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United States Coast Guard

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United States Coast Guard

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NAVIGATION AND VESSEL INSPECTION CIRCULAR NO. 02-06

Subj: FOLLOW-UP PROGRAMS FOR FIRE-SAFETY TYPE-APPROVED PRODUCTS

1. PURPOSE. This circular establishes a U.S. Coast Guard policy for follow-up programs for fire-safety products type approved by the U.S. Coast Guard under the U.S. Code of Federal Regulations and the International Code for Application of Fire Test Procedures.

2. ACTION. Manufacturers and U.S. Coast Guard accepted independent laboratories should note that a follow-up program is required for most fire-safety products type approved by the U.S. Coast Guard. This includes all products requiring approval under the International Code for Application of Fire Test Procedures (FTP Code) and other products as identified in this NVIC. Submittals for U.S. Coast Guard type approvals for products identified in this NVIC should include documentation of the follow-up program based on the guidance in this NVIC. The Circular will be distributed by electronic means only. It is available on the World Wide Web at http://www.uscg.mil/hq/g-m/nvic/.

3. DIRECTIVES AFFECTED. None.

4. BACKGROUND.

   a. In the U.S. Coast Guard type-approval program, the subparts of Subchapter Q of Title 46 of the Code of Federal Regulations (46 CFR) specify the approach to monitoring the production of the items. If the pertinent subpart specifies production inspections and tests, then 46 CFR 159.007 specifies the requirements for records, reports, and provides the option of using a laboratory labeling and marking program by an independent laboratory. 46 CFR 159.010 specifies the requirements and procedures for acceptance of independent laboratories by the U.S. Coast Guard.

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b. Changes in fire suppression technology have resulted in the U.S. Coast Guard establishing new approval categories since fire suppression systems are required to be type approved per the CFR. SOLAS, FTP Code, and decisions by the International Maritime Organization (IMO) have mandated the addition of type approval categories. As these type approval categories have not been incorporated into the CFR, there is no specific guidance regarding the production inspections and tests or follow-up program.

5. DISCUSSION.

a. Paragraph 5.2.2 of the FTP Code specifies that the "Administration shall require that the manufacturers shall have a quality control system audited by a competent authority to ensure continuous compliance with the type approval conditions." The U.S. Coast Guard satisfies this requirement by using a follow-up program developed and performed by a USCG-accepted independent laboratory to ensure compliance with the type approval conditions. Guidance on the follow-up program is in enclosure (1).

b. For CFR fire-safety type approval categories, the policy has been to require a follow-up program in line with common U.S. industrial practice. While some approval categories require retesting every 5 years, retesting has been waived if the product is continuously under a follow-up program. As the number of laboratories involved in listing products has increased, the definition of common industrial practice has become ill-defined. As a result, the follow-up programs for the CFR approval categories identified in paragraph 6(a) should follow this NVIC.

c. A list of independent laboratories accepted by the U.S. Coast Guard can be found on the internet at http://cgmix.uscg.mil/EQLabs/. Requirements for type approval can be found at http://www.uscg.mil/hq/g-m/mse4/mse4home.htm. The U.S. Coast Guard requires the laboratory to select the test sample for the type approval tests. This visit to the manufacturer's factory is also the start of developing the follow-up program as described in enclosure (1).

d. The development of quality standards such as ISO 9001 and the rise of certification bodies have created a system of third parties who perform general audits of quality management systems. Guidance on how a laboratory may give credit for the role of a certification body in certified quality management systems is provided in enclosure (2). The purpose is to avoid the duplication of effort while preserving the product oriented approach using an independent laboratory. Enclosure (2) may only be used in conjunction with enclosure (1).

e. The U.S. Coast Guard's preference is for the testing and follow-up to be performed by the same laboratory. Recognizing that there can be reasons to have the testing and follow-up be performed by different laboratories, the guidance in enclosure (3) has been developed for preparing a request to have another laboratory perform the follow-up service other than the testing laboratory.

f. To avoid delays in receiving type approval, documentation of the follow-up program should be submitted in the application package for type approval. It is the manufacturer's responsibility to submit a complete application package. A list of items that should be in the application package can be found on the internet at http://www.uscg.mil/hq/g-m/mse4/approve.htm.

