



QUALITY ASSURANCE PROGRAM

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**OREGON DEPARTMENT OF TRANSPORTATION
QUALITY ASSURANCE PROGRAM**

I. OVERVIEW

The Oregon Department of Transportation (ODOT) has implemented a Quality Assurance (QA) program approach that complies with the FHWA Guidelines for a QA program for construction projects on the National Highway System. This program defines the responsibilities of the contractor and ODOT in order to satisfy the needs of the program. This program is currently used for all construction projects administered by ODOT or its consultants.

ODOT recognizes that there are other benefits of developing and implementing Quality Assurance specifications into its construction program. These benefits include:

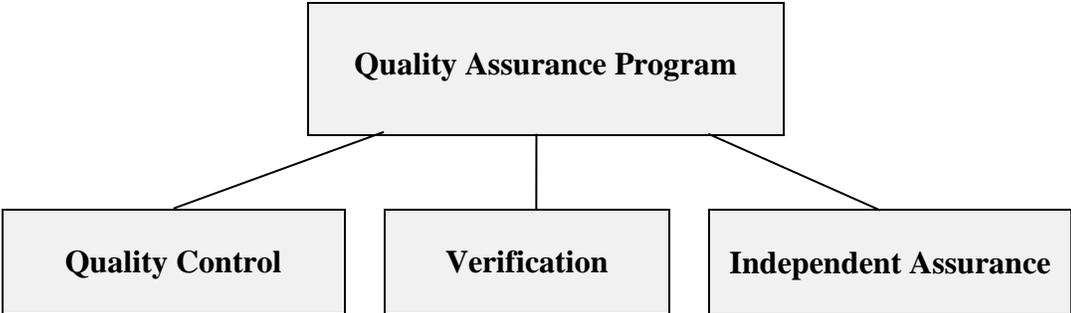
- To improve the overall quality of highway and bridge construction; and
- To place responsibility on the contractor for quality control in contracted work.

The success of the Departments Quality Assurance program is dependent on three primary features. The first is the Laboratory Certification program, which is discussed in Section III, Pg. 7, of this document. The second is the Technician Certification program, which is discussed in Section IV, Pg. 14, and the final feature is the specific product QC/QA testing plan detailed in Section VI, Pg. 26, of this document.

Quality Assurance (QA)

Quality Assurance is defined as: *All those planned and systematic actions necessary to provide confidence that a product or service will satisfy given requirements for quality.*

ODOT has developed its QA Program, which includes three separate and distinct sub-programs as illustrated below:



Quality Control (QC)

Quality Control is defined as: *All contractor/vendor operational techniques and activities that are performed or conducted to fulfill the contract requirements.*

The contractor is responsible for providing quality control sampling and testing, furnishing material of the quality specified, and furnishing QL levels during aggregate production, when required. The contractor's Quality Control technician must perform or observe the sampling operations. Testing operations will be performed by a Certified Technician. The certified technician, who performs the sampling and testing procedures, must sign the testing documentation.

Contractor quality control tests will be used for acceptance only if verified by tests performed by an independent group (Region QA).

Small quantities of some materials may be accepted when requested by the contractor and approved by the Project Manager (see Section 4(B) of MFTP).

ODOT will perform testing for all source/compliance tests and those non-field tested items associated with construction products (e.g. asphalt's, emulsions, tack, water, cement, lime, etc.).

Verification

Verification is defined as: *Sampling and testing performed to validate the quality of the product.*

Verification samples are taken randomly (minimum ten-percent frequency of subplot quantity identified in Section 4(D) of the MFTP) and tested by an independent group (Region QA) to verify that products meet required specification(s). Quality Control samples shall not be used for verification.

Independent Assurance

Independent Assurance is defined as: *Activities that are an unbiased and independent evaluation of all the sampling and testing procedures used in the acceptance program.*

ODOT's Independent Assurance (IA) Program uses a combination approach requiring laboratory certification, technician certification, proficiency samples, and where possible, split samples of verification or QC tests. The Construction Section certifies quality control and quality assurance testing laboratories and technicians. Contractor's test results of split IA samples are compared to Region QA test results for compliance using ODOT IA parameters. The PM performs random inspections of QC labs and technicians for compliance. The quality of Region QA test results are constantly monitored through the Departments proficiency samples program, which is outlined in, Section V, Pg. 24.

