



CIRCULAR

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No : 2017-1-E

Date : 2017.01.16

To : All surveyors

Subject : 8.58 Instruction for the approval of test laboratory

1. Application

- (1) This instruction applies to the approval of the test laboratory (hereinafter referred to as "test laboratory") where tests are carried out in accordance with relevant Rules for classification or standards for ship equipment and the certificate of CE and USCG 46 CFR Part 162.060-30.
- (2) A corporate body, where separately carries out tests, can apply the Test Laboratory Approval Scheme to its own tests, provided that they are considered acceptable by the Society. However, in case of test according to USCG 46 CFR Part 162.060-30, the Scheme can only be applied if the corporate body is registered as a sub-IL of KR by USCG.
- (3) The test at approved test laboratory for the relevant rules or regulations prescribed of the witness may be partially or wholly exempt.

2. Scope of service and standards

- (1) The scope of service is within range of the items which are required to be tested in accordance with the Rules for Classification and/or certified international standards (KS/ISO/IEC/EN Standard/ USCG 46 CFR Part 162.060-30 etc).
- (2) The approval standards should be complied with the requirements of ISO/IEC 17025, and the test assessment is to be carried out within the scope of document assessment, on-site inspection and the verification of test person capabilities.
- (3) In case of USCG, the test shall be carried out by designated tester according to the QAPP which has been approved by the IL (KR).

3. Approval application documents

- (1) Submission of the data
The test laboratory wishing to obtain the approval of the test laboratory is to submit a copy of the application together with two copies of the following data in no.(2) to the Society.
- (2) Data to be submitted
 - (a) Scope of service : test field to be approved
 - (b) A detailed list of the Laboratory test equipment and manual
 - (c) A detailed list of the test standards to be used and details of test procedures employed
 - (d) Details of the Laboratory staff with their competency data, e.g. name, qualifications, experience, etc.
 - (e) List of quality manuals and procedures
 - (f) If applicable, Test Laboratory Certificate (IEC, KOLAS or organizations as deem appropriate by ILAC MRA) or the certificate of other approval laboratories (other classifications, notification body of a country of a EC or a EA(European co-operation for Accreditation MRA) and certificate of test laboratory of the flag State recognized by this Society).
 - (g) Test report of application scope (issuing test report)

4. Assessment

- (1) General
 - (a) Document assessment and on-site inspection are to be conducted by the personnel of expert who have completed

the educational course of ISO/IEC 17025 and/or make a specialty of the applied areas shall carry out the assessment according to the check list (Form AF-04).

- (b) In case where the non-conformity is found during the assessment, the inspector should issue Corrective action request (Form AF-4) to the test laboratory. Corrective actions should be taken within the determined period. For the major non-conformity, the reassessment should be carried out after the completion of corrective actions.
- (c) Major non-conformity and minor non-conformity is classified according to check list (Form AF-04).
- (d) In case of the initial assessment, more than 1 Man-day is required and in case of the surveillance, 1 Man-day is required.
- (e) After completion of on-site assessment inspector approved test laboratory assessment report (PA-04) approve the assessment by writing to the applicant shall be informed.

(2) Initial assessment

Upon satisfactory outcome of the assessment of the clause 4.(1) application documents according to clause 2, shall be the on-site assessment.

(3) Surveillance

- (a) Surveillance is to be carried out to the test laboratory annually within 3 months before and after the anniversary date to verification that the approved standard, etc. of the test laboratory are maintained satisfactorily.
- (b) The assessment for expansion of approval scope, if conducted in conjunction with the year of surveillance can be carried out.
- (c) Surveillance should be planned for maintenance of test laboratory qualifications and relevant test items related to issued test results for the equipment of the Society and products certified by CE
- (d) The Society may conduct special surveillance when the following cases take place;
 - ① When a dispute in the result of test laboratory takes place
 - ② When a client raises a question
 - ③ When more than twice of dissatisfaction continuously takes place in identical test results
 - ④ When corrective measures against the dissatisfaction of the test result are not taken into action.
 - ⑤ When the Society requests

(4) Renewal assessment

- (a) The test laboratory to validity of approval certificate before its expiration date within 3 months shall be applying for renewal assessment.
- (b) The renewal assessment procedures and Initial assessment procedures are applied equally.