6. IMPLEMENTATION.

a. Independent laboratories should be guided by enclosure (1) in setting up the follow-up program for products covered by the FTP Code and the following CFR approval categories. Such follow-up programs shall be considered equivalent to the requirements in the corresponding subparts of the CFR.

| Approval Categories | |
|---|---|
| 162.029 | Fixed Fire Extinguishing Systems (Pre-engineered) |
| 162.033 | Foam Type Fire Extinguishing System |
| 162.038 | Carbon Dioxide Type Fire Extinguishing System |
| 162.135 | Water Mist Nozzles |
| 162.161 | Engineered Halocarbon Fire Extinguishing System |
| 162.162 | Engineered Inert Gas Fire Extinguishing System |
| 164.007 | Structural Insulation |
| 164.008 | Bulkhead Panels |
| 164.009 | Noncombustible Materials |
| 164.012 | Interior Finish |
| 164.040 | Fiber Reinforced Plastic Gratings |

b. In accordance with standard U.S. practice, the following approval categories require follow-up programs complying with ANSI/UL 1803. A follow-up complying with this NVIC will not be accepted in lieu of a follow-up complying with ANSI/UL 1803.

| Approval Categories | |
|---|---|
| 162.028 | Portable Fire Extinguishers |
| 162.039 | Semiportable Marine Type Fire Extinguisher |

c. If the manufacturer has a certified quality management system for the product of interest, the laboratory may use the criteria in enclosure (2) in conjunction with enclosure (1) in setting up the follow-up program.

d. Manufacturers and laboratories should use enclosure (3) when making proposals where the independent laboratory performing the follow-up is not the independent laboratory conducting the approval tests.

7. DISCLAIMER. While the guidance contained in this document may assist industry, laboratories, the general public, the U.S. Coast Guard, as well as other federal and state regulators, in applying statutory and regulatory requirements, the guidance is not a substitute

for applicable legal requirements, nor is it a regulation itself. Thus, it is not intended to nor does it impose legally binding requirements on any party, including the U.S. Coast Guard, other federal or state agencies, or the regulated community.

8. CHANGES. This Circular will be posted on the web at http://www.uscg.mil/hq/g-m/nvic/. Changes to this circular will be issued as necessary. Questions or suggestions for improvements to this Circular should be submitted in writing to Commandant (G-PSE-4).

9. FORMS AND REPORTS. None.

T. H. GILMOUR
Rear Admiral, U.S. Coast Guard
Assistant Commandant for Prevention

Encl: (1) Follow-up Program Guidelines
(2) Evaluation of the Role of Certification Body in Certified Quality Management Systems
(3) Requests for Using Two Laboratories

**FOLLOW-UP PROGRAM GUIDELINES**

1. PURPOSE.

This enclosure provides guidance for the U.S. Coast Guard accepted independent laboratory in developing a follow-up program for products that will be type approved by the U.S. Coast Guard. The purpose of the follow-up program is to ensure continuous compliance with the type approval conditions. This enclosure is premised on one laboratory performing both the approval testing and follow-up.

2. DEFINITIONS**.**

*Audit* is a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

*Certification body* is an independent third-party that certifies that a manufacturer's quality control system meets the quality control standard stated in the certificate.

*Factories* are the facilities at specific addresses listed on the type approval certificate where the product is manufactured or processed, and the finished item is marked as type-approved. Processing does not include storage, repackaging, or shipping after the product is marked as long as the markings are unaffected.

*Indicative test* is a test consisting of a single sample run of the type approval test. For example the noncombustibility test is normally conducted using five sample runs. An indicative test would consist of using a single sample run of the noncombustibility procedure and comparing the resultant data to the data from the original data from the qualifying type approval test.

*Laboratory* is an independent laboratory accepted by the U.S. Coast Guard under 46 CFR 159.010 and acting within the scope of its acceptance.

*Product* is the finished item that is the subject of the type approval.

*Raw materials* are those materials that the manufacturer procures to use in manufacturing the product.

*Reference samples* are samples of materials used to identify materials used in original test specimen and compare to materials used in production after approval.