The Quality Assurance Testing (both Verification and Independent Assurance) will be performed by a Quality Assurance Laboratory designated by the Agency in compliance with 23CRF637.

Quality Assurance Program Components

Third-Party Resolution

Third Party Resolution is used when the Agency's Quality Assurance test results conflict with ongoing Quality Control test results and when verification requirements are not met or the conflict cannot be resolved. Third-Party Resolution can be requested by either the Contractor or the Project Manager.

Third Party Resolution testing shall be performed by a Dispute Resolution Laboratory. The Construction Section's Central Materials Laboratory performs third party dispute resolutions. This is normally done by testing quality control production backup samples, but may include other resolution techniques or procedures as determined by the agencies technical expert for the corresponding specification section.

The test result(s) of the Dispute Resolution Laboratory performing dispute resolution materials testing for any or all disputed test results will be considered the actual test results and will therefore be used for acceptance of the material.

CERTIFICATION ADVISORY COMMITTEE

The certification programs (both Technician and Laboratory Certifications) for ODOT's Quality Assurance program will be overseen by a Certification Advisory Committee. The purpose of this committee is to review and provide general oversight to the certification programs. The committee will be responsible for establishing policy as related to the certification programs and will also be responsible for reviewing allegations concerning abuse by technicians. The Certification Advisory Committee will perform other duties as required to successfully implement and continue the Certification Programs. A meeting of the committee may be called at any time by the Chair of the Certification Advisory Committee or by written request of at least two members of the Committee. A majority of the members of the Committee shall be present for transaction of official business.

Membership

Membership of the Certification Advisory Committee will include the following:

ODOT Construction and Materials Engineer (Chair)
ODOT Pavements Services Engineer
ODOT Quality Assurance Engineer
ODOT Structural Services Engineer
ODOT Laboratory Services Manager
APAO Executive Director or Representative

OCAPA Executive Director or Representative
AGC Heavy Highway Representative
Industry “At Large” Representative (appointed by Committee)

Random Samples

The Quality Assurance Program is based on theoretical conditions and the application of statistical acceptance procedures. Sampling shall be by simple random, stratified random or systematic means as specified.

To obtain a representative sample, a reliable system of random sampling shall be employed. Some work, like process control, lends itself quite well to the use of the Random Units Table and the Random Sample Location forms that ODOT has developed. ODOT TM 400 Determining Random Sampling and Testing Locations is also available to assist with Random Number determinations and test site locations. This is the preferred method to assure that the samples are representative and eliminate sampling bias. In other work, like Verification or Independent Assurance, it may be difficult to apply random numbers to sample selection. In this case, it is imperative that the samples are taken at locations or times, which do not have an identifiable pattern, and are completely random and without bias.

Commercial Source Quality Control

The ODOT quality assurance program allows some freedom for commercial sources to establish their own quality control plan that is tailored to the operation of the specific commercial source. The commercial supplier is required to submit a written quality control plan to the appropriate Region Quality Assurance Coordinator for approval. All testing for the approved quality control plan is required to be performed by a certified technician in an ODOT certified laboratory. Specific details on ODOT Approved Commercial Aggregate Product Program may be found in Appendix A, Pg. 46.

II. ROLES AND RESPONSIBILITIES

Contractor

The contractor's responsibilities are to:

- Furnish a written quality control plan (See Appendix B, Pg. 48, for minimum requirements);
- Furnish and incorporate materials/products which are of the quality specified;
- Provide ODOT certified technicians and laboratories;
- Perform quality control of all materials/products used on ODOT construction projects;
- Sample and test materials using appropriate devices and procedures;
- Furnish QL when required;
- Sample and provide splits to ODOT upon request, witnessed by an agency representative;
- Perform required tests on contractor's split of IA samples;
- Properly document, sign and deliver test results as required, on ODOT forms according to Section 3 criteria; and
- Retain splits of all QC samples until PM determines that the split samples may be discarded.
- Retain all split portions of IA samples until notified in writing by the Project Manager to discard.

