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ASSESSMENT AND EVALUATION MANUAL



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NVLAP ASSESSMENT AND EVALUATION MANUAL

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National Voluntary Laboratory
Accreditation Program

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FOREWORD

The National Voluntary Laboratory Accreditation Program (NVLAP), established in 1976, is administered by the National Institute of Standards and Technology (NIST) formerly the National Bureau of Standards (NBS). NVLAP is a voluntary system for assessing and evaluating testing laboratories and accrediting those found competent to perform specific test methods or types of test methods. Laboratory Accreditation programs are established for specified product or service areas in response to requests and demonstrated need.

This publication, intended for the NVLAP technical experts (TEs) who serve as assessors and evaluators, describes general policies and practices of NVLAP assessment and evaluation. The specific technical criteria for assessing and evaluating laboratories are provided elsewhere, in NVLAP Handbooks and checklists for each technical area.

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NVLAP ASSESSMENT AND EVALUATION MANUAL

I. INTRODUCTION

This manual describes the role of a NVLAP Technical Expert (TE) in performing the laboratory assessment and evaluation functions of the National Voluntary Laboratory Accreditation Program (NVLAP). The information covers the responsibilities of a NVLAP TE as a representative of NVLAP who must understand all aspects of the accreditation process, including NVLAP policies and procedures, the prescribed sequence of events, and the conduct of an on-site assessment.

The NVLAP accreditation process is described in handbooks specifically prepared for each field of testing in which accreditation is offered. Handbooks are included in the application packages provided to prospective participants in a given laboratory accreditation program. Each handbook also identifies the specific criteria and other technical requirements for that particular program.

II. NVLAP APPROACH TO ACCREDITATION

NVLAP provides an unbiased third-party evaluation of an applicant organization. Potential clients of that organization can consider NVLAP accreditation as an indicator of confidence in selecting required services.

NVLAP helps both laboratories and their clients. It provides assistance and support to applicant organizations and encourages self-improvement. Users are supplied with information about accredited organizations so that they can make appropriate choices with respect to the services they need.

The NVLAP approach is non-adversarial; it is non-antagonistic, and helpful, but not patronizing. There are no unreasonable demands nor unnecessary requirements. Although conformance with the accreditation criteria is firmly required, flexibility is exercised by assisting applicants in achieving that conformance.

III. ROLE OF NVLAP TECHNICAL EXPERTS

NVLAP TEs carry out several functions in the accreditation process. They conduct on-site assessments of applicant laboratories, evaluate pertinent information (including assessment reports, responses to reports of deficiencies, and proficiency test results) for the purpose of recommending appropriate accreditation actions, and they are a technical resource to NVLAP.

The TE's main contribution is technical expertise. TEs provide technical advice and analyses required to evaluate a laboratory's compliance with the accreditation requirements. NBS technical staff and others may also contribute technical expertise at various stages of the development and implementation of NVLAP activities.

Each laboratory must be evaluated, as uniformly as possible in relation to others. Assessments and evaluations must be fair and even-handed. Interpretations of requirements must be consistent among all TEs within the same technical area. If doubts arise about a requirement, they should be discussed with other TEs as well as the cognizant NVLAP staff.

On-site Assessor

As an on-site assessor, a TE travels to the laboratory site and performs an in-person assessment of personnel, equipment, procedures and records. In this role, a TE represents NVLAP directly and is expected to act in a friendly, courteous, professional manner. Two types of assessments are performed, a regular on-site, where all aspects of the laboratory are reviewed, and monitoring visits, where the review is limited.

Technical Evaluation

In conducting a Technical Evaluation, the TE reviews the complete file of information gathered on a laboratory to determine if the technical requirements for accreditation have been met. This may be done individually, in a group meeting with other TEs, via conference telephone call, by mail or other appropriate means. The result will be a recommendation to accredit, a request for further information, or a recommendation not to accredit.

Technical Resource

Issues requiring technical assistance occasionally arise. The NVLAP staff may not include the requisite technical experts and hence must have access to appropriate technical resources. These resources may be immediately available from an NIST technical division; otherwise, the NVLAP TEs for that technical area will be called upon for assistance.