*Test specimen* is the specific item that is used in the type approval tests to determine if the product meets the requirements for approval.

*Type approval test*s are the tests or evaluations used to determine if the product meets the requirements for approval.

## 3. DISCUSSION.

The follow-up program provides a periodic and independent check on the production of the approved product. The intent is to provide reasonable assurance that the manufactured product will perform in the same manner as the specimen tested in the type approval tests. The program is intended to guard against changes that affect the performance of the product. These changes are possible due to the level of understanding of the manufacturer and its suppliers of the product's properties relevant to the type approval test. It is a condition of type approval that all planned changes will be approved through the laboratory and the U.S. Coast Guard prior to the changes being made in production.

The foundation of a follow-up program is the accurate and detailed description of the test specimen used in the type approval tests. This description is more than an identification of the sample such as a catalog number and location. It should be sufficient that one can detect and identify small changes in the product that possibly affect the results of the type approval test. This description is developed in the site visit of the factory when the test specimen is selected for the approval test.

It is not the intent of the U.S. Coast Guard to specify a standard follow-up program. Each laboratory has different resources, experiences, and cost structure. Each manufacturer will have different manufacturing processes with their strengths and weaknesses. Likewise, each will have different quality control systems. In developing the follow-up program, the laboratory should design the program to account for these differences. The laboratory may take into account the production tests performed by the manufacturer that relate to the ability of the product to pass the type approval tests. The laboratory may also take into account the role of a certification body in the manufacturer's certified quality management system per enclosure (2) of this NVIC.

## 4. KEY ASPECTS OF FOLLOW-UP PROGRAM.

A follow-up program involves an initial visit to the factory and the production examinations and testing. The initial visit is conducted prior to the approval tests. Guidelines specific to the initial factory visit are provided in section 4.1. Information gained from that factory visit is used to develop the baseline for the activities discussed in sections 4.2 through 4.7, which are conducted after type approval is granted.

If type approval is to cover production at more than one factory, the follow-up program must address each factory separately. The laboratory will have to determine that the production from each factory is the same as the others. This may require separate approval tests for each factory. Regardless of whether the determination is made by examination or by testing, each factory must be visited for performance of sections 4.1.3, 4.1.4, 4.2, and 4.3.

4.1 Initial Factory Visit Conducted Prior To Approval Test.

Prior to the performance of the type approval tests, the laboratory should conduct an initial visit of manufacturer's production factories. The purpose of this visit is to select the test specimens and to develop the accurate and detailed description of the product to enable the detection of any changes in manufacturing process, materials, and construction details that could possibly affect the product's performance in the type approval tests. In the initial factory and production visit, the laboratory should accomplish the following tasks.

4.1.1 Witness the fabrication of the test specimen in order to verify construction per submitted drawings and specifications. For a test specimen which will be assembled at the laboratory, the manufacturing of the components should be witnessed at the factory. For items that take more than a day to produce, the laboratory may witness the production phases on different assembly lines and then select a test specimen.

4.1.2 Mark the selected test specimens such that it can be verified that these are the specimens used for approval tests.

4.1.3 Collect reference samples of materials as appropriate to enable the detection of changes or variations of materials during the follow-up program. This should be performed in support of the planned procedures for performing the annual check per section 4.2. Examples of reference samples are ticking or fabric used in upholstered furniture or mattresses; resin, hardener, and glass fiber used in pipes; weather stripping, caulk, and spacers used in windows; and adhesives used in bulkheads. Reference samples such as of resins may be cured materials when appropriate due to stability with time.

4.1.4 Collect additional information on manufacturing processes as necessary for establishing the follow-up program. Examples of possible additional information are thread and torque for bolts; tolerances on dimensions, method of welding including use of flux; heat treatments and quenching; method of application of resin such as wet lay-up or infusion; quality control procedures.

4.2 Annual Check.

The laboratory should conduct at least an annual check on the product including a detailed check of conformity to the description in the approval certificate and drawings.

