	4.28	4.33	4.36	4.39	4.42	4.47	4.49	4.51	4.52
1.52	0.00	0.00	2.82	2.97	3.59	3.93	4.07	4.15	4.20	4.23	4.26	4.29	4.34	4.36	4.38	4.39
1.53	0.00	0.00	2.63	2.82	3.45	3.80	3.94	4.02	4.07	4.11	4.13	4.17	4.21	4.24	4.26	4.27
1.54	0.00	0.00	2.45	2.67	3.31	3.67	3.81	3.89	3.95	3.98	4.01	4.04	4.09	4.11	4.13	4.15
1.55	0.00	0.00	2.27	2.52	3.18	3.54	3.69	3.77	3.82	3.86	3.89	3.93	3.97	3.99	4.01	4.02
1.56	0.00	0.00	2.09	2.38	3.05	3.41	3.56	3.65	3.70	3.74	3.78	3.82	3.87	3.89	3.90	
1.57	0.00	0.00	1.92	2.24	2.92	3.29	3.44	3.53	3.58	3.62	3.66	3.72	3.77	3.79	3.79	
1.58	0.00	0.00	1.75	2.10	2.79	3.18	3.32	3.41	3.46	3.50	3.53	3.59	3.66	3.68	3.69	3.69
1.59	0.00	0.00	1.59	1.96	2.66	3.06	3.20	3.29	3.34	3.38	3.41	3.47	3.55	3.57	3.58	3.58
1.60	0.00	0.00	1.43	1.83	2.54	2.92	3.09	3.17	3.23	3.27	3.30	3.33	3.44	3.47	3.48	
1.61	0.00	0.00	1.27	1.69	2.41	2.81	2.97	3.06	3.12	3.16	3.18	3.22	3.33	3.36	3.37	
1.62	0.00	0.00	1.12	1.57	2.29	2.69	2.86	2.95	3.01	3.04	3.07	3.11	3.22	3.25	3.26	
1.63	0.00	0.00	0.97	1.44	2.18	2.58	2.75	2.84	2.90	2.93	2.96	3.00	3.12	3.15	3.16	
1.64	0.00	0.00	1.43	3.31	4.06	4.47	4.64	4.73	4.79	4.83	4.86	4.90	4.99	5.01		
1.65	0.00	0.00	1.38	3.19	3.99	4.36	4.53	4.62	4.68	4.72	4.75	4.79	4.88	4.90		
1.66	0.00	0.00	1.13	3.07	3.84	4.25	4.43	4.52	4.58	4.62	4.65	4.69	4.78	4.80		
1.67	0.00	0.00	1.02	2.95	3.73	4.15	4.32	4.42	4.48	4.52	4.55	4.59	4.68	4.70		
1.68	0.00	0.00	0.89	2.84	3.63	4.05	4.22	4.32	4.38	4.42	4.45	4.49	4.58	4.60		
1.69	0.00	0.00	0.77	2.72	3.52	3.94	4.12	4.22	4.28	4.32	4.35	4.39	4.48	4.50		
1.70	0.00	0.00	0.66	2.62	3.41	3.84	4.02	4.12	4.18	4.22	4.25	4.30	4.38	4.41		
1.71	0.00	0.00	0.55	2.51	3.31	3.75	3.93	4.02	4.09	4.13	4.16	4.20	4.28	4.31		
1.72	0.00	0.00	0.45	2.41	3.21	3.65	3.83	3.93	3.99	4.04	4.07	4.11	4.19	4.22		
1.73	0.00	0.00	0.36	2.30	3.11	3.56	3.74	3.84	3.90	3.94	3.98	4.02	4.09	4.13		
1.74	0.00	0.00	0.27	2.20	3.02	3.46	3.65	3.75	3.81	3.85	3.89	3.93	3.99	4.04		
1.75	0.00	0.00	0.19	2.11	2.93	3.37	3.56	3.66	3.73	3.77	3.80	3.84	3.90	3.95		
1.76	0.00	0.00	0.13	2.01	2.83	3.28	3.47	3.57	3.63	3.68	3.71	3.76	3.81	3.86		
1.77	0.00	0.00	0.06	1.92	2.74	3.20	3.38	3.48	3.55	3.59	3.63	3.67	3.73	3.76		
1.78	0.00	0.00	0.02	1.83	2.66	3.11	3.30	3.40	3.47	3.51	3.54	3.59	3.64	3.67		
1.79	0.00	0.00	0.00	1.74	2.57	3.03	3.21	3.32	3.38	3.43	3.46	3.51	3.56	3.59		
1.80	0.00	0.00	0.00	1.65	2.49	2.94	3.13	3.24	3.30	3.35	3.38	3.43	3.48	3.51		
1.81	0.00	0.00	0.00	1.57	2.40	2.86	3.05	3.16	3.22	3.27	3.30	3.35	3.40	3.43		
1.82	0.00	0.00	0.00	1.49	2.32	2.79	2.98	3.08	3.15	3.19	3.22	3.27	3.33	3.36		
1.83	0.00	0.00	0.00	1.41	2.25	2.71	2.90	3.00	3.07	3.11	3.15	3.19	3.25	3.28		
1.84	0.00	0.00	0.00	1.34	2.17	2.63	2.82	2.93	2.99	3.04	3.07	3.13	3.18	3.21		
1.85	0.00	0.00	0.00	1.26	2.09	2.56	2.75	2.85	2.92	2.97	3.00	3.06	3.11	3.14		
1.86	0.00	0.00	0.00	1.19	2.02	2.48	2.68	2.78	2.85	2.89	2.93	2.97	3.03	3.06		
1.87	0.00	0.00	0.00	1.12	1.95	2.41	2.61	2.71	2.78	2.82	2.86	2.90	2.96	2.99		
1.88	0.00	0.00	0.00	1.06	1.88	2.34	2.54	2.64	2.71	2.75	2.79	2.83	2.89	2.92		
1.89	0.00	0.00	0.00	0.99	1.81	2.28	2.47	2.57	2.64	2.68	2.72	2.77	2.83	2.86		