(5) Occasional assessment

In case of any alteration to the certified system of the test laboratory or where the test field is changed or added, it is to be informed to the Society. Occasional assessment may be required when deemed necessary by the Society.

5. Approval

- (1) Upon completion of the audit for the test laboratory satisfactorily, the general manager of Marine & Ocean Equipment Team shall approved test laboratory and issue an approval certificate.
- (2) The general manager of Marine & Ocean Equipment Team related to the Society in order to utilize an approved test laboratory to test work under the latest information related to the Society shall be posted on the website.
 - (a) Test laboratory approval certification number
 - (b) Date of approval
 - (c) Approval test laboratory name and location
 - (d) Valid date
 - (e) Scope of service

6. Validity and Sustainability

- (1) The valid date of test laboratory is 3 years from the initial approval date, when the scope of approval is extended the remaining period is transferred to the valid date.
- (2) Only for the initial and renewal assessment, test laboratories, which belong to IEC, ILAC MRA or/and EA MRA, can omit some of the Society assessment criteria stipulated in the paragraph 4, provided the result of assessment is appropriate.

7. Securing of the liability of test samples after approval

- (1) The Society writes an official document in which information on test samples sealing and marking ways for identification are recorded, and sends the document to the test laboratory in order to confirm the reliability of applied test samples.
- (2) Test laboratory is required to identify the unique identification marks of the Society on the test samples, and take photo of the marks with test samples, which later are to be added in the test report after the test finishes.
- (3) If the reliability of identification mark is doubted, prior to the commencement of test, test laboratory should be consulted with a Society attending surveyor on the test procedures.
- (4) If the test for USCG 46 CFR Part 162.060-30 is carried out, it shall be performed according to QAPP for Component Testing of BWMS Ch. 3.

8. The use of KR Mark

According to the relevant Rules of Classification, the test laboratory approved by the Society can publish the test results or the reports with either of the marks below, and can mark a sign to indicate the approved test laboratory of the Society. Except for the Society-related tasks, the commercial use of the marks is not allowed.



9. Others


- (1) With regard to the extension of the validity, suspension/cancellation of Approval Certificate, it should be followed with Guidance for Approval of Manufacturing Process and Type approval etc. Ch.5.
- (2) The test laboratory whose approval was cancelled, may apply for re-approval provided that they have corrected the non-conformities which resulted in cancellation, and this Society is able to confirm they have effectively implemented the corrective action.
- (3) The Society may reissue Approval Certificate when the test laboratory requests to reissue with reasons of loss or damage of Approval Certificate and change of company's name. The validity of reissued Certificate is succeeded previous one.
- (4) Approval fee for the Society shall be determined in accordance separately.

Attached : 1. Application 1 copy.