4.2.1 The laboratory should use its expertise to determine the appropriate procedures (combination of examination and test) for the annual check of the product. Examination may be sufficient for products that are mechanical constructions of materials such as steel and aluminum; details of the examination would include such things as a material thickness, spacing of bolts, and application rates of adhesives. Tests of materials (such as FTIR or mass loss) may be appropriate when the relevant properties are not readily observed such as organic content, chemical composition, and when the issues are ignition or flame spread; the baseline would be developed

from the samples of materials collected per section 4.1.3. An acceptable alternative would be an indicative test consisting of a single run of the type approval test with the goal of determining whether the product or material remains unchanged. In this approach, the results of the indicative run would have to fall within the normal scatter of the runs from the original approval test for the product to be deemed unchanged.[1]

4.2.2 All test specimens and samples of materials should be randomly selected by the independent laboratory. This would normally be done in conjunction with a site visit (section 4.3) of the manufacturer's factory. There should be some means of traceability to ensure that the test specimen received by the laboratory is the one selected at the site.

4.2.3 The laboratory may accept without testing the properties of materials for which there is a high degree of standardization and the laboratory is confident that there is little risk. Examples are steel and aluminum for bulkheads.

4.2.4 The laboratory may at its discretion deem any component that is under a separate U.S. Coast Guard type approved to be in compliance with the terms of its type approval regardless of the issuer of the type approval (i.e., by Commandant (G-PSE-4) or through the US/EC Mutual Recognition Agreement).

4.3 Site Visits.

The laboratory should conduct periodic site visits of each factory. These visits should be at least annually. At the laboratory's discretion, the laboratory may increase the frequency of site visits and waive a site visit for a year during which there is no production. There should be some randomness in the scheduling of site visits. The visits should be either unannounced or provide very little advance notice; the goal is to avoid a "straightening up" for the visit. The program should contain the provision for unannounced visits that are to be made at the discretion of the laboratory. The site visits should be performed as an audit addressing the following.

4.3.1 Manufacturing process for the approved product should be audited for changes in processes.

4.3.2 Records of raw materials should be audited for changes in such items as suppliers or specifications of materials.

4.3.3 Manufacturer's production tests including calibration of test equipment, performance of tests, and records of tests should be audited.

4.3.4 Verification that the manufacturer is complying with the U.S. Coast Guard marking requirements (i.e., product is permanently and legibly marked with the name of the

[1] For example, a material may require testing to both Part 5 and Part 2 of the FTP Code. The laboratory would choose the test method most likely to detect a change in the product as the indicative test method. In cases where the material barely met the criteria of one of the parts of the FTP Code, that part would most likely be chosen as the basis of the indicative test.

manufacturer, the brand or designation, the lot number or date of manufacture, and the Coast Guard approval number) and any laboratory-related marking requirements.

4.4 Evaluation of Changes.

The laboratory should evaluate changes of the manufacturing process and the associated materials to determine the effect on the product. This evaluation should determine if the change is acceptable or unacceptable. Acceptable changes are those that do not affect the performance of the product relative to the approval and do not conflict with the description of the product in the approval certificate including referenced drawings and manuals. Unacceptable changes are those that either may affect the performance of the product relative to the approval, conflict with the description of the product in the approval certificate, or otherwise result in noncompliance with the terms of the type approval. Unacceptable changes should be reported to the manufacturer and Commandant (G-PSE-4) with a description of the change, an assessment of the severity, and a recommended course of action.

4.5 Status Reports.

The laboratory should submit status report of follow-up to accompany the manufacturer's request for renewal of the certificate of approval or modification of the certificate of approval.

4.6 Records.

4.6.1 The laboratory should retain the laboratory's test data, results, and other records required to compare current production to the initial production and to monitor production as long as the product remains under the follow-up program.

4.6.2 The laboratory should retain records not covered under section 4.6.1 for five years after creation of the record or until termination of the follow-up program, whichever occurs first.

4.7 Notification.

The laboratory should notify Commandant (G-PSE-4) when the following occur.

4.7.1 The laboratory discovers any unacceptable changes of the product.

4.7.2 The laboratory has reason to doubt that the product would pass the type approval tests.

4.7.3 The laboratory discovers that the product or production does not comply with the type approval conditions.

4.7.4 The product is no longer under continuous follow-up by the laboratory or the follow-up program can not be executed. This includes termination of the follow-up program

by either the laboratory or the manufacturer, except when the U.S. Coast Guard terminates the approval.