Project Manager (PM)

The Project Manager has the authority and responsibility to enforce the provisions of the contract. The PM's Quality Control Compliance Specialist (QCCS) is involved with the project QA activities and is experienced and certified in all areas of field testing and documentation. The QCCS is required to maintain certification in CAgt, CEBT, CAT 1, CDT and QCT. Certification in CAT II, CCT and CMDT are recommended.

The Project Manager is responsible to ensure that:

- The project meets the requirements specified in the plans and specifications.
- All required tests are performed, documented, and submitted. The PM is also responsible for informing the QAC of project schedules, current quantities, and anticipated sampling requirements so verification testing can be accomplished.
- The contractor's QC program meets required standards. This is accomplished by performing inspections of contractor's personnel, testing procedures, and testing equipment.
- The contractor and Region Quality Assurance Laboratory is notified in writing within 5 working days of an IA/Verification sample's completion, as to which backup samples may be discarded or that an investigation is in progress. Upon the completion of an investigation inform the contractor, in writing, as to which backup samples may be discarded. Written notification will identify the Lot/Sublots, include the IA test results and if required the resolution of an IA investigation.

Region Quality Assurance Team

The Region Quality Assurance Team consists of a Quality Assurance Coordinator (QAC), Assistant Quality Assurance Coordinator and Quality Assurance Technicians (QAT). They are resources for the PMs, inspectors, technicians, other agencies, and contractors. They are also experienced in construction and design and certified in testing of construction materials.

Specific duties include, but are not limited to, the following:

- Maintain uniformity in construction and testing activities;
- Witness Quality Control Technician Sampling for IA and verification testing;
- Perform all required IA and verification testing;
- Properly document on ODOT forms according to Section 3 criteria;
- Calibrate or verify calibration of all nuclear moisture density gauges for ODOT, industry, and other agencies;
- Administer the Region's radiation safety program;
- Troubleshoot construction problems related to materials;
- Recommend changes to mix designs;
- Assist in the technician certification program;
- Oversee Region testing facilities;
- Inspect contractor facilities and/or technicians; and
- Assist in QC laboratory certification.
- Retain IA/Verification splits until notified by the PM.
- Administer the Commercial Source Program

Construction Section

The Construction Section's duties include:

- Support of the QA program by coordinating training and certification for technicians and by certifying all testing labs associated with ODOT construction projects;
- Administer the proficiency sample program;
- Provide third-party dispute resolution, according to the QA program, when necessary.
- Utilize the QA Steering Committee to establish and ensure statewide consistency in the QA Program.

III. LAB CERTIFICATION PROGRAM

OVERVIEW

The Construction Section (CS) developed this laboratory certification program to support the Oregon Department of Transportation's (ODOT) Quality Assurance Program for Construction Materials. This program recognizes three categories of laboratories that will test materials for ODOT construction projects: Quality Control, Quality Assurance, and Dispute Resolution. To ensure that laboratories consistently provide quality test results, they shall be certified according to this Program.

PROGRAM DESCRIPTION

Quality Control Laboratories

Quality control of construction materials is the responsibility of the contractor. Laboratories performing quality control testing may be the contractor's own, the material supplier's or an independent testing laboratory.

The ODOT Central Laboratory will certify all Quality Control Laboratories for those test methods necessary to perform Quality Control tests of construction materials for ODOT construction projects. An outline of the on-site inspection process and laboratory certification criteria is found in the "On-Site Laboratory Inspection Criteria", Pg. 9. This certification will be valid for one year. If a laboratory's certification expires and the laboratory has a continued need to test materials for ODOT construction projects, the laboratory shall apply for re-certification.

This laboratory certification process is designed to provide a "snapshot" of the quality of a laboratory. The ODOT Central Laboratory or its authorized representative will examine the laboratory's testing equipment for accuracy and conformance to specifications. If the laboratory's equipment is properly calibrated and within specifications, and if the laboratory meets all other conditions specified in the Lab Certification Program and On-Site Inspection Criteria section, ODOT will certify the laboratory as competent and able to test materials for ODOT construction projects.