2. Certificate 1 copy.

3. Audit report for approval of test laboratory (Form PA-4), 1 copy.

4. Check list for approval of test laboratory (Form AF-4), 1 copy. (The End)


Executive Vice President
Survey Division

한국선급

KOREAN REGISTER OF SHIPPING



Application for Approval of Test Laboratory

신규/Initial 갱신/Renewal 사후관리/ Surveillance 임시/Occasional

| Content of Application 신청내용 | | | |
|---|---|-------------------------------|--|
| Scope of Service 승인범위 | <input type="checkbox"/> 역학시험 (Mechanical Testing) <input type="checkbox"/> 화학시험 (Chemical Testing) <input type="checkbox"/> 전기시험 (Electrical Testing) <input type="checkbox"/> 열 및 온도측정 (Heat and Temperature Measurement) <input type="checkbox"/> 음향 및 진동시험 (Acoustic and Vibration Testing) <input type="checkbox"/> USCG 환경시험(USCG Component testing) <input type="checkbox"/> 생물학시험(Biological Testing) <input type="checkbox"/> 기타(Others) | | |
| Test Items 시험항목 | | | |
| Test Laboratory Name 시험기관명 | | | |
| Address of Test Laboratory 시험기관주소 | | | |
| Tel. No. 전화번호 | Fax. No. 팩스번호 | E-Mail 전자우편 | |
| Date of Approval Audit 승인심사에 정일 | Date to be approved 승인희망일 | | |
| Attachments 첨부자료 | <input type="checkbox"/> 승인범위 및 적용규격/Approval scope of service and applicable Standards <input type="checkbox"/> 기타 첨부자료에 대하여는 한국선급의 인터넷 홈페이지 참조(http://www.krs.co.kr) Other Data to be submitted(details can be found on KR Website, http://www.krs.co.kr) | | |
| <p>아래에 서명한 신청자는 한국선급의 "선급 및 강선규칙"과 "제조법 및 형식승인등에 관한 기준", "USCG 46 CFR Part 162.060-30" 또는 "ISO/IEC 17025"에 따라서 상기의 시험범위에 대한 승인을 받고자 신청하며, 또한 상기의 승인과 관련하여 발생하는 모든 경비와 승인심사수수료를 지불하는 것에 동의합니다.</p> <p>The undersigned hereby requests Korean Register of Shipping to carry out the Approval process for the above mentioned scope of service in accordance with the requirements of the "Rules for Classification, Steel Ships" and/or the "Guidance for Approval of the Manufacturing Process and Type Approval, Etc.", "USCG 46 CFR Part 162.060-30" and/ or "ISO/IEC 17025", and also agrees to pay all approval fee and expenses which will be incurred in the aforesaid approval.</p> | | | |
| Date 신청일 () YY 년 () MM 월 () DD 일 | | | |
| Applicant 신청자 | | (Signature or Stamp 서명 또는 날인) | |
| Address of Applicant 신청자주소 | | | |
| Tel. No. 전화번호 | Fax. No. 팩스번호 | E-Mail 전자우편 | |
| Person in Charge 수검담당자 | | | |

| 시험기관 승인신청서 점검표 | | | JOB ID No. |
|--|---------|-----|-----------------------------------|
| 접수번호 | 신청서 접수일 | 담당자 | |
| Check Item 신청검토 내용 | | | 담당자(본부) |
| <input type="checkbox"/> Any special information or requirements including MOU or agreement <input type="checkbox"/> The relevant standards in the department's master list (If not, refer to) <input type="checkbox"/> This department has the necessary capability (If not, other source(s)) <input type="checkbox"/> Compliance with the Classification/Statutory requirements | | | Instruction 지시내용 |
| Remark : (☒ : 적합 ☐ : N.A). The items in bold line are for surveyor use. 굵은선 내의 사항은 본 선급 검사원이 작성 | | | Reviewed by (Signature) 검토자 |

APPROVAL CERTIFICATE FOR TEST LABORATORY

Certificate No. : **Date of Approval** :
Service : Mechanical/Chemical/Electrical/Heat & Temperature Measure/Acoustic & Vibration/USCG
46 CFR Part 162.060-30/Biological
Test Laboratory :
Address :
Approval Condition :

THIS IS TO CERTIFY that the Test Laboratory of the above-mentioned including testing facilities, quality control and general standards of testing procedures has been audited by this Society and that the System is found to be in compliance with the requirement of this Society's Rules and /or of the recognized standards as follows and entered in the "List of Approved Test Laboratories"

Ch. 5 of the Guidance for Approval of Manufacturing Process and Type Approval, etc, ISO/IEC 17025(2005) and/or USCG 46 CFR Part 162.060-30.

This Certificate is valid until 30th October, 2011 subject to periodical audit.
Issued at Daejeon, Korea on 31st October, 2008.

KOREAN REGISTER OF SHIPPING

(Choi Jong-yuel)
General Manager of
Marine & Ocean Equipment Team

Note : 1. : This certificate will be valid subject to complying with the approval conditions described on the certificate and/or on the Rules of this Society.

2. : This certificate will be invalid from the expiry date aforementioned unless the extension or renewal has been granted to the test laboratory.

3. Any significant modifications or changes that may affect the validity of this certification without approval from this Society will render this certificate invalid

4. Should the specified rules, regulations or standards be amended during the validity of this certificate, the test laboratory is to be re-approved by this Society in accordance with the requirements as amended

Test Laboratory Approval Condition

Certificate No. :

Date of Approval :

Endorsement for Surveillance

Certificate No : _____

Date of Approval : _____

Anniversary Date : _____

This is to certify that the Test Laboratory is considered to be fit to obtain / retain the Society's approval in accordance with Ch. 6 of the Guidance for Approval Manufacturing Process and Type Approval, Etc., and/or USCG 46 CFR Part 162.060-30 and is valid until 30th October, 2009.

■ Surveillance /Confirmation/Occasional Assessment

Surveillance /Confirmation/Occasional Assessment has been carried out and the Test Laboratory is considered to be fit to retain the Society's approval and is valid until _____

Report No. : _____
Branch(Office) : _____
Date : _____
Inspector : _____

■ Surveillance /Confirmation/Occasional Assessment

Surveillance /Confirmation/Occasional Assessment has been carried out and the Test Laboratory is considered to be fit to retain the Society's approval and is valid until _____

Report No. : _____
Branch(Office) : _____
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Date : _____
Inspector : _____

■ Surveillance /Confirmation/Occasional Assessment

Surveillance /Confirmation/Occasional Assessment has been carried out and the Test Laboratory is considered to be fit to retain the Society's approval and is valid until _____

Report No. : _____
Branch(Office) : _____
Date : _____
Inspector : _____

Note : The approval will be automatically suspended and the Certificate become invalid if not endorsed annually within 3months after the anniversary date of this Certificate

한 국 선 급

KOREAN REGISTER OF SHIPPING

시험기관승인 평가보고서

ASSESSMENT REPORT FOR APPROVAL OF TEST LABORATORY

신청자코드
Applicant's Code

보고서 번호
Report No.

아래 품목의 시험범위에 대하여 다음의 심사를 시행하고 그 결과를 보고 합니다.
Following audits on the test laboratory of the undermentioned scope of service has been carried out by the undersigned auditor.

A 승인 범위 Scope of Service _____

B 시험기관명 Name of Test Laboratory _____

시험기관명 Name of Test Laboratory _____
주소 Address _____
전화 Tel No _____ 팩스 Fax No _____
전자우편 E-mail _____ 임직원 수 Number of Employee _____ 명 Persons
담당자의 성명 Name of Person in Charge _____

C 평가 종류 Kind of Assessment

최초 Initial 갱신 Renewal 사후관리 Surveillance 임시 Occasional

D 평가일자 Date of Assessment

평가일자 Date of Assessment D M Y 승인증서의 유효기간 Expiry Date of Approval Certificate D M Y

E 발견된 부적합사항의 수 Number of Non-conformity D M Y

중 부적합사항 Major NC 건 items 시정조치예정일 Proposed Complete Date
경 부적합사항 Minor NC 건 items 시정조치예정일 Proposed Complete Date
관찰사항 Observation NC 건 items

F 평가결과 Assessment Result

- 시험기관승인제도 승인(유지) Accept to obtain (retain) the TL Approval
- 재방문심사 필요 Re-Audit is required
- 승인 정지 Suspension of TL Approval
- 승인 취소 Withdrawal of TL Approval

G 평가팀 Assessment Team

평가팀장 Leader Inspector _____ 평가원 Inspector _____

H 의견 Description

Verified by

Endorse

Leader Auditor ()

첨부서류 (Attachment) TL평가계획서 TL Assessment Plan TL평가점검표 TL Assessment Checklist

TL평가결과요약 TL Assessment Summary 시정조치요구서 Corrective Action Request 관찰사항보고서 Observation Report

* 재방문심사를 한 경우에는 평가보고서를 별도로 작성한다
Where Re-Audit was performed, assessment report to be prepared separately

TL Assessment Summary



| | | | | | | | |
|-----------------|---|-----------|-------------|-----------|--|---------------|-------|
| Kind of audit | <input type="checkbox"/> Initial <input type="checkbox"/> Periodical <input type="checkbox"/> Renewal <input type="checkbox"/> Occasional | | | | | Page : | / |
| Name of Lab. | | | | | | P.I.C. of Lab | |
| Job ID. | Department | | | | | | |
| Date of audit | audit or | | | | | | Total |
| Name of auditor | | | | | | | |
| | Time(AM/PM) | | | | | | |
| | Time(AM/PM) | | | | | | |
| 4.(1) | Organization | | | | | | |
| 4.(2) | Management system | | | | | | |
| 4.(3) | Document control | | | | | | |
| 4.(4) | Review of requests, tenders and contracts | | | | | | |
| 4.(5) | Subcontracting of tests and calibrations | | | | | | |
| 4.(6) | Purchasing services and supplies | | | | | | |
| 4.(7) | Service to the customer | | | | | | |
| 4.(8) | Complaints | | | | | | |
| 4.(9) | Control of nonconforming testing and/or calibration work | | | | | | |
| 4.(10) | Improvement | | | | | | |
| 4.(11) | Corrective action | | | | | | |
| 4.(12) | Preventive action | | | | | | |
| 4.(13) | Control of records. | | | | | | |
| 4.(14) | Internal audits | | | | | | |
| 4.(15) | Management reviews | | | | | | |
| 5.(1) | Genera | | | | | | |
| 5.(2) | Personnel | | | | | | |
| 5.(3) | Accommodation and environmental conditions | | | | | | |
| 5.(4) | Test and calibration methods and method validation | | | | | | |
| 5.(5) | Equipment | | | | | | |
| 5.(6) | Measurement traceability | | | | | | |
| 5.(7) | Sampling | | | | | | |
| 5.(8) | Handling of test and calibration items | | | | | | |
| 5.(9) | Assuring the quality of test and calibration results | | | | | | |
| 5.(10) | Reporting the results | | | | | | |
| Total | | | | | | | |
| Total | | Major N/C | | Minor N/C | | OB | |
| 결과 | √ : Conformity ● : Major N/C, ○ : Minor N/C, Δ : OB(Observations) | | | | | | |
| Auditor Name : | (signature) | Name : | (signature) | date : | | | |

<Distribution : Copy to test laboratory and Branch Office, Original to Head office>

| Requirements | Assessment items | Location/ department | Result | | | NCR NO. | Remark |
|-----------------------------------|---|-------------------------|--------|----|----|------------|--------|
| | | | C | NC | OB | | |
| 4. Management requirements | | | | | | | |
| (1) Organization | <ul style="list-style-type: none"> - The laboratory or the organization of which it is part shall be an entity that can be held legally responsible. - It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition. - The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities. - If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest. - The laboratory shall have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures - Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system. | | | | | | |
| (2) Management system | <ul style="list-style-type: none"> - The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. - The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. - Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. - Top management shall ensure that the integrity | | | | | | |

| Requirements | Assessment items | Location/ departme nt | Result | | | NCR NO. | Remark |
|--|---|-----------------------------|--------|----|----|------------|--------|
| | | | C | NC | OB | | |
| | of the management system is maintained when changes to the management system are planned and implemented. | | | | | | |
| (3) Document control | <ul style="list-style-type: none"> - The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals. - All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents. - Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval. | | | | | | |
| (4) Review of requests, tenders and contracts | <ul style="list-style-type: none"> - The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. - Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract. - The customer shall be informed of any deviation from the contract. | | | | | | |
| (5) Subcontracting of tests and calibrations | <ul style="list-style-type: none"> - When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question. | | | | | | |
| (6) Purchasing services and supplies | <ul style="list-style-type: none"> - The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations. - The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list | | | | | | |

| Requirements | Assessment items | Location/ department | Result | | | NCR NO. | Remark |
|---|---|-------------------------|--------|----|----|------------|--------|
| | | | C | NC | OB | | |
| | those approved. | | | | | | |
| (7) Service to the customer | <ul style="list-style-type: none"> - The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers. - The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service. | | | | | | |
| (8) Complaints | <ul style="list-style-type: none"> - The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory. | | | | | | |
| (9) Control of nonconforming testing and/or calibration work | <ul style="list-style-type: none"> - The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. | | | | | | |
| (10) Improvement | <ul style="list-style-type: none"> - The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. | | | | | | |
| (11) Corrective action | <ul style="list-style-type: none"> - The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified. - The laboratory shall monitor the results to ensure that the corrective actions taken have been effective. | | | | | | |
| (12) Preventive action | <ul style="list-style-type: none"> - Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement. | | | | | | |
| (13) Control of records | <ul style="list-style-type: none"> - The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions. - All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration | | | | | | |

| Requirements | Assessment items | Location/ departme nt | Result | | | NCR NO. | Remark |
|----------------------------------|--|-----------------------------|--------|----|----|------------|--------|
| | | | C | NC | OB | | |
| | and to prevent loss. Retention times of records shall be established. | | | | | | |
| (14) Internal audits | <ul style="list-style-type: none"> - The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. - Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken. | | | | | | |
| (15) Management reviews | <ul style="list-style-type: none"> - In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. | | | | | | |
| 5. Technical requirements | | | | | | | |
| (1) General | <ul style="list-style-type: none"> - The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses. - Factors : human factors, accommodation and environmental conditions, test and calibration methods and method validation, equipment, measurement traceability, the handling of test and calibration items | | | | | | |
| (2) Personnel | <ul style="list-style-type: none"> - The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. - The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and | | | | | | |

| Requirements | Assessment items | Location/ departme nt | Result | | | NCR NO. | Remark |
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| | <p>anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.</p> <ul style="list-style-type: none"> - (USCG) The test of related USCG shall be carried out by personnel who are reported in the procedure (Application, QAPP, etc.). | | | | | | |
| (3)Accommodation and environmental conditions | <ul style="list-style-type: none"> - The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. - The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. - (USCG) The test of related USCG shall be carried out by equipments which are reported in the procedure (Application, QAPP, etc.). | | | | | | |
| (4) Test and calibration methods and method validation | <ul style="list-style-type: none"> - The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. - The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. - The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. - When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use. - A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations. - Calculations and data transfers shall be subject to appropriate checks in a systematic manner. | | | | | | |
| (5) Equipment | <ul style="list-style-type: none"> - The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met. - Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programmes shall be established for key | | | | | | |

| Requirements | Assessment items | Location/ department | Result | | | NCR NO. | Remark |
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| | <p>quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use.</p> <ul style="list-style-type: none"> - Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel. - Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following - The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. | | | | | | |
| (6) Measurement traceability | <ul style="list-style-type: none"> - All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment. | | | | | | |
| (7) Sampling | <ul style="list-style-type: none"> - The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. - The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. - (USCG) The laboratory shall inspect the sample is matched by drawing from the IL(KR). - (USCG) After inspection of sample, the laboratory shall submit the COC and be confirmed by IL(KR). | | | | | | |
| (8) Handling of test and calibration items | <ul style="list-style-type: none"> - The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. - The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the | | | | | | |

| Requirements | Assessment items | Location/ department | Result | | | NCR NO. | Remark |
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| | <p>life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.</p> <ul style="list-style-type: none"> - The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. | | | | | | |
| (9) Assuring the quality of test and calibration results | <ul style="list-style-type: none"> - The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. - Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. | | | | | | |
| (10) Reporting the results | <ul style="list-style-type: none"> - The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods. - When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces. | | | | | | |

Internal Information

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|---|--|
| Consideration for next audit | |
| Information or suggestions to the headquarter/branch | |
| Remark | |

시정조치 요구서 Corrective Action Request



평가일자(Date) : _____

| | | | |
|---|--|-----------------------------|--|
| 시험기관명 (Test Laboratory Name) | | 평가자 서명 (Inspector' Sign) | |
| 승인평가 보고서 No. (Assessment Report No.) | | 책임자 서명 (Institute Rep.) | |

| Report No.(1) | 부서/장소 (Department/ Place) | 부적합(불일치)내용 (Non-conformity) | 종류 (KInd) | 관련 규정 (Relevant Requirement) (2) | 시정조치 예정일 (Proposed Completion Date) | 시정조치 완료일 (Actual completion Date) |
|---------------|------------------------------|--------------------------------|--|--|--|--------------------------------------|
| | | | <input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> Major <input type="checkbox"/> Minor | | | |

<Remarks>

(1) Report No.는 1, 2, 3,순으로 기재함.(Report No. is entered in the order of 1, 2, 3....)

(2) 관련 규정은 평가항목별 시험기관 승인제도 요건의 번호를 기재함.(Each item no. of TL requirement is entered.)

<Distribution : Copy to Head office and Branch Office, Original to test laboratory>

관찰사항 보고서

Observation Report



<관찰사항은 시정조치의 의무는 없으나 귀사의 업무 개선 자료로 활용하시기 바랍니다.>
 <It is not required to take corrective action for the observation, but they may be used as information for improving your quality system>

| | | | |
|---------------------------------|--|---|--|
| 시험기관명 (Test Laboratory Name) | | 승인평가 보고서 No. (Assessment Report No.) | |
| 평가일자 (Date) | | 평가자 서명 (Inspector' Sign) | |

| Report No. (1) | 부서/장소 (Department/ Place) | 관찰사항 (Observation) | 비고 Remarks |
|-------------------|---------------------------------|-----------------------|---------------|
| | | | |

Remarks (1) Report No.는 1, 2, 3,순으로 기재함.(Report No. is entered in the order of 1, 2, 3....)

<Distribution : Copy to Head office and Branch Office, Original to test laboratory>