Conflicts of Interest

Since the TEs review extensive information about applicants, perhaps including sensitive data about the operation competition, or other business practices of the applicant organization, it is vital to avoid any real or apparent conflict of interest. If a TE knows or anticipates that there is or may be a conflict of interest with a given assignment it is incumbent on that TE to advise the appropriate NVLAP staff immediately.

IV. PREPARATION FOR AN ON-SITE VISIT

NVLAP assignment of a TE

The assignment of TEs to perform assessments is based on matching individual expertise with an applicant's requested scope of accreditation, at the same time avoiding any conflict of interest. A TE should notify NVLAP immediately if technically unprepared to assess or evaluate a laboratory or if aware of possible conflict of interest. Normally, different assessors are scheduled on successive visits to a laboratory.

For the first one or two assessments, an assessor is usually accompanied by a NVLAP staff person. The assessor subsequently works alone although a NVLAP staff person, or possibly a new TE in training, may occasionally accompany an assessor.

Laboratories have the right, with appropriate cause, to refuse acceptance of an assessor. Since applicants are usually informed in advance about the proposed assessor, any objections will normally be considered prior to the assessor's contacting the applicant or going to the premises. In the event that an applicant refuses an assessor when called, or at the door, the assessor should notify NVLAP staff immediately.

When a TE is assigned to perform an assessment, NVLAP will send copies of the applicant's application form, any proficiency test data, the last assessment report, any deficiency response letters from the applicant, and any other pertinent information. These documents should be kept in confidence. After the assessment has been completed, the TE must return all documents to NVLAP.

An assessor typically has at least 60 days to schedule and complete the assigned assessment(s). A faster response may occasionally be requested.

Preparation

An assessor must prepare for an assessment by thoroughly reviewing all information and organizing the time available during the assessment to the best possible advantage. Inadequate preparation will slow down the assessment, create an unfavorable impression of NVLAP and the assessor, waste the applicant's time, and render the results less valuable.

Preparation for an initial assessment (first-time applicant) may be substantially different from that of a renewal applicant. The initial assessment will require more concentration in all areas of activity, whereas the renewal assessment should concentrate on problems previously noted.

When preparing for an assessment, the TE should:

1. Notify the applicant at least one month in advance.
2. Discuss with the applicant by telephone: the laboratory location, directions, dates, time of arrival, security arrangements, names of laboratory staff who will be involved in the assessment, suitable lodging arrangements, proposed agenda, requested demonstrations of specific tests.
3. Request that the applicant send appropriate information for the TE to review before the visit (e.g., QA manual and procedures). Explain to the applicant that any documents sent in advance will be held in confidence and will be returned upon completion of the assessment.
4. Review all relevant information (e.g., criteria, test methods, QA manual, application information, previous assessment reports, deficiency correction letters, proficiency test results). Prepare

questions based on previous assessment reports and correspondence to address weaknesses previously observed. Review any proficiency test results and look for trends that might indicate weakness of any apparatus or of procedures. This information may be used to decide what tests need to be demonstrated.

5. Develop an agenda. If time allows, send the proposed agenda to the applicant.

V. ON-SITE ASSESSMENT

The on-site assessment is an extremely important element of the evaluation process. An assessment is conducted before initial accreditation and periodically thereafter. Assessments may last from one to several days and may involve more than one assessor depending on the scope of accreditation desired by the applicant.

Checklists

The assessment is conducted with checklists, which are used to:

- ensure uniformity of assessments among assessors;
- guide each assessment;
- provide a place for recording notes during an assessment;
- help assessors prepare exit briefings and assessment reports;
- provide physical evidence that an assessment was performed and that all applicable aspects of the laboratory were examined; and
- provide information for future assessments, thus facilitating continuity.

The structure and content of assessment checklists differ with technical area. Specific instructions are provided with each set of checklists.

Some general tips in completing the checklists:

- Be sure that each item on the checklists has been completed or that there is a definite indication that no answer was feasible or applicable.
- Keep as many notes as possible on the checklists; if there is insufficient space, use additional sheets of paper;
- Although many of the items on the checklists are arranged in a suggested sequence, the sequence may be altered as necessary.