Quality Assurance Laboratories

Quality assurance is the responsibility of ODOT (the owner). Quality Assurance Laboratories perform Independent Assurance (IA) and/or Verification tests in coordination with Quality Control Laboratories performing quality control tests of materials for ODOT construction projects. This provides ODOT with an independent analysis of the quality control test results to ensure that the results of quality control tests are valid.

Quality Assurance Laboratories will usually be ODOT Region Laboratories, but may also be the ODOT Central Laboratory or an ODOT contracted independent testing laboratory.

Quality Assurance Laboratories perform Independent Assurance (IA) and/or Verification tests during production of materials. These laboratories perform a portion of the tests that the Quality Control Laboratories perform. The quality control and quality assurance test results are compared to each other to determine the reliability of the quality control testing program.

The ODOT Central Laboratory will certify all Quality Assurance Laboratories for those test methods necessary to perform quality assurance tests of construction materials for ODOT construction projects. This certification will be valid for one year. If a laboratory's certification expires and the laboratory has a continued need to test materials for ODOT construction projects, the laboratory shall apply for re-certification. An outline of the on-site inspection process and laboratory certification criteria is located under the "On-Site Laboratory Inspection Criteria" section, Pg. 9.

This laboratory certification process is designed to provide not only a "snapshot" of the quality of a laboratory, but also an evaluation of the laboratory's performance in maintaining quality and consistency. ODOT Central Laboratory inspectors will examine the laboratory's testing equipment for accuracy and conformance to specification. In addition, the quality assurance laboratory is required to participate in the ODOT Central Materials Laboratory Proficiency Sample Program, see Section V, Pg. 24. If the laboratory's equipment is properly calibrated and within specifications, and if the laboratory meets all other conditions specified in the "On-Site Laboratory Inspection Criteria" section, then ODOT will certify the laboratory as competent and able to perform independent assurance and/or verification tests of materials for ODOT construction projects.

Dispute Resolution Laboratories

When Quality Control and Quality Assurance test results conflict and the conflict cannot be resolved; a neutral Dispute Resolution Laboratory will test the material in question. The test results of the Dispute Resolution Laboratory will decide the dispute.

The ODOT Central Laboratory will perform all third party dispute resolutions unless a potential for conflict of interest exists.

In the event that the ODOT Central Laboratory acts as the Quality Assurance laboratory, and that the dispute is therefore between the Quality Control Laboratory and ODOT Central Laboratory, the ODOT Central Laboratory will defer its dispute resolution duties to a certified laboratory agreed upon between ODOT and the Contractor.

The ODOT Central Laboratory shall certify dispute Resolution Laboratories., other than the ODOT Central Laboratory.

Any Laboratory which has run Independent Assurance, Verification or Quality Control testing on the material under dispute is considered to have a conflict of interest and shall not perform Dispute Resolution on its own tests.

ON-SITE LABORATORY INSPECTION CRITERIA FOR QUALITY CONTROL AND QUALITY ASSURANCE LABORATORIES

A laboratory desiring information and/or an application package for ODOT laboratory certification may contact the ODOT Central Laboratory at the following address:

Oregon Department of Transportation
Construction Section, Materials Laboratory
Attn: Lab Certification Coordinator
800 Airport Road SE
Salem, OR 97301-4798
Telephone (503) 986-3087

Laboratories requesting ODOT certification shall make arrangements to receive an on-site inspection. Forms will be included in the application package to facilitate the laboratory's response to this requirement. These forms are available electronically at the following URL address:

ftp://ftp.odot.state.or.us/techserv/construction/QA_Certification/lab_app_pkt_cert.pdf

It is the responsibility of the requesting laboratory to have their lab clean, organized and in complete operating order at the time of inspection. All equipment must be readily available and accessible. The ODOT Laboratory Certification Team does not search for stowed equipment. In addition an authorized representative must be present at the time of inspection to answer questions or respond to identify and present equipment. Failure to meet this criterion or to find unorganized, unkempt facilities may result in a canceled inspection.

On-Site Inspection

The Lab Certification Inspector will visit each laboratory whose application for certification has been accepted. The laboratory inspector will evaluate the laboratory using criteria A through H listed below. A discussion of the criteria follows:

- A. **Requirement: The laboratory shall maintain facilities (fixed or mobile) for proper control of the laboratory environment.** This criterion is used to evaluate the laboratory's physical ability to provide an appropriate environment in which to test materials. General requirements include: the facility shall be physically able to function as a laboratory (e.g. adequate power, water, lighting, floor space etc.) and have the capability of maintaining temperatures that are specified in the test methods for which the laboratory is seeking certification.