5. DOCUMENTATION.

5.1 Follow-up Program Document. The follow-up program document describes the laboratory's plan for conducting the follow-up program described in section 4. It is developed using information gained from the initial visit and may be completed after the type approval tests. The purpose is to create a common understanding between the laboratory, manufacturer, and Commandant (G-PSE-4) of the follow-up program. The document will be reviewed by Commandant (G-PSE-4) prior to issuing a type approval. It should be submitted with the application for type approval. The document should contain the following items:

5.1.1 Identity of the approval holder (manufacturer), product, and factory including physical address.

5.1.2 An agreement between the manufacturer and the laboratory that the manufacturer will not make any changes to the product and the manufacturing process without confirmation that the change is acceptable.[2]

5.1.3 A short description of the actual factory visit as conducted per section 4.1. The description should give the reader an understanding of the scope of the visit. The description should touch on each section from 4.1.1 through 4.1.4. The markings used to mark the test specimens per section 4.1.2 should be described. The reference samples collected per section 4.1.3 should be described as to the material, quantity, and point of collection (e.g., source). The additional information collected per section 4.1.4 may be described in such a way to give the reader an understanding of the nature of the collected information.

5.1.4 The procedures for the annual check in section 4.2 for this product. There should be sufficient detail to understand what will be checked and how it will be checked. The details should include such items as dimensions and tolerances to be checked, reference drawings, and test procedures with list of corresponding materials. Common test procedures can be named or referenced without a full description of the procedure.

5.1.5 The procedures for site visits in section 4.3 including frequency and scope. This should not be a list of names, phone numbers, and directions to get to the site; it should be a description of a typical site visit including expected duration. There should be sufficient detail to understand what the inspector might do at the site, such as items to be checked and tests to be witnessed.

[2] On the back of the Certificate of Approval there is a statement that "No modification in the approved design, construction, or materials is to be adopted until the modification has been presented for consideration by the Commandant and confirmation received that the proposed alteration is acceptable."

5.1.6 The procedures for the evaluation of changes in section 4.4 for the product and its manufacturing process. Describe the procedures for determining whether a change is acceptable or unacceptable. Describe the procedures for subsequent notification.

5.1.7 Revisions of previously reviewed version of follow-up program document. Versions of the follow-up program document should be identified by some means, such as revision numbers and dates. Revised sections should be identified, such as by a vertical line in the margins.

5.2 Status Report of Follow-up for Renewal of Certificate of Approval. The status report is the laboratory's statement of the condition of the follow-up program per section 4.5. It aids Commandant (G-PSE-4) in determining whether the conditions for the original type-approval remain valid. The status report should be specific to an approval number. The status report should contain the following information.

5.2.1 Approval identification:

- Identity of approval holder.
- Name of product.
- Factory including physical address.
- U.S. Coast Guard approval number.

5.2.2 A statement as to whether the follow-up program has been in continuous effect and is in good standing. If it is not in good standing, explain the reasons.

5.2.3 A statement of the laboratory's opinion as to whether the product complies with the type approval with respect to performance and conditions of type approval based on the results of the follow-up program.

5.2.4 Reference any correspondence concerning unacceptable changes of the product.

5.3 Reports and Correspondence. (Reference sections 4.4 and 4.7) All correspondence to Commandant (G-PSE-4) should contain the following identifying information.

- Identity of approval holder.
- Name of product.
- Factory including physical address.
- U.S. Coast Guard approval number.

**EVALUATION OF THE ROLE OF CERTIFICATION BODY IN CERTIFIED QUALITY MANAGEMENT SYSTEMS**

1. PURPOSE.

This enclosure provides guidance for the laboratory to evaluate the role of a certification body (CB) who has certified a manufacturer's quality control system. This guidance is to assist the independent laboratory in deciding to what degree the independent laboratory may incorporate the CB's certification and reports into the laboratory's follow-up program.

2. CERTIFICATION BODY.

The CB must be an organization accredited by the U.S. accreditation body or by a signatory to Multilateral Cooperative Accreditation Arrangement with the U.S. accreditation body, if that signatory is also a member of the International Accreditation Forum (IAF).