Typical Steps of an Assessment

After the entry briefing, an assessment may be performed in any order. It is generally advisable to follow the checklist sequence, but not always required. Some assessors plan a sequence of activities with which they are more comfortable. The purpose of the assessment is to verify that the laboratory complies with all applicable NVLAP accreditation requirements.

During the assessment, the laboratory contact person should be kept informed of any deficiencies that are uncovered so that corrective actions can be effected as soon as possible, perhaps even prior to the exit interview. This policy avoids surprises at the exit interview, establishes good rapport, and makes for a smoother assessment.

A typical sequence of an assessment follows:

1. Conduct an entry briefing. Upon arrival at the laboratory to be assessed:
 - meet with the laboratory's authorized representative and all others who will assist with the assessment;
 - explain the purpose of the assessment and announce the agenda;
 - request an escort who is knowledgeable about the laboratory's management, quality assurance, and procedural systems to ensure cooperation of laboratory personnel;
 - confirm that any laboratory documents previously reviewed are still current;
 - request a place to review laboratory documentation and records, to complete the checklists, and to compose findings;
 - discuss the schedule for the day, conforming as far as possible to the laboratory's working hours, lunch hour, and coffee breaks;
 - agree on a tentative time for holding the exit briefing;
 - write down all names and positions of relevant persons for future reference;
2. Walk through all areas of the laboratory where testing activities are carried out pertinent to the requested accreditation to become acquainted with the layout and to meet the cognizant laboratory personnel.
3. Examine QA manuals, personnel competency records, equipment maintenance and calibration records, sample handling, and recordkeeping procedures.
4. Examine test plans, reports, data logs, and related records.

5. Trace one or more samples through the laboratory process, from receipt to final test report. Three possible approaches are to:
 - trace a test through the testing process forward from receipt of sample to final test report;
 - trace a test back from final test report to receipt of sample; or
 - randomly select certain files, data sheets, reports, etc.

The first two approaches are generally more efficient and effective than the third. Indeed, some questions on the checklists are sequenced for these two approaches. The third approach should be used when a large number of test methods must be covered.

6. Witness demonstrations of selected procedures by laboratory staff. These should usually be performed by the individuals who normally do them, not by the supervisor or manager.
7. Interview technicians. If possible, conduct these interviews in private with the supervisor not present.
8. Physically examine equipment and facilities. Observe the equipment for appropriateness, general appearance and working condition. Do not operate, disassemble or otherwise manipulate the equipment. Ask the regular operator to perform any operation, adjustment or disassembly required to establish evaluation conditions.
9. Complete the assessment report. Review all checklist items, notes and other information collected. Summarize all findings on the report form and add anything thought to be significant, whether complimentary or negative. Specify any items that are deficient and require a response from the laboratory.

Be sure to discuss any observed deficiencies. Sometimes further information can be provided and change first impressions. If a deficiency is found, ask questions to discover the cause. After determining the underlying cause, suggest corrective action that might help to satisfy requirements. A constructive suggestion for corrective action is likely to be acted upon promptly by the laboratory, particularly if it is easy to implement and holds promise of being effective.

Note whether the laboratory is already aware of a deficiency. If so, determine what action has been taken to determine the cause and to implement corrective action.

Some deficiencies are more critical than others. It is virtually impossible, however, to provide decision rules for objectively ranking deficiencies. Here the assessor's expert technical judgment comes into play.

Some typical causes of deficiencies can be categorized as follows:

- Measures have not been taken to ensure that an activity is performed, or that it is performed properly.
- Lack of indoctrination/training of the personnel
- Lack of time--too much pressure of work, overwork, or inadequate manpower.
- Lack of resources--incorrect equipment.
- Lack of top management support.

Typical deficiencies include:

- Required items in the criteria are not addressed.
- Contents of instructions are not adequate.
- Procedures/test plans do not have sufficient detail.
- Outdated copies of documents are still in use.
- Procedures described in the QA manual or instructions have been ignored.
- Samples/specimens bear no identification to permit traceability.
- Responsibility for keeping documents updated has not been assigned.
- No planned maintenance records of equipment are available.
- Equipment is out-of-tolerance and/or has not been calibrated or verified at requisite intervals.
- Cleanliness is inadequate.
- No provision is made for protected storage in the laboratory.
- Substitute equipment is used without acceptable evidence that it performs as specified by the pertinent standard involved.
- Supervision is inadequate.
- On-the-job practice is careless.
- Personnel are not adequately trained to perform their tasks.
- Objective evidence that attests to the training/certification of competence of the personnel is not available in laboratory files.