TABLE XI —Continued

Table for Estimating the Lot Percent Defective Using Standard Deviation Method

Qμ	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
1.90	0.00	0.00	0.00	0.93	1.73	2.21	2.40	2.51	2.57	2.62	2.65	2.70	2.76	2.79	2.82	2.83
1.91	0.00	0.00	0.00	0.87	1.66	2.14	2.34	2.44	2.51	2.56	2.59	2.63	2.69	2.72	2.75	2.77
1.92	0.00	0.00	0.00	0.81	1.62	2.08	2.27	2.38	2.45	2.49	2.52	2.57	2.63	2.66	2.69	2.70
1.93	0.00	0.00	0.00	0.76	1.56	2.02	2.21	2.32	2.38	2.43	2.46	2.51	2.57	2.60	2.62	2.64
1.94	0.00	0.00	0.00	0.70	1.50	1.96	2.15	2.25	2.32	2.37	2.40	2.45	2.51	2.54	2.56	2.58
1.95	0.00	0.00	0.00	0.65	1.44	1.90	2.09	2.19	2.26	2.31	2.34	2.39	2.45	2.48	2.50	2.52
1.96	0.00	0.00	0.00	0.60	1.38	1.84	2.03	2.14	2.20	2.25	2.28	2.33	2.39	2.42	2.44	2.46
1.97	0.00	0.00	0.00	0.56	1.33	1.78	1.97	2.08	2.14	2.19	2.22	2.27	2.33	2.36	2.39	2.40
1.98	0.00	0.00	0.00	0.51	1.27	1.73	1.92	2.02	2.09	2.13	2.17	2.21	2.27	2.30	2.33	2.34
1.99	0.00	0.00	0.00	0.47	1.22	1.67	1.86	1.97	2.03	2.08	2.11	2.16	2.22	2.25	2.27	2.29
2.00	0.00	0.00	0.00	0.43	1.17	1.62	1.81	1.91	1.98	2.03	2.06	2.10	2.16	2.19	2.22	2.23
2.01	0.00	0.00	0.00	0.39	1.12	1.57	1.76	1.86	1.93	1.97	2.01	2.05	2.11	2.14	2.17	2.18
2.02	0.00	0.00	0.00	0.36	1.07	1.52	1.71	1.81	1.87	1.92	1.95	2.00	2.06	2.09	2.11	2.13
2.03	0.00	0.00	0.00	0.32	1.03	1.47	1.66	1.76	1.82	1.87	1.90	1.95	2.01	2.04	2.06	2.08
2.04	0.00	0.00	0.00	0.29	0.98	1.42	1.61	1.71	1.77	1.82	1.85	1.90	1.96	1.99	2.01	2.03
2.05	0.00	0.00	0.00	0.26	0.94	1.37	1.56	1.66	1.73	1.77	1.80	1.85	1.91	1.94	1.96	1.98
2.06	0.00	0.00	0.00	0.23	0.90	1.33	1.51	1.61	1.68	1.72	1.76	1.80	1.86	1.89	1.92	1.93
2.07	0.00	0.00	0.00	0.21	0.86	1.28	1.47	1.57	1.63	1.68	1.71	1.76	1.81	1.84	1.87	1.88
2.08	0.00	0.00	0.00	0.18	0.82	1.24	1.42	1.52	1.59	1.63	1.66	1.71	1.77	1.79	1.82	1.84
2.09	0.00	0.00	0.00	0.16	0.78	1.20	1.38	1.48	1.54	1.59	1.62	1.66	1.72	1.75	1.78	1.79
2.10	0.00	0.00	0.00	0.14	0.75	1.16	1.34	1.44	1.50	1.54	1.58	1.62	1.68	1.71	1.73	1.75
2.11	0.00	0.00	0.00	0.12	0.71	1.12	1.30	1.39	1.46	1.50	1.53	1.58	1.63	1.66	1.69	1.70
2.12	0.00	0.00	0.00	0.10	0.67	1.08	1.26	1.35	1.42	1.46	1.49	1.54	1.59	1.62	1.63	1.66
2.13	0.00	0.00	0.00	0.08	0.64	1.04	1.22	1.31	1.38	1.42	1.45	1.50	1.55	1.58	1.61	1.62
2.14	0.00	0.00	0.00	0.07	0.61	1.00	1.18	1.28	1.34	1.38	1.41	1.46	1.51	1.54	1.57	1.58
2.15	0.00	0.00	0.00	0.06	0.58	0.97	1.14	1.24	1.30	1.34	1.37	1.42	1.47	1.50	1.53	1.54
2.16	0.00	0.00	0.00	0.05	0.55	0.93	1.10	1.20	1.26	1.30	1.34	1.38	1.43	1.46	1.49	1.50
2.17	0.00	0.00	0.00	0.04	0.52	0.90	1.07	1.16	1.22	1.27	1.30	1.34	1.40	1.42	1.45	1.46
2.18	0.00	0.00	0.00	0.03	0.49	0.87	1.03	1.13	1.19	1.23	1.26	1.30	1.36	1.39	1.41	1.42
2.19	0.00	0.00	0.00	0.02	0.46	0.83	1.00	1.09	1.15	1.20	1.23	1.27	1.32	1.35	1.38	1.38
2.20	0.000	0.000	0.000	0.013	0.437	0.803	0.968	1.061	1.120	1.161	1.192	1.233	1.287	1.314	1.340	1.352
2.21	0.000	0.000	0.000	0.010	0.413	0.772	0.936	1.028	1.087	1.128	1.158	1.199	1.253	1.279	1.305	1.316
2.22	0.000	0.000	0.000	0.006	0.389	0.743	0.903	0.996	1.054	1.095	1.125	1.166	1.219	1.245	1.271	1.283
2.23	0.000	0.000	0.000	0.003	0.366	0.715	0.873	0.965	1.023	1.063	1.093	1.134	1.186	1.212	1.238	1.250
2.24	0.000	0.000	0.000	0.002	0.343	0.687	0.843	0.935	0.992	1.032	1.061	1.102	1.154	1.180	1.205	1.218
2.25	0.000	0.000	0.000	0.001	0.324	0.660	0.816	0.903	0.962	1.002	1.031	1.071	1.123	1.148	1.173	1.186
2.26	0.000	0.000	0.000	0.000	0.304	0.634	0.789	0.876	0.933	0.972	1.001	1.041	1.092	1.117	1.142	1.155
2.27	0.000	0.000	0.000	0.000	0.285	0.609	0.762	0.848	0.904	0.943	0.972	1.011	1.062	1.087	1.112	1.124
2.28	0.000	0.000	0.000	0.000	0.267	0.585	0.735	0.821	0.876	0.915	0.943	0.982	1.033	1.058	1.082	1.094
2.29	0.000	0.000	0.000	0.000	0.253	0.561	0.710	0.794	0.849	0.887	0.915	0.954	1.004	1.029	1.053	1.065