The U.S. accreditation body is:

American National Standards Institute
ANSI-ASQ National Accreditation Board
P.O. Box 586
Milwaukee, WI 53201-0586
800-606-5394
http://www.anab.org

3. DISCUSSION.

The objective of the evaluation is to enable the laboratory to avoid duplication of effort while preserving the oversight role of the independent laboratory. To obtain credit for the certification of the quality control system, the manufacturer should agree to maintain the certification and to forward the CB's audit and survey reports to the laboratory as a required part of the follow-up program.

The existence of a certified quality control system means that there is another independent third party, CB. This certification provides a third-party check that the manufacturer's quality control procedures meet a designated standard and that the manufacturer is following their quality control system. This is not a replacement for a follow-up program as it does not seek to provide an independent check that the product will perform the same as the tested sample. Most manufacturers have some means of monitoring the quality of their production. Laboratory labeling and listing programs have generally taken into consideration the existence of the manufacturer's system. This enclosure provides guidance for the laboratory in deciding what activities of the CB overlaps or duplicates the activities of the laboratory. For those items, the laboratory may reduce its efforts and monitor the CB's reports.

For example, if the laboratory notes that the CB provides a check of the calibration of test equipment equivalent to the laboratory's check, then the laboratory may reduce the frequency or

modify their check of equipment calibration. Similar areas can be the performance of production tests, tests of raw materials by the manufacturer and associated records.

The laboratory may enter into agreements with the CB, such as to avoid duplication of efforts and make the best use of each organization's strengths.

5. INDEPENDENT LABORATORY'S EVALUATION.

All three of the following criteria should be met before any of the CB's activities are to be considered with regard to the follow-up. If any one of the three criteria is not met, this enclosure should not be used.

(a) The CB's accreditation should be in good standing with the accreditation organization.
(b) The product should be within the CB's scope of accreditation.
(c) The CB's certification of the manufacturer's quality control system should include the product being considered for type approval.

Provided that all of the above are met, the laboratory should use the information in the Table 1 in making their determination of how much credit they may give to the activities of the CB.

**Table 1. Evaluation Factors and Criteria of the role of the CB**

| EVALUATION AREA | EVALUATION FACTOR | EVALUATION CRITERIA | CREDIT |
|---|---|---|---|
| 2. Can credit be given for the CB's audit of production-related tests and inspections (e.g., tests of raw materials, quality control tests during production, quality check on finished product)? | (a) Does the quality-system documentation include descriptions of all of the following?<br>• Required qualifications of personnel performing the tests and the inspections, including training.<br>• Production-related tests and inspections.<br>• Records appropriate to the tests and inspections. Records include such items as training records, calibration data, test data, and inspection reports. | The documentation should include all of the items relating to the test or the inspections of interest. The description should be adequate for comparing what the manufacturer is doing to what the manufacturer should be doing per their planned system. | For those tests and inspections where evaluation factors (a), (b), and (c) are satisfactorily met, the laboratory may reduce the frequency of their audit of the pertinent tests and inspections. It should not be reduced to less than once every five years. |
| | (b) What is the frequency of CB's witnessing the tests? | The CB should be witnessing the tests at least as often as the laboratory would normally witness the tests. | |
| | (c) Will the laboratory have access to records or results of CB witnessing the tests? | The laboratory should be able to determine the results of the CB witnessing the tests. | |