10. Conduct an exit briefing.

The laboratory will decide who attends the exit briefing. However, the assessor should request that, as a minimum, the laboratory's QA manager or equivalent and the laboratory supervisor should attend. For future reference, the assessor should identify the attendees at the exit briefing on the first page of the assessment report.

For each deficiency, describe the finding, the justification or reason for stating the finding and, if appropriate, the proposed corrective action. Make sure that the laboratory understands each deficiency and what is required to achieve compliance.

Some identified deficiencies may be challenged. The laboratory's technical staff are also experts hence differences of opinion may arise. Try to resolve disagreements and be satisfied that the NVLAP criteria have been met. If the laboratory is adamant about a contrary position, don't argue: ask them to document their position in a written response to NVLAP. The NVLAP accreditation process provides a second level evaluation, including a review by other technical experts and NVLAP staff of each assessment report.

Advise the laboratory to write NVLAP within 30 days describing action taken or planned to be taken for each specific deficiency identified in the assessment report. The letter must be signed by the authorized representative of the laboratory, who can verify the statements made in the letter.

Laboratories assessed for initial accreditation must correct or provide a substantive plan for correction of all deficiencies prior to accreditation. If considerable time will be required to meet the criteria, they may request that NVLAP hold their application inactive until they are ready to proceed.

If any deficiencies are noted at laboratories which are currently accredited, such deficiencies must be corrected within 30 days or they may face suspension or revocation of accreditation. When out-of-calibration apparatus is cited, emphasize that the apparatus should not be used until corrective action has been completed.

During the exit briefing, watch for warning signs of difficulties in obtaining compliance. Normally, the management should be advised of all problems encountered at the laboratory. However, in unusual circumstances, a separate follow-up note to NVLAP should be considered if major problems at the laboratory could not be openly or comfortably discussed with the laboratory's management.

Make any necessary revisions or additions to the assessment report in light of the exit briefing. At least one laboratory representative, preferably the authorized representative, must sign the assessment report indicating that it has been discussed during the exit briefing. Leave a copy of the report with the person who signs it or allow the laboratory to photocopy the report. Do not leave a copy of the checklists.

After leaving the laboratory, mail the original copy of the checklists and the signed original of the report to NVLAP. Retain a copy of all sheets in case the originals are lost in the mail, and to refer to during the technical evaluation. After an accreditation decision is made by NIST, return all documents pertaining to the assessment to NVLAP. Mail all documents to:

NVLAP
National Institute of Standards and Technology
Bldg. 411, Room A124
Gaithersburg, MD 20899

Monitoring Visits

In addition to regularly scheduled on-site visits, an assessor may be asked to conduct monitoring visits. These may be scheduled for cause or on a random selection basis during the accreditation period. These visits serve to verify reported changes in the laboratory facilities and operations or to explore possible reasons for poor performance in proficiency testing. The scope of the monitoring visit may range from checking a few designated items from the checklists to a complete review. An assessment report is written and left with the laboratory as is done during a regular assessment, but only pertinent checklist items need be covered or completed.

When an assignment is made for a monitoring visit, NVLAP will specify what should be examined, but the assessor has considerable latitude to make judgments about other items that should be reviewed. Monitoring visits generally last no longer than one day.

General Assessment Conduct and Technique

A successful assessment will require more than technical expertise. Courtesies to be observed, attitudes to be taken, ethical issues, assessment concepts, and questioning techniques all come into play.

While conducting an assessment, an assessor should:

- Conform to the normal operating schedule of the laboratory insofar as possible.
- Be determined, decisive and direct.
- Keep the assessment moving and be aware of the overall progress to avoid wasting time. Having obtained enough evidence to form the basis for a sound judgement, there is no point in going over the same ground.
- Be honest and fair. Personal dislike/prejudices must not interfere with the assessment.