Qμ	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
2.30	0.000	0.000	0.000	0.000	0.233	0.538	0.685	0.769	0.823	0.861	0.888	0.927	0.977	1.001	1.025	1.037
2.31	0.000	0.000	0.000	0.000	0.218	0.516	0.661	0.743	0.797	0.834	0.862	0.900	0.949	0.974	0.997	1.009
2.32	0.000	0.000	0.000	0.000	0.203	0.495	0.637	0.719	0.772	0.809	0.836	0.874	0.923	0.947	0.971	0.982
2.33	0.000	0.000	0.000	0.000	0.189	0.476	0.614	0.693	0.746	0.784	0.811	0.848	0.897	0.921	0.944	0.956
2.34	0.000	0.000	0.000	0.000	0.175	0.456	0.592	0.672	0.724	0.760	0.787	0.824	0.872	0.895	0.918	0.930
2.35	0.000	0.000	0.000	0.000	0.163	0.438	0.571	0.650	0.701	0.736	0.763	0.799	0.847	0.870	0.893	0.903
2.36	0.000	0.000	0.000	0.000	0.151	0.416	0.550	0.628	0.678	0.714	0.740	0.776	0.823	0.846	0.869	0.880
2.37	0.000	0.000	0.000	0.000	0.139	0.398	0.530	0.606	0.656	0.691	0.717	0.753	0.799	0.822	0.845	0.856
2.38	0.000	0.000	0.000	0.000	0.128	0.381	0.510	0.586	0.635	0.670	0.695	0.730	0.777	0.799	0.822	0.833
2.39	0.000	0.000	0.000	0.000	0.118	0.364	0.491	0.566	0.614	0.648	0.674	0.709	0.754	0.777	0.799	0.810
2.40	0.000	0.000	0.000	0.000	0.109	0.348	0.473	0.546	0.594	0.628	0.653	0.687	0.732	0.755	0.777	0.787
2.41	0.000	0.000	0.000	0.000	0.100	0.332	0.455	0.527	0.575	0.608	0.633	0.667	0.711	0.733	0.755	0.766
2.42	0.000	0.000	0.000	0.000	0.091	0.317	0.437	0.509	0.555	0.588	0.613	0.646	0.691	0.712	0.734	0.744
2.43	0.000	0.000	0.000	0.000	0.083	0.302	0.421	0.491	0.537	0.569	0.593	0.627	0.670	0.692	0.713	0.724
2.44	0.000	0.000	0.000	0.000	0.076	0.288	0.404	0.474	0.519	0.551	0.575	0.608	0.651	0.672	0.693	0.703
2.45	0.000	0.000	0.000	0.000	0.069	0.275	0.389	0.457	0.501	0.533	0.556	0.589	0.632	0.653	0.673	0.684
2.46	0.000	0.000	0.000	0.000	0.063	0.262	0.373	0.440	0.484	0.516	0.539	0.571	0.613	0.634	0.654	0.664
2.47	0.000	0.000	0.000	0.000	0.057	0.249	0.359	0.423	0.468	0.499	0.521	0.553	0.595	0.615	0.635	0.646
2.48	0.000	0.000	0.000	0.000	0.051	0.237	0.344	0.409	0.452	0.482	0.505	0.536	0.577	0.597	0.617	0.627
2.49	0.000	0.000	0.000	0.000	0.046	0.226	0.331	0.394	0.436	0.466	0.488	0.519	0.560	0.580	0.600	0.609
2.50	0.000	0.000	0.000	0.000	0.041	0.214	0.317	0.380	0.421	0.451	0.473	0.503	0.543	0.563	0.582	0.592
2.51	0.000	0.000	0.000	0.000	0.037	0.204	0.304	0.366	0.407	0.436	0.457	0.487	0.527	0.546	0.565	0.575
2.52	0.000	0.000	0.000	0.000	0.033	0.193	0.292	0.352	0.393	0.421	0.442	0.472	0.511	0.530	0.549	0.558
2.53	0.000	0.000	0.000	0.000	0.029	0.184	0.280	0.339	0.379	0.407	0.428	0.457	0.495	0.514	0.533	0.542
2.54	0.000	0.000	0.000	0.000	0.026	0.174	0.268	0.326	0.365	0.393	0.413	0.442	0.480	0.499	0.517	0.527
2.55	0.000	0.000	0.000	0.000	0.023	0.165	0.257	0.314	0.352	0.379	0.400	0.428	0.465	0.484	0.502	0.511
2.56	0.000	0.000	0.000	0.000	0.020	0.156	0.246	0.302	0.340	0.366	0.386	0.414	0.451	0.469	0.487	0.496
2.57	0.000	0.000	0.000	0.000	0.017	0.148	0.236	0.291	0.327	0.354	0.373	0.401	0.437	0.455	0.473	0.482
2.58	0.000	0.000	0.000	0.000	0.015	0.140	0.226	0.279	0.316	0.341	0.361	0.388	0.424	0.441	0.459	0.468
2.59	0.000	0.000	0.000	0.000	0.013	0.133	0.216	0.269	0.304	0.330	0.349	0.375	0.410	0.428	0.445	0.454
2.60	0.000	0.000	0.000	0.000	0.011	0.125	0.207	0.258	0.293	0.318	0.337	0.363	0.398	0.415	0.432	0.441
2.61	0.000	0.000	0.000	0.000	0.009	0.118	0.198	0.248	0.282	0.307	0.325	0.351	0.385	0.402	0.419	0.428
2.62	0.000	0.000	0.000	0.000	0.008	0.112	0.189	0.238	0.272	0.296	0.314	0.339	0.373	0.390	0.406	0.415
2.63	0.000	0.000	0.000	0.000	0.007	0.105	0.181	0.229	0.262	0.285	0.303	0.328	0.361	0.378	0.394	0.402
2.64	0.000	0.000	0.000	0.000	0.005	0.099	0.172	0.220	0.252	0.275	0.293	0.317	0.350	0.366	0.382	0.390
2.65	0.000	0.000	0.000	0.000	0.004	0.094	0.165	0.211	0.243	0.265	0.283	0.307	0.339	0.355	0.371	0.379
2.66	0.000	0.000	0.000	0.000	0.004	0.088	0.157	0.202	0.233	0.256	0.273	0.296	0.328	0.344	0.359	0.367
2.67	0.000	0.000	0.000	0.000	0.003	0.083	0.150	0.194	0.224	0.246	0.263	0.286	0.317	0.333	0.348	0.356
2.68	0.000	0.000	0.000	0.000	0.002	0.078	0.143	0.186	0.216	0.237	0.254	0.277	0.307	0.322	0.338	0.345
2.69	0.000	0.000	0.000	0.000	0.002	0.073	0.136	0.179	0.208	0.229	0.245	0.267	0.297	0.312	0.327	0.335

TABLE X –Continued

Table for Estimating the Lot Percent Defective Using Standard Deviation Method

Q_L	Sample Size															
	3	4	5	7	10	13	20	25	30	35	40	50	75	100	150	200
2.70	0.000	0.000	0.000	0.000	0.001	0.009	0.140	0.171	0.200	0.220	0.236	0.256	0.284	0.302	0.317	0.329
2.71	0.000	0.000	0.000	0.000	0.001	0.004	0.134	0.164	0.192	0.212	0.229	0.249	0.278	0.293	0.307	0.319
2.72	0.000	0.000	0.000	0.000	0.000	0.000	0.128	0.157	0.184	0.204	0.219	0.241	0.269	0.283	0.298	0.309
2.73	0.000	0.000	0.000	0.000	0.000	0.000	0.123	0.151	0.177	0.197	0.211	0.233	0.260	0.274	0.288	0.298
2.74	0.000	0.000	0.000	0.000	0.000	0.000	0.117	0.144	0.170	0.189	0.204	0.226	0.252	0.264	0.279	0.288
2.75	0.000	0.000	0.000	0.000	0.000	0.000	0.102	0.138	0.163	0.182	0.196	0.216	0.243	0.257	0.271	0.277
2.76	0.000	0.000	0.000	0.000	0.000	0.000	0.097	0.133	0.157	0.175	0.189	0.209	0.233	0.249	0.262	0.269
2.77	0.000	0.000	0.000	0.000	0.000	0.000	0.092	0.128	0.151	0.168	0.182	0.201	0.227	0.241	0.254	0.260
2.78	0.000	0.000	0.000	0.000	0.000	0.000	0.087	0.121	0.145	0.162	0.175	0.194	0.220	0.233	0.246	0.252
2.79	0.000	0.000	0.000	0.000	0.000	0.000	0.083	0.115	0.139	0.156	0.169	0.187	0.213	0.225	0.238	0.244
2.80	0.000	0.000	0.000	0.000	0.000	0.000	0.079	0.110	0.133	0.150	0.163	0.181	0.206	0.218	0.230	0.237
2.81	0.000	0.000	0.000	0.000	0.000	0.000	0.075	0.105	0.128	0.144	0.156	0.174	0.198	0.211	0.223	0.229
2.82	0.000	0.000	0.000	0.000	0.000	0.000	0.071	0.101	0.122	0.138	0.150	0.168	0.192	0.204	0.216	0.222
2.83	0.000	0.000	0.000	0.000	0.000	0.000	0.067	0.096	0.117	0.133	0.145	0.162	0.185	0.197	0.209	0.215
2.84	0.000	0.000	0.000	0.000	0.000	0.000	0.064	0.092	0.112	0.128	0.139	0.156	0.179	0.190	0.202	0.208
2.85	0.000	0.000	0.000	0.000	0.000	0.000	0.060	0.088	0.108	0.122	0.134	0.150	0.173	0.184	0.195	0.201
2.86	0.000	0.000	0.000	0.000	0.000	0.000	0.057	0.084	0.103	0.118	0.129	0.145	0.167	0.178	0.189	0.195
2.87	0.000	0.000	0.000	0.000	0.000	0.000	0.054	0.080	0.099	0.113	0.124	0.139	0.161	0.171	0.183	0.188
2.88	0.000	0.000	0.000	0.000	0.000	0.000	0.051	0.076	0.094	0.108	0.119	0.134	0.155	0.166	0.177	0.182
2.89	0.000	0.000	0.000	0.000	0.000	0.000	0.048	0.073	0.090	0.104	0.114	0.129	0.150	0.160	0.171	0.176
2.90	0.000	0.000	0.000	0.000	0.000	0.000	0.046	0.069	0.087	0.100	0.110	0.125	0.145	0.155	0.165	0.171
2.91	0.000	0.000	0.000	0.000	0.000	0.000	0.043	0.066	0.083	0.096	0.106	0.120	0.140	0.150	0.160	0.165
2.92	0.000	0.000	0.000	0.000	0.000	0.000	0.041	0.063	0.079	0.092	0.101	0.115	0.135	0.145	0.155	0.160
2.93	0.000	0.000	0.000	0.000	0.000	0.000	0.038	0.060	0.076	0.088	0.097	0.111	0.130	0.140	0.149	0.154
2.94	0.000	0.000	0.000	0.000	0.000	0.000	0.036	0.057	0.072	0.084	0.093	0.107	0.125	0.135	0.144	0.149
2.95	0.000	0.000	0.000	0.000	0.000	0.000	0.034	0.054	0.069	0.081	0.090	0.103	0.121	0.130	0.140	0.144
2.96	0.000	0.000	0.000	0.000	0.000	0.000	0.032	0.051	0.066	0.077	0.086	0.099	0.117	0.126	0.135	0.140
2.97	0.000	0.000	0.000	0.000	0.000	0.000	0.030	0.049	0.063	0.074	0.083	0.095	0.112	0.121	0.130	0.135
2.98	0.000	0.000	0.000	0.000	0.000	0.000	0.028	0.046	0.060	0.071	0.079	0.091	0.108	0.117	0.126	0.130
2.99	0.000	0.000	0.000	0.000	0.000	0.000	0.027	0.044	0.057	0.068	0.076	0.088	0.104	0.113	0.122	0.126
3.00	0.000	0.000	0.000	0.000	0.000	0.000	0.025	0.042	0.055	0.065	0.073	0.084	0.101	0.109	0.118	0.122
3.01	0.000	0.000	0.000	0.000	0.000	0.000	0.024	0.040	0.053	0.062	0.070	0.081	0.097	0.105	0.114	0.118
3.02	0.000	0.000	0.000	0.000	0.000	0.000	0.022	0.038	0.050	0.059	0.067	0.078	0.093	0.101	0.110	0.114
3.03	0.000	0.000	0.000	0.000	0.000	0.000	0.021	0.036	0.048	0.057	0.064	0.075	0.090	0.098	0.106	0.110
3.04	0.000	0.000	0.000	0.000	0.000	0.000	0.019	0.034	0.045	0.054	0.061	0.072	0.087	0.094	0.102	0.106
3.05	0.000	0.000	0.000	0.000	0.000	0.000	0.018	0.032	0.043	0.052	0.059	0.069	0.083	0.091	0.099	0.103
3.06	0.000	0.000	0.000	0.000	0.000	0.000	0.017	0.030	0.041	0.050	0.056	0.066	0.080	0.088	0.095	0.099
3.07	0.000	0.000	0.000	0.000	0.000	0.000	0.016	0.029	0.039	0.047	0.054	0.064	0.077	0.085	0.092	0.096
3.08	0.000	0.000	0.000	0.000	0.000	0.000	0.015	0.027	0.037	0.045	0.052	0.061	0.074	0.081	0.089	0.092
3.09	0.000	0.000	0.000	0.000	0.000	0.000	0.014	0.026	0.036	0.043	0.049	0.059	0.072	0.079	0.086	0.089