**Table 1. Evaluation Factors and Criteria of the role of the CB**

| EVALUATION AREA | EVALUATION FACTOR | EVALUATION CRITERIA | CREDIT |
|---|---|---|---|
| 3. Can credit be given for the CB's audit of records relating to tests, calibrations, and inspections? | (a) Does the quality-system documentation include all the following?<br>• Identification of tests.<br>• Identification of inspections.<br>• Descriptions of the records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned. | The description should be adequate for comparing what the manufacturer is doing to what the manufacturer should be doing per the planned system. | For those records where evaluation factors (a), (b), and (c) are satisfactorily met, then the laboratory may reduce the frequency of their audit of the pertinent records. It should not be reduced to less than once every five years. |
| | (b) What is the frequency of CB's auditing the records? | The CB should be witnessing the tests at least as often as the laboratory would normally audit the records. | |
| | (c) Will the laboratory have access to records or results of CB's audit of records? | The laboratory should be able to determine the results of the CB's audit. | |
| 4. Can credit be given for the CB's audit of the manufacturer's compliance with U.S. Coast Guard marking and laboratory labeling? | (a) Does the quality-system documentation correctly and completely describe the pertinent marking and labeling requirements? | The description should be adequate to apply correctly the markings and labels. | Where evaluation factors (a), (b), and (c) are satisfactorily met, the laboratory may reduce the frequency of their audit. It should not be reduced to less than once every five years. |
| | (b) What is the frequency of CB's audit? | The CB's audit should be at least as often as laboratory would normally audit compliance. | |
| | (c) Will the laboratory have access to records or results of CB's audit? | The laboratory should be able to determine the results of the CB's audit. | |

The CB's activities should not be construed as relieving or being a substitute for the laboratory's performance of the following activities.

(a) Conducting an annual check on the product through inspection and testing of the product or materials as described in section 4.2 of enclosure (1) of this NVIC.

(b) Selecting test specimens.

(c) Reduce the number of site visits of the laboratory to less than one per year. This does not preclude the laboratory from modifying its activities at the site visit and shortening the duration of the visit.

(d) Evaluating changes of the manufacturing process and the associated materials to determine the effect on the product. Evaluation of changes is discussed in section 4.4 of enclosure (1) of this NVIC.

(e) Retaining records.

(f) Reporting on matters relating to the follow-up. Making reports per sections 4.4 and 4.7 of enclosure (1) of this NVIC.

(g) Providing oversight (i.e., responsibility for) of the follow-up program.

6. DOCUMENTATION.

If the CB's activities are incorporated into the follow-up program, the laboratory will document their evaluation and any agreements with the CB. The CB's activities included in the follow-up should be clearly identified in the follow-up program document.

The laboratory should retain the following records until termination of the follow-up program.

(a) Details of the evaluation.
(b) Agreements with the manufacturer and the CB.

The laboratory should retain the following for five years after creation or until termination of the follow-up program, whichever occurs first.

(a) Reports of the CB used by or relied upon by the laboratory.

**REQUESTS FOR USING TWO LABORATORIES**

1. PURPOSE.

The standard procedure is for the approval tests and follow-up procedure to be performed by the same laboratory. This enclosure provides guidance for preparing requests involving a deviation of using separate laboratories for approval testing and follow-up.

2. DISCUSSION.

The goal is to ensure traceability of the approved product to the test specimens used in the type approval test. This requires proper description and documentation of the test specimen including manufacturing process.

Commandant (G-PSE-4) will not get involved in disputes between the laboratories except with respect to interpretation of the tests.

The manufacturer should notify Commandant (G-PSE-4) prior to contracting for the approval tests and follow-up. Failure to give advance notification may result in not obtaining type approval.

The laboratories should be guided by this document in determining their responsibilities with respect to the U.S. Coast Guard for the approval.

3. GUIDELINES.

3.1 Both laboratories shall be independent laboratories acceptable to the U.S. Coast Guard under 46 CFR 159.010 for the product being tested.

3.2 The manufacturer should grant permission for unrestricted exchange of information and data between the laboratories as the laboratories consider necessary to facilitate testing and development of the follow-up program.

3.3 The laboratory that will be performing the follow-up is the principle laboratory for the approval. The principle laboratory is responsible for the inspection of the manufacturing plant prior to the approval test, selecting the test specimen, developing a description of the product, and developing the follow-up procedure. The principle laboratory should mark the test specimen and inform the testing laboratory of the markings used on the test specimen.

3.4 The testing laboratory is responsible for the proper conduct of the tests and preparing the test report. They should provide the test report to the principle laboratory and the manufacturer.

4. DOCUMENTATION.

The manufacturer's request for having a different laboratory for follow-up should contain the following information:

- name and address of the applicant and of the manufacturer,
- location(s) where the product is manufactured,
- name or trade name of product,
- a statement of the approval category for which approval is sought,
- names of the laboratories,
- description of plan of testing and site visits including the respective roles of the laboratories, and
- statement as to whether the laboratories have agreed with the plan.