- Be independent. The assessor decides what will be examined.
- Recognize the difference between a "clean-up" job and a "cover-up" job.
- Discuss and clarify problems right away to deter later arguments after memories have grown hazy, then collect new information. If the discussion reaches an impasse, do not argue but proceed to the next item.
- Be prepared to return to an area, if necessary, to obtain new information and to reassess the operation in the light of new information.
- Keep a sense of proportion. Keep the magnitude and significance of a deficiency in perspective. Don't pursue trivial matters which waste time and effort and risk alienating the laboratory.
- Be constructive at all times. If a deficiency is found, an assessor may suggest possible corrective action.
- Admit mistakes when wrong; this elicits cooperation and respect from the laboratory.
- Be helpful. Suggest procedures that may be beneficial to the laboratory. Such helpful suggestions need not be NVLAP-oriented. Be careful, however, not to give away another laboratory's "trade secret" in an attempt to be helpful. Open literature sources are preferred.
- At the end of each day, give the laboratory representatives a brief summary of activities, as a courtesy measure. It limits the need to make embarrassing revelations at the exit briefing and in the assessment report and forewarns the laboratory about any deficiencies encountered. A deficiency observed early in the assessment can often be corrected before the exit briefing.
- Try to answer all questions posed; if you lack information, offer to provide an answer at a later date, but be sure to follow up or to refer questions to the NVLAP staff.
- Thank the laboratory for its assistance and hospitality. Even if there were some contentious issues and differences indicate that you appreciated the laboratory's cooperation.
- Treat privileged information as such.
- Avoid all situations which might be construed as undue or improper influences on your assessment findings.
- Do not request favors from laboratories which can be construed as improper or an imposition.

- Plan to pay for all meals. In some cases, the only eating facility is a laboratory-operated cafeteria. Lunch supplied by a laboratory in these cases is acceptable. However, always offer to pay.
- Avoid making derogatory remarks about specific manufacturers or suppliers of equipment or about their products.
- Do not promote any specific vendors products.
- Avoid making derogatory remarks about individuals either within or outside the laboratory.
- Avoid becoming involved in intra-laboratory personnel problems.

Information Collection

Assessment is an information collection process that includes verification of application information; questioning staff; examining facilities, equipment, and records; and reviewing applicable proficiency testing results. An assessor should collect information by observing and listening (allowing laboratory staff to do most of the talking). While conducting the assessment, please note the following:

- key persons interviewed;
- applicable document designations, revision dates, where found, and descriptions;
- equipment numbers and identification to cross reference with calibration and maintenance records;
- sample/specimen identification system;
- identification of document/information/equipment recipients in laboratory;
- flow charts showing how the laboratory functions in terms of input(sample receipt), prerequisites (people, equipment, etc), processing (testing procedures), and output (test report), latest revision dates in the QA manual, procedures, and instructions.
- Do the laboratory staff members know their jobs?
- Do the lab managers/supervisors want to answer all questions? Some may want to address them all, either fearing that subordinates will commit an error that reflects adversely on the laboratory, or because they feel it is their right and responsibility to be the knowledgeable spokesman. Make it clear that the "worker" should answer the questions, explaining that the purpose of the assessment is to determine what is actually being done and to verify that the procedures are implemented as indicated in the quality manual.

- Does the staff try to bluff its way out of a tight corner?
- Does the staff know the QA manual and associated procedures and where these documents are?
- What is the condition of facilities and equipment? Are the requisite calibration tags or stickers on the equipment?
- Does it appear that the QA and procedural documents are used?

Questioning Techniques

Effective questioning is vital to an assessment's success. It is of great value to keep the systems concept in mind, to separate the laboratory's work into input, prerequisites, process, and output, and to ask questions on each of these individually and in turn. Verbalizing an understanding of how the system works will allow the laboratory to correct any misconceptions.

Ask questions that require a substantive response (e.g., "Who, What, How, When, Where, and Why" questions force a substantive response), rather than a "Yes/No" answer. Questions that require a "Yes/No" answer are useful to clarify particular points. Statements or questions such as: Show me what you do./Where do you put that?/How do you do that?/ are recommended. If there is a variation from written procedures, then ask "Why do you do it that way?"

Hypothetical questions are good when little objective evidence is available. "What if..." or "Let us suppose..." or "I don't understand..." is usually effective in such situations. Avoid questions that suggest the expected answers.