Q_L	Sample Size															
	3	4	5	7	10	13	20	25	30	35	40	50	75	100	150	200
3.10	0.000	0.000	0.000	0.000	0.000	0.002	0.013	0.034	0.044	0.041	0.047	0.056	0.069	0.076	0.083	0.086
3.11	0.000	0.000	0.000	0.000	0.000	0.002	0.012	0.033	0.032	0.039	0.045	0.054	0.066	0.073	0.080	0.083
3.12	0.000	0.000	0.000	0.000	0.000	0.002	0.011	0.022	0.031	0.038	0.043	0.052	0.064	0.070	0.077	0.080
3.13	0.000	0.000	0.000	0.000	0.000	0.002	0.011	0.021	0.029	0.036	0.041	0.050	0.061	0.068	0.074	0.077
3.14	0.000	0.000	0.000	0.000	0.000	0.001	0.010	0.019	0.028	0.034	0.040	0.048	0.059	0.065	0.071	0.075
3.15	0.000	0.000	0.000	0.000	0.000	0.001	0.009	0.018	0.026	0.033	0.038	0.046	0.057	0.063	0.068	0.072
3.16	0.000	0.000	0.000	0.000	0.000	0.001	0.009	0.017	0.025	0.031	0.036	0.044	0.055	0.060	0.066	0.069
3.17	0.000	0.000	0.000	0.000	0.000	0.001	0.008	0.016	0.024	0.030	0.035	0.042	0.053	0.058	0.064	0.067
3.18	0.000	0.000	0.000	0.000	0.000	0.001	0.007	0.015	0.022	0.028	0.033	0.040	0.050	0.056	0.062	0.065
3.19	0.000	0.000	0.000	0.000	0.000	0.001	0.007	0.013	0.021	0.027	0.032	0.038	0.049	0.054	0.059	0.062
3.20	0.000	0.000	0.000	0.000	0.000	0.001	0.006	0.014	0.020	0.026	0.030	0.037	0.047	0.052	0.057	0.060
3.21	0.000	0.000	0.000	0.000	0.000	0.000	0.006	0.013	0.019	0.024	0.029	0.035	0.045	0.050	0.055	0.058
3.22	0.000	0.000	0.000	0.000	0.000	0.000	0.005	0.012	0.018	0.023	0.027	0.034	0.043	0.048	0.053	0.056
3.23	0.000	0.000	0.000	0.000	0.000	0.000	0.005	0.011	0.017	0.022	0.026	0.032	0.041	0.046	0.051	0.054
3.24	0.000	0.000	0.000	0.000	0.000	0.000	0.005	0.011	0.016	0.021	0.025	0.031	0.040	0.044	0.049	0.052
3.25	0.000	0.000	0.000	0.000	0.000	0.000	0.004	0.010	0.015	0.020	0.024	0.030	0.038	0.043	0.048	0.050
3.26	0.000	0.000	0.000	0.000	0.000	0.000	0.004	0.009	0.015	0.019	0.023	0.028	0.037	0.041	0.046	0.048
3.27	0.000	0.000	0.000	0.000	0.000	0.000	0.004	0.009	0.014	0.019	0.022	0.027	0.035	0.040	0.044	0.046
3.28	0.000	0.000	0.000	0.000	0.000	0.000	0.003	0.008	0.013	0.017	0.021	0.026	0.034	0.038	0.042	0.044
3.29	0.000	0.000	0.000	0.000	0.000	0.000	0.003	0.008	0.012	0.016	0.020	0.025	0.032	0.037	0.041	0.043
3.30	0.000	0.000	0.000	0.000	0.000	0.000	0.003	0.007	0.012	0.015	0.019	0.024	0.031	0.035	0.039	0.042
3.31	0.000	0.000	0.000	0.000	0.000	0.000	0.003	0.007	0.011	0.015	0.018	0.023	0.030	0.034	0.038	0.040
3.32	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.006	0.010	0.014	0.017	0.022	0.029	0.032	0.036	0.039
3.33	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.006	0.010	0.013	0.016	0.021	0.027	0.031	0.035	0.037
3.34	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.006	0.009	0.013	0.015	0.020	0.026	0.030	0.034	0.036
3.35	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.005	0.009	0.012	0.015	0.019	0.025	0.029	0.032	0.034
3.36	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.005	0.008	0.011	0.014	0.018	0.024	0.028	0.031	0.033
3.37	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.005	0.008	0.011	0.013	0.017	0.023	0.026	0.030	0.032
3.38	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.004	0.007	0.010	0.013	0.016	0.022	0.025	0.029	0.031
3.39	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.004	0.007	0.010	0.012	0.016	0.021	0.024	0.028	0.029
3.40	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.004	0.007	0.009	0.011	0.015	0.020	0.023	0.027	0.028
3.41	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.003	0.006	0.009	0.011	0.014	0.020	0.022	0.026	0.027
3.42	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.003	0.006	0.008	0.010	0.014	0.019	0.022	0.025	0.026
3.43	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.003	0.005	0.008	0.010	0.013	0.018	0.021	0.024	0.025
3.44	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.003	0.005	0.007	0.009	0.012	0.017	0.020	0.023	0.024
3.45	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.003	0.005	0.007	0.009	0.012	0.016	0.019	0.022	0.023
3.46	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.005	0.007	0.008	0.011	0.016	0.018	0.021	0.022
3.47	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.004	0.006	0.008	0.011	0.015	0.017	0.020	0.021
3.48	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.004	0.006	0.007	0.010	0.014	0.016	0.019	0.020
3.49	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.002	0.004	0.005	0.007	0.010	0.014	0.016	0.019	0.020

TABLE X —Continued

Table for Estimating the Lot Percent Defective Using Standard Deviation Method

Q_U	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
3.30	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.007	0.009	0.013	0.015	0.016	0.019
3.31	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.006	0.009	0.013	0.013	0.017	0.016
3.32	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.006	0.008	0.013	0.014	0.017	0.016
3.33	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.000	0.004	0.006	0.008	0.012	0.014	0.016	0.017
3.34	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.000	0.004	0.000	0.008	0.011	0.013	0.015	0.016
3.35	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.000	0.004	0.000	0.007	0.011	0.012	0.015	0.016
3.36	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.004	0.005	0.007	0.010	0.013	0.014	0.015
3.37	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.005	0.006	0.010	0.011	0.013	0.014
3.38	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.004	0.006	0.009	0.011	0.013	0.014
3.39	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.000	0.003	0.004	0.006	0.009	0.010	0.012	0.013
3.40	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.004	0.006	0.008	0.010	0.012	0.013
3.41	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.004	0.005	0.008	0.010	0.011	0.012
3.42	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.003	0.005	0.008	0.009	0.011	0.012
3.43	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.005	0.007	0.009	0.010	0.011
3.44	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.007	0.008	0.010	0.011
3.45	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.007	0.008	0.010	0.010
3.46	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.004	0.006	0.008	0.009	0.010
3.47	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.003	0.004	0.006	0.007	0.009	0.010
3.48	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.002	0.004	0.006	0.007	0.008	0.009
3.49	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.002	0.003	0.005	0.007	0.008	0.009

Q_U	Sample Size															
	3	4	5	7	10	15	20	25	30	35	40	50	75	100	150	200
3.70	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.002	0.002	0.003	0.005	0.006	0.008	0.008
3.71	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.005	0.006	0.007	0.008
3.72	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.005	0.006	0.007	0.007
3.73	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.005	0.006	0.007	0.007
3.74	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.005	0.007	0.007
3.75	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.005	0.006	0.007
3.76	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.002	0.004	0.005	0.006	0.006
3.77	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.004	0.004	0.006	0.006
3.78	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.005	0.006
3.79	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.005	0.006
3.80	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.005	0.006
3.81	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.005	0.005
3.82	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.004	0.005
3.83	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.003	0.003	0.004	0.005
3.84	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.002	0.003	0.004	0.004
3.85	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.002	0.003	0.004	0.004
3.86	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.002	0.003	0.003	0.004
3.87	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.004
3.88	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.004	0.004
3.89	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.003	0.004
3.90	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.002	0.003	0.003	0.004

APPENDIX B

WINCHESTER ENGINEERING AND ANALYTICAL CENTER

PROCEDURES FOR LABORATORY COMPLIANCE TESTING OF HIGH-INTENSITY MERCURY VAPOR DISCHARGE LAMPS

JUNE 1980

FOOD AND DRUG ADMINISTRATION
WINCHESTER ENGINEERING AND ANALYTICAL CENTER

PROCEDURES FOR LABORATORY COMPLIANCE TESTING OF HIGH-INTENSITY MERCURY VAPOR DISCHARGE LAMPS

JUNE 1980

INTRODUCTION

The purpose of this document is to establish procedures for laboratory compliance testing of high-intensity mercury vapor discharge lamps that are certified by the manufacturer as in compliance with appropriate standards. High-intensity mercury vapor discharge lamps are tested for compliance with the Performance Standard for Mercury Vapor Lamps published in 21 CFR 1010 and 21 CFR 1040.30 and as amended. The procedures described in this document are applicable to any high-intensity mercury vapor discharge lamp that is designed, intended, or promoted for illumination purposes. Definitions of terms used in this document are identical to definitions published in 21 CFR Parts 1000 through 1040.

SPECIAL INSTRUCTIONS

PERFORM ALL OPERATIONS WITH EXTREME CARE. ULTRAVIOLET RADIATION, ELECTRICAL SHOCK, MERCURY VAPOR, OZONE, AND GLASS FRAGMENTS ARE ALL HAZARDS INHERENT WITH THESE TESTS.

GENERAL INSTRUCTIONS

1. Laboratory control of high-intensity mercury vapor discharge (HID) lamp samples shall be maintained as specified in the FDA Regulatory Procedures Manual, the Analyst Guidance Manual, and the Compliance Program 7394.804E "Compliance Testing of Mercury Vapor Lamps and Sunlamp Products at WEAC".

2. Upon notification of assignment of an HID lamp sample for analysis the analyst shall arrange with the Sample Custodian to transfer the sample to the testing laboratory.

3. All test data shall be recorded on Analyst Worksheets (FD-431 and FD-431a) and appropriate special data sheets.

4. The sample number shall be acquired from the "Official Seal" (form FD-415a) on the sample and verified with the "Collection Report" (form FD-464) and be clearly printed on all worksheets. If no "Official Seal" is present on the sample, consult your Supervisor.

5. Before breaking the seal and removing the HID lamp from its shipping carton, the Analyst shall initiate an Analyst Worksheet (form FD-431) in accordance with Chapter 9 of the Analyst Operations Manual.

6. Caution shall be taken in handling HID lamps.

7. Measurement of extinguishing time for HID lamps shall be carried out according to the procedures outlined in Appendix A "Testing Procedures for Measurement of the Extinguishing Time of Self-Extinguishing High-Intensity Mercury Vapor Discharge Lamps".

8. All accompanying materials shall be read and understood before any testing procedures are initiated. Consult your Supervisor if any problems are encountered with the materials.

COMPLIANCE TESTING

I. Introduction

The compliance tests delineated in this part are performed on all HID lamps collected for analysis at WEAC under Compliance Program 7394.804E.

II. Labels, Warnings, and Identifications

A. Labels

1. Identification Labeling

a. Visually examine the identification label for (a) presence, (b) permanence, (c) legibility, and (d) accessibility.

b. Record the name of the manufacturer of the lamp and the month and year of manufacture as marked on the lamp, inscribing tags, or labels, or on the lamp packaging.

c. Visually examine the outer envelope of the lamp and other parts of the lamp that will be visible after the outer envelope of the lamp is broken or removed, for either the required "T" or "R" label as required under either 1040.30(d)(2) or 1040.30(e)(1).

2. Lamp Packaging Labeling

a. Visually examine "T" labelled lamp packaing and verify that the packagings clearly and prominently display, as required under 1040.30(d)(3)(ii):

> "This lamp should self-extinguish within 15 mintues after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation."

or the same quotation with the removal of the phrase "or punctured" from the first sentence for a lamp manufactured on or before September 7, 1981.

b. Visually examine "R" labelled lamp packaging and verify that the packagings clearly and prominently display, as required under 1040.30(e)(2)(ii):

> "WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available."

or the same quotation with the removal of the phrase "or punctured" from the last sentence for a lamp manufactured on or before September 7, 1981 and/or a slight wording variation concerning commercial availability.

3. Certification Labeling

a. Visually examine the certification label, as required under 1010.2 for: (a) presence, (b) permanence, (c) legibility, and (d) accessibility.

B. Lamp Advertisement

1. Visually examine all "R" labelled lamp advertisings, if submitted with the sample, for prominently displaying the following wording, as required under 1040.30(e)(3):

> "WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available."

or the same quotation with the removal of the phrase "or punctured" from the last sentence for a lamp manufactured on or before September 7, 1981 and/or a slight wording variation concerning commercial availability.

C. Documentation

1. Photographic or other appropriate reproductive method may be used.

2. Documentation of the following is required:

a. For all HID lamps

(1) full view of the lamp

b. For "R" labelled lamps:

(1) The "R" label on the outer envelope.
(2) The "R" label on the other part of the lamp that is visible after the outer envelope of the lamp is broken or removed if the "R" label is not visible on the intact lamp.
(3) The "R" label on the lamp packaging.

(4) The "WARNING: This lamp .... available." wording on the lamp packaging.
(5) The "WARNING: This lamp .... available." wording in the lamp advertisement.

(Document items (3) through (6) only if original material is not submitted.)

c. For "T" labelled lamps:

(1) The "T" label on the outer envelope.
(2) The "T" label on the other part of the lamp that is visible after the outer envelope of the lamp is broken or removed.
(3) The "T" label on the lamp packaging if the original material is not submitted.
(4) The "This lamp .... radiation" wording on the lamp packaging if the original material is not submitted.
(5) Full view of the lamp mounted in the test stand after extinguishability testing. Particular attention shall be made to document that complete breakage or removal of the outer envelope (with the exception of fragments extending 50 millimeters or less from the base shell) was accomplished.
(6) View of the lamp component(s) employed to cause the lamp to extinguish.

3. Documentation techniques showing combinations of the above should be used whenever possible. All documentation must be properly mounted and clearly labelled.

III. Self Extinguishing Testing

A. Measurement of the Extinguishing Time of Self-Extinguishing HID Lamps

1. Only lamp samples identified by the manufacturer as certified to meet the requirements of 1040.30(d)(1) shall be tested.

2. All testing shall be conducted as described in Appendix A "Procedures for Measuring the Extinguishing Time of Self-Extinguishing High-Intensity Mercury Vapor Discharge Lamps".

3. Notify your Supervisor in the event that the outer envelope is not broken or removed as specified under 1040.30(d).

APPENDIX A

PROCEDURES FOR THE MEASUREMENT OF THE EXTINGUISHING TIME OF SELF-EXTINGUISHING HIGH-INTENSITY MERCURY VAPOR DISCHARGE LAMPS

I. INTRODUCTION

These testing procedures are for all HID lamps certified by the manufacturer to comply with 21 CFR 1040.30(d)(1).

II. GENERAL INSTRUCTIONS

1. These test procedures shall be performed only by analysts specially trained in HID lamp testing.

2. All testing shall be performed in the WEAC HID lamp testing chamber. Appendix C provides a detailed description of the testing chamber.

3. All testing shall be performed using the WEAC HID lamp testing stand. Appendix B provides a detailed description of the testing stand.

4. Any HID lamp designed to be operated only in a specific fixture or luminaire that the lamp manufacturer specifies shall be tested in that fixture or luminaire.

5. Extreme caution shall be taken in handling the HID lamps. Lamps should only be handled by their base shell. Gloves shall be worn whenever handling the glass envelope(s) of the lamps.

6. Perform all operations with extreme care due to the hazards of ultraviolet radiation, electrical shock, mercury vapor, ozone, and glass fragments inherent with these tests.

III. TESTING PROCEDURES

1. Insert the lamp in the WEAC HID lamp testing stand located inside of the WEAC HID testing chamber. The lamp is to be orientated as specified for use by the manufacturer. If the manufacturer has not specified a particular orientation the lamp shall be orientated base up or as specified by BRH.

2. The test stand shall be adjusted appropriately for the HID lamp that is being tested.

3. Close the chamber door and turn on the WARNING light.

4. Turn on the timer and set the control panel of the timer.

5. Open the compressed air tank and set the regulator to 125 psi.

6. Record the test chamber temperature. If the temperature is not in the range of 25 ± 5°C, notify your Supervisor.

7. Adjust the reference ballast to proper impedance for testing the lamp. Set the voltage for testing the lamp at the value indicated or recommended by the manufacturer for the operation of the intact lamp. Check to insure that the current is in the proper range. Record the settings and values of the reference ballast.

8. Start the lamp by switching on the ballast-to-lamp power supply switch. Record the time at which the lamp is started.

9. Operate the lamp for fifteen (15) minutes.

10. Switch on the "Lamp Breaker" switch.

11. Record the reading shown on the timer. If more than twenty (20) minutes have elapsed and the timer has not displayed a time reading, check to see if the lamp is still operating by looking through the filter window. Switch off the ballast to lamp power supply switch and record the time and the timer reading.

12. Turn off the "Lamp Breaker" switch.

13. Wait fifteen (15) minutes and repeat steps 8, 9, and 11.

14. Turn on the testing chamber exhaust switch.

15. Do not enter the testing chamber until two (2) minutes have elapsed since switching on the exhaust vent switch.

16. Verify that there are no fragments of glass extending 50 mm or more from the base shell. Photograph the broken HID lamp while it is still in the test stand. If glass fragments extending 50 mm or more are found, notify your Supervisor.

17. Verify the cause of the lamp outage.

18. Carefully remove the remaining lamp components from the testing stand.

19. Repeat steps 1-7.

20. Repeat step 10.

21. Repeat steps 14 and 16.

22. Repeat step 8.

23. Repeat step 11.

24. Verify the cause of the outage.

25. Repeat step 18.

26. Turn off the compressed air supply, the timer, and the WARNING light.

27. Dispose of all broken glass and broken HID lamps in the proper containers.

28. Return any untested lamps to the sample custodian.

APPENDIX B

WEAC HID LAMP TESTING STAND

The HID lamp breaker was fabricated by the Facility Maintenance Section of the Winchester Engineering and Analytical Center (WEAC). The lamp envelope breaker test stand provides a means to hold all lamp sizes, except the H9FJ, T-9½, 55 inch tube type. The test stand consists of a steel rod structure with laminated phenolic board end panels, as shown in Figure I. The stand measures 24 inches by 19 inches. One end of the stand has a 12 inch diameter hole in the center to allow the broken glass envelope to fall into a catch container housed in a table that the stand is positioned on, as shown in Figure II. The stand consists of three pairs of ½" steel rods, 24 inches long. Each pair of rods is used as rails on which an adjustable metal bracket rides. The bracket, as shown in Figures IIIa, b, c, measures 4 by 5 inches. Two slots allow the air cylinder, which is mounted on the bracket, to be positioned so that the air cylinders rod penetrates the lamp's outer envelope by 3/16". The bracket further adjusts so that the angle that the penetrating cylinder rod strikes the lamp's envelope can be preset to the lamp envelope's surface . This adjustment allows for configurations which minimize deflections that would result in failure of the cylinder rods to successfully rupture the evenlope.

Three steel rods are located in between the rod pairs. These three rods are used to hold steel stops that keep large lamps from being pushed aside rather than penetrated by the cylinder rods.

The three air cylinders are operated by a compressed air supply. The compressed air supply supplies air at 125 psi. The air is held by a solenoid valve. When the switch is closed the solenoid opens allowing the compressed air to flow through a manifold which supplies the air to each of the three cylinders simultaneously. The air pressure delivery system is shown in Figure IV. Each of the cylinders respond by projecting its rod the full 1" throw. The air pressure in the cylinders is then relieved when the first solenoid closes and a second solenoid opens. The loss of air pressure causes the cylinder rods to retract by means of internal springs. Thus, instantaneous breakage of the outer envelope is achieved. The closing of the switch that opens the first solenoid also starts the electronic timer. A znp-100 photodiode is located in back of the observation window. When the lamp extinguishes, the photodiode circuit closes, allowing 5 volts to be supplied to the timer. This signal terminates the timer and the interval for which the lamp was operating after the outer envelope was removed is displayed.

Figure V shows the universal lamp socket that allows for the lamp to be removed from the test stand after breakage. By loosening the socket's clamp the lamp base is freed from the socket. Thus, the problem of unscrewing a lamp that has had its outer envelope removed is eliminated. Two such sockets have been fabricated. One for medium and admedium bases and a second for mogal bases. The test stand itself can be positioned on the test stand table such that lamps can be operated in either base up, base down, or horizontal, as shown in Figures VI and VII.

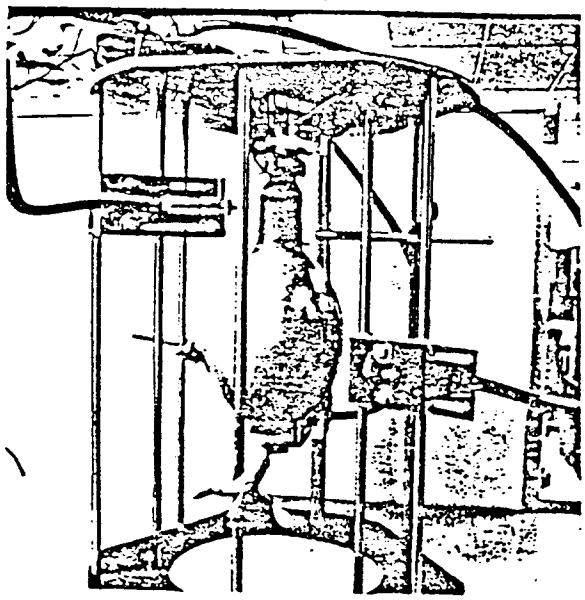

Figure I

HID lamp breaker

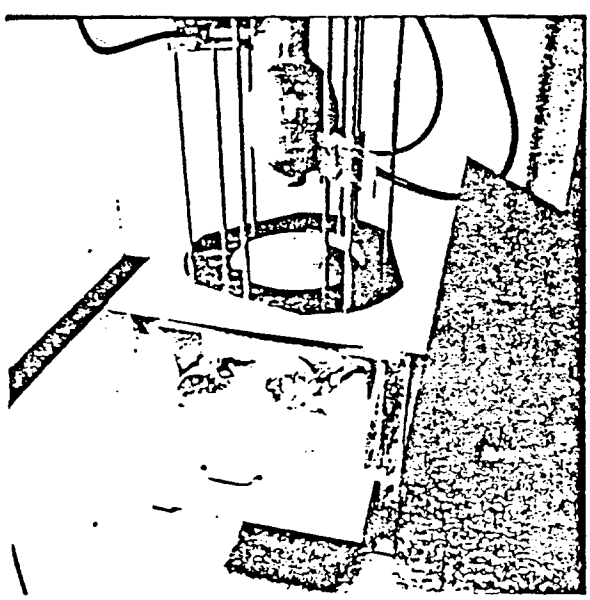

Figure II

Catch container

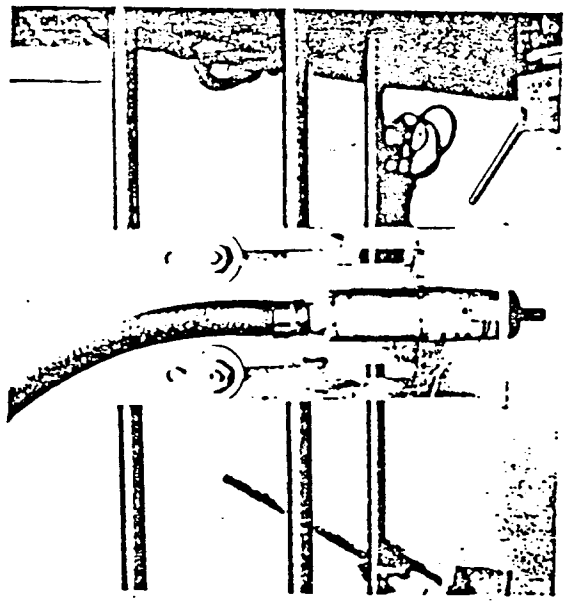

Figure IIIa

Air cylinder bracket

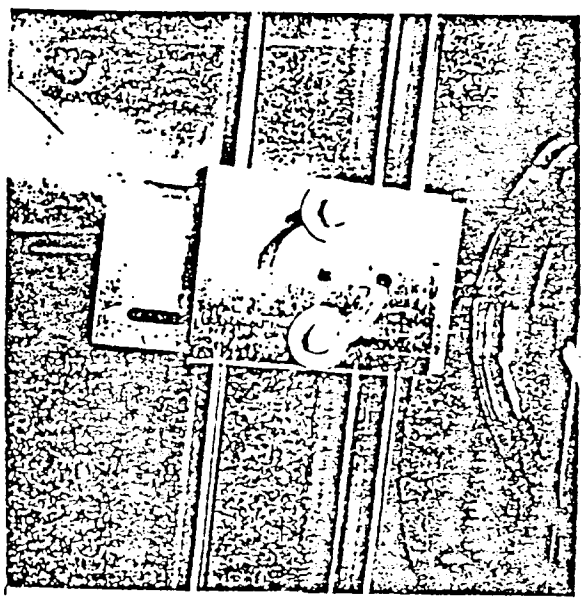

Figure IIIb

Adjustment slots

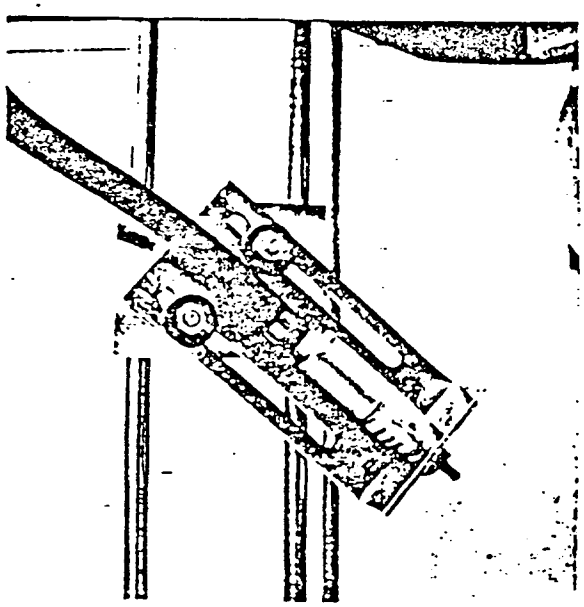

Figure IIIc

Adjusted air cylinder

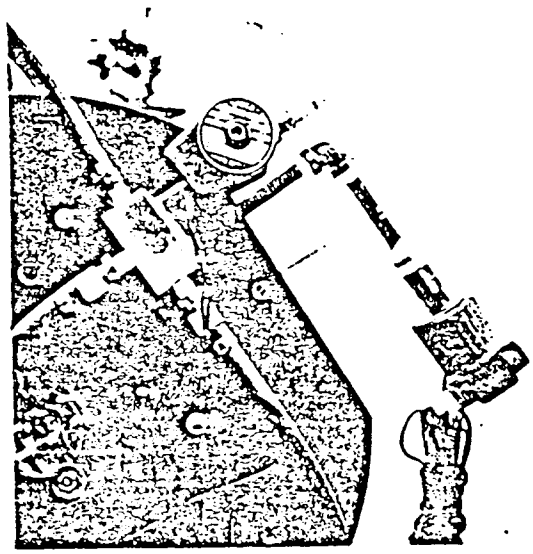

Figure IV

Air Pressure Delivery System

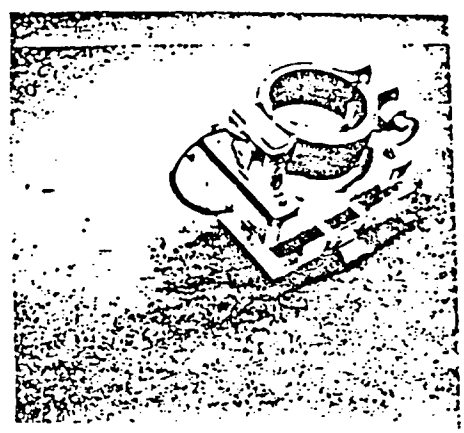

Figure V

Universal Lamp Sockets

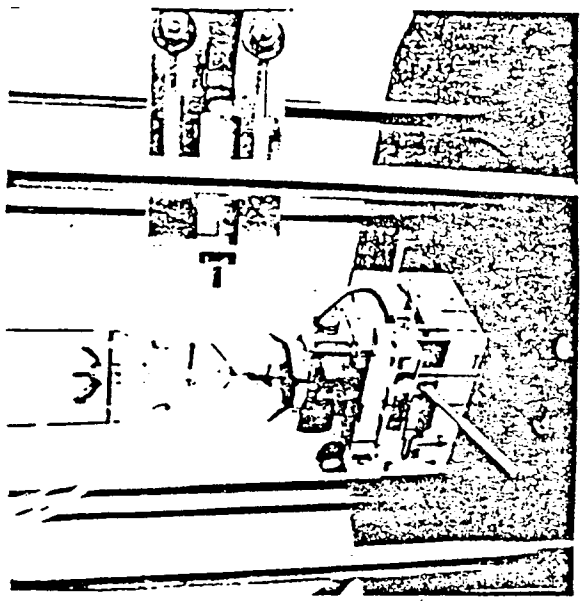

Figure VI

Horizontal Breaker position

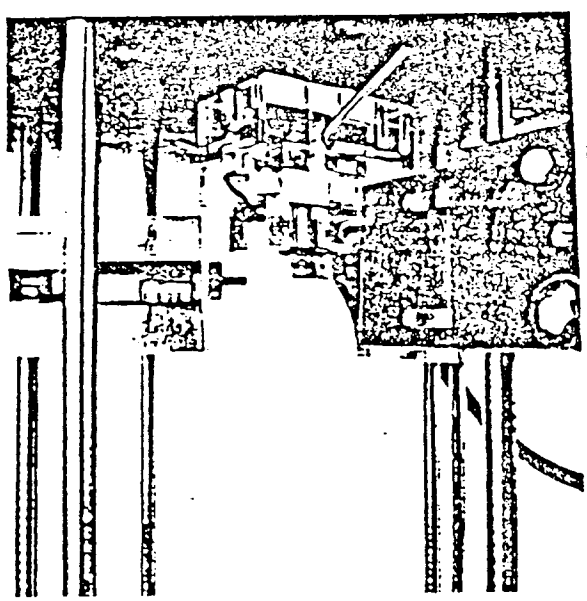

Figure VII

Vertical (Base up) position

APPENDIX C

WEAC HID LAMP TESTING CHAMBER

The WEAC HID testing chamber (Figure I) is 5 feet square and 7 feet high. The back wall is cement block and one side wall is 5/8" plasterboard. The ceiling and remaining walls are 1/4" plywood. The two plywood walls are adjacent to each other. A hollow core paneled door 3 feet wide by 6½ feet high is located in one of the plywood walls. A 12 inch square window is located in the other plywood wall. The window opening has a 12 inch square piece of UF-3 ultraviolet absorbing plastic permanently mounted on the interior side of the wall (Figure II). On the outside of the wall there are two sliding frames in a track so that either or neither frame can be positioned in front of the plastic window. One frame holds a 12 inch square piece of welders filter shade #12 glass and the other holds a 12 inch square piece welders filter shade #8 glass (Figure III). AC power, 120 volts, is supplied into the chamber, two of the outlets can be switched from outside the chamber. A squirrel cage fan is mounted on the laboratory building roof and is ducted into the ceiling of the testing chamber. When a lamp is being tested a WARNING light is switched on outside the testing chamber entrance door.

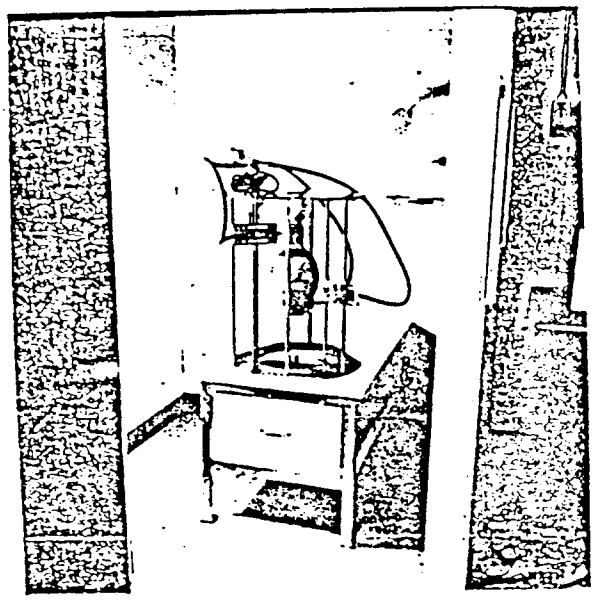

Figure I

HID Testing Chamber

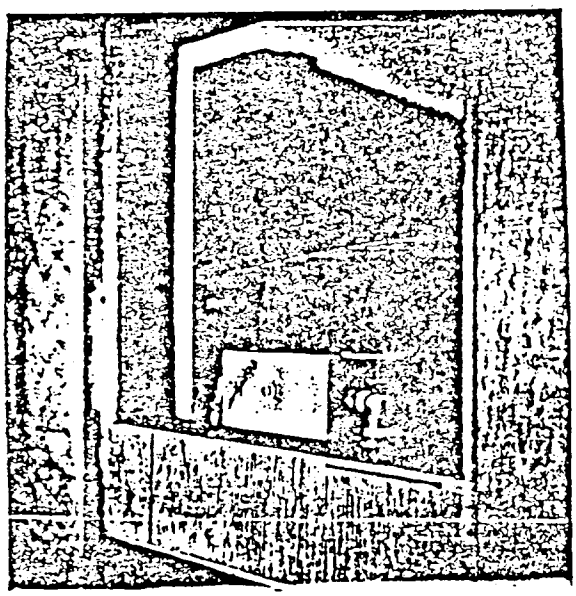

Figure II

UF-3 UV absorbing plastic

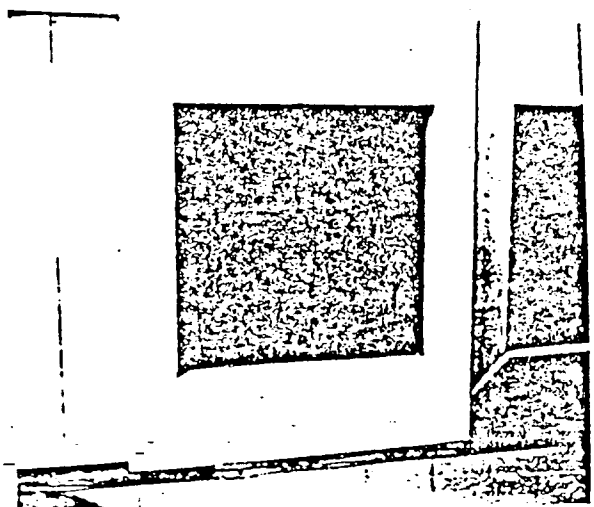

Figure III

Welder's filter