- B. **Requirement: The laboratory shall maintain facilities for proper storage, handling, and conditioning of test specimens and samples.** This criterion is used to evaluate a laboratory's physical ability to store samples and keep them organized. The laboratory shall maintain separate areas on its premises to store samples and splits of samples in an organized manner so that samples are not lost or discarded and may be found at a future date. In addition, the laboratory shall have facilities for the conditioning of samples as required by any test method for which the laboratory seeks certification.

- C. **Requirement:** Calibration certificates held by laboratories shall meet the requirements of ISO/IEC 17025 and shall include appropriate statements of uncertainty. Laboratories shall use accredited calibration service providers. The laboratory shall maintain necessary calibration equipment and reference standards. A laboratory shall have, on hand, calibration and verification equipment necessary to ensure the accuracy of its equipment. Such equipment could include calibration weights for scales or balances; manometers for the verification of vacuum pumps; thermometers etc.
- D. **Requirement:** The laboratory shall maintain equipment conforming to specification requirements necessary for the testing performed. This criterion is used to ensure that the laboratory's testing equipment conforms to the specifications listed in the test methods for which the laboratory is seeking certification.
- E. **Requirement:** The laboratory shall demonstrate adequate care when recording and processing data and test results. This criterion is used to evaluate the laboratory's ability to produce accurate test reports. The laboratory shall have procedures in place that facilitate the timely and accurate recording of data and the ultimate accuracy of its test reports.
- F. **Requirement:** The laboratory shall demonstrate proper techniques for selection, identifying, handling, conditioning, storing, and retaining test samples. This criterion is similar to criteria B but is concerned with the laboratory's internal policies and procedures rather than its physical capabilities in regards to the above activities. The laboratory shall have policies and procedures in place to ensure that its personnel and technical staff have the ability to select, identify, handle, condition, store, and retain test samples as required by the test methods for which the laboratory is seeking certification.
- G. **Requirement:** The laboratory shall include the laboratory's name and address and the name(s) of the technician(s) performing the test(s) on their test reports. This criterion is used to ensure that the above information appears on the laboratory's test reports that are submitted to ODOT. In addition to the above, the technician(s) certification card number shall be entered on all test reports.
- H. **Requirement:** The laboratory shall have on site at the time of inspection and during production operations, a copy of the current MFTP and all equipment (except items listed as **mobile equipment**) necessary to perform the test methods for which they have requested certification. The ODOT Lab Certification inspection team has a Color Coded Tagging System, which identifies various lab equipment that has met the certification criterion. The unique Colored Tag is valid for a 1 year period and starts from the date of the Final Report. (Note: Not all testing equipment is tagged; reference the appropriate test procedure to identify required equipment.)

Mobile equipment for additional test procedures may be added at a later date provided the following conditions are met:

- The laboratory must demonstrate adequate workspace and electrical system to operate required equipment.
- If equipment is new, they must provide copies of invoices that include the make, model and serial number of the equipment.
- If the equipment is rented or borrowed, it must come from another ODOT certified laboratory and provide the make, model and serial number as well as the number and color of the ODOT inspection tag.

Mobile Equipment

1. Ignition Oven
2. Gyrotory Compactor
3. Field concrete equipment

Preliminary Report

The ODOT Lab Certification Inspector will prepare a preliminary report of findings and present it to the laboratory manager at the conclusion of the on-site inspection. The preliminary inspection report will list all discrepancies for each test method in which the laboratory has requested certification. The inspector will discuss each discrepancy noted in the preliminary report with the laboratory manager in sufficient detail so that the laboratory manager understands the scope of the problem(s) and what corrective action is required in order to obtain certification for the test method(s) in question. When the inspector and the laboratory manager have covered all of the deficiencies, both parties will sign the preliminary report. These signatures indicate that both parties have read the report and understand its contents. The inspector will leave the original copy of the report with the laboratory manager and place a copy in the laboratory's permanent file.

The laboratory inspector will immediately (same or next day) FAX or hand delivers a copy of the report to the project manager and the region QA personnel for their files and general information.

Laboratories are expected to correct all deficiencies within thirty-days so that a certification may be issued. If a laboratory needs more than thirty-days to correct deficiencies, the laboratory shall notify the laboratory inspector, in writing, explaining why they need additional time. The laboratory will not be certified until all deficiencies are corrected.

If the ODOT Lab Certification Inspector within the thirty-days receives no response to the preliminary report allowed, then the laboratory will be immediately decertified until the deficiencies are corrected or a written response has been received.

Final Report

Once all of the deficiencies have been corrected the ODOT Lab Certification Inspector will prepare a final report of findings and mail it to the laboratory.

The laboratory inspector will mail copies of the final report to the project manager and the region QA office.

Certificate of Laboratory Certification

The ODOT Central Laboratory will prepare a Certificate of Laboratory Certification for a laboratory when the laboratory has met the requirements listed in “On-Site Laboratory Inspection Criteria”, Pg. 9, and has corrected all deficiencies noted by the inspector. The certificate will be mailed to the laboratory with the final report of findings. The Certificate will include the type of certification, laboratory name, test methods the laboratory has been certified to perform, color of the inspection tag and the Construction Section Manager’s signature. This Certificate is proof of a laboratory’s ODOT certification for the listed test methods and may be presented as such to any ODOT project manager.

The laboratory inspector will mail copies of the Certification with the final report to the project manager and the region QA office.

Certificates of Laboratory Certification are valid for one-year from the date of the inspection.

Follow Up On-Site Inspections

If at any time during a laboratory’s term of certification, the project manager or region QA personnel suspect that any of the contractor’s laboratory equipment, conditions outlined under Requirement H or the laboratory building itself are out of specification, the project manager or region QA personnel may request an additional on-site inspection. The project manager or region QA personnel will contact the Lab Certification Inspector and schedule the follow up on-site inspection.

If the follow up on-site inspection reveals that the laboratory is deficient in one or more areas, the laboratory inspector will immediately decertify the laboratory for those test methods affected by the deficient equipment or facilities. The laboratory inspector will recertify the laboratory following correction of all deficiencies. A laboratory may not perform materials tests using test methods for which it has been decertified.

Laboratory Decertification

A Quality Control or Quality Assurance Laboratory may have its entire certification or its certification for specific test methods revoked by ODOT if it is found to not conform to the specifications and standards of its ODOT certification. A laboratory that has had its certification revoked for a specific test method(s) may not test materials that require the use of such revoked test certification(s). A laboratory that has had its entire certification revoked shall promptly cease testing materials for ODOT construction projects.

A laboratory that has had its certification partially or entirely revoked may seek reinstatement by demonstrating conformance to the ODOT Laboratory Inspection requirements.

In addition, any laboratory/company intentionally misrepresenting the status of their certification or falsifying test results will be subject to disciplinary action up to a one-year suspension of their certification. Any allegation regarding the practices of a certified laboratory will be made in writing to the Certification Advisory Committee. The Certification Advisory Committee will investigate the complaint and take appropriate disciplinary action. In all cases, the parties involved in the complaint will be provided an opportunity to appear before the committee before any actions are taken.

IV. TECHNICIAN CERTIFICATION PROGRAM

INTRODUCTION / BACKGROUND

The Oregon Department of Transportation's Quality Assurance Program will require all personnel and laboratories performing testing on ODOT projects to be certified. The level of certification is dependent on the specific type of testing to be performed. The Certification Advisory Committee, described in Section I, Pg. 3, of the QA Program, will provide approval and General oversight for the certification programs. Specific direction and administration of the individual certifications will be provided by ODOT unless other groups are specifically referenced in the description of the individual certifications.

The Oregon Department of Transportation is a member of the Western Alliance for Quality Transportation Construction (WAQTC), which consists of 11 western states committed to the quality of our transportation systems. WAQTC has developed a technician-training program, which is comprised of instructional, and student modules used to assist in the training process of material field-tested procedures. ODOT has adopted the training packages for all certifications except for ODOT specific certifications and those controlled by entities other than WAQTC such as