Silence can be extremely powerful. When faced with a silent person, some people may feel a response is expected, or because they are not quite sure what the response should be, they may say more than they otherwise would. This often produces useful information.

Be aware of what the laboratory staff does not say. If answers are superficial or evasive, be prepared to continue the line of questioning.

Be alert to differences in information presented from different sources (i.e., conflicting answers from staff members or differences between documented procedures and what is actually observed or said).

Attempt to put the staff at ease at the beginning of a questioning session since they will probably be nervous and, if so, may become withdrawn or defensive, or worse--by responding aggressively. Do not be aggressive in return, but be thorough (and occasionally persistent) enough to establish the factual situation. Keep the following points in mind:

- Direct questions to the person who performs the task being assessed, not to that person's superior.
- Never talk down to anyone.
- Talk the "lab's language".
- Give credit where credit is due. A compliment, sincerely given, goes a long way towards eliciting cooperation.
- Be interested in the laboratory's work and responses.
- Don't appear to be distrustful of people or to regard their responses with criticism.
- Be calm and courteous and thank people for their time.

VI. TECHNICAL EVALUATION

A technical evaluation (second level review) of all applicants is performed prior to granting accreditation. Normally, one or more TEs who were not involved in the assessment, along with NVLAP staff, review the evaluation folder for each laboratory. The evaluators provide technical judgments on whether an applicant complies with the conditions and criteria for accreditation and make recommendations on appropriate accreditation actions. In some cases, a special form is used to record TE evaluation recommendations. A TE recommendation is based on:

- information provided on the application;
- assessment reports;
- actions taken by the laboratory to correct deficiencies observed during the on-site visit;
- results of proficiency testing from current and previous assessment periods; and
- information from any monitoring visits.

If a laboratory is not considered to be in compliance with all requirements, it is notified with a request for additional information to demonstrate compliance. An additional assessment may occasionally be scheduled.

The NVLAP staff prepares the paperwork, including the transmittal of correspondence to any laboratory for which the evaluators need additional information concerning deficiencies that must be resolved before accreditation can be recommended.

When a laboratory is notified about specific deficiencies, it must respond within 30 days to provide documentation or certification by an authorized member of management that the specified deficiencies have been corrected. Clarification of some issues may be requested by telephone. All deficiencies must be corrected before accreditation is granted.

Whenever an applicant laboratory satisfies all requirements, a certificate and scope of accreditation is sent to the laboratory.

SUMMARY

NVLAP is a system which provides fair, unbiased evaluation of the competence of testing laboratories to provide various but specific testing services. Rigorous criteria, are rigorously applied. The resulting accreditation benefits both the accredited laboratory and the potential user of laboratory services who may use accreditation as a selection factor that will inspire confidence.

The NVLAP Technical Experts play an extremely important role in the accreditation process, both as on-site assessors and as technical evaluators. To carry out their functions these individuals must possess extensive technical knowledge and excellent communication skills.

The principles and techniques described in this manual, if understood and followed, will provide a solid basis for performing the functions of a NVLAP technical expert. An individual who represents NVLAP, is expected to demonstrate the highest standards of competence, character and ethical conduct.

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The National Voluntary Laboratory Accreditation Program (NVLAP), established in 1976, is administered by the National Institute of Standards and Technology (NIST) formerly the National Bureau of Standards (NBS). NVLAP is a voluntary system for assessing and evaluating testing laboratories and accrediting those found competent to perform specific test methods or types of test methods. Laboratory Accreditation programs are established for specified product or service areas in response to requests and demonstrated need.

This publication, intended for the NVLAP technical experts (TEs) who serve as assessors and evaluators, describes general policies and practices of NVLAP assessment and evaluation. The specific technical criteria for assessing and evaluating laboratories are provided elsewhere, in NVLAP Handbooks and checklists for each technical area.

12. KEY WORDS (6 TO 12 ENTRIES; ALPHABETICAL ORDER; CAPITALIZE ONLY PROPER NAMES; AND SEPARATE KEY WORDS BY SEMICOLONS)

accreditation; assessment; assessor; evaluation; evaluator; laboratory; technical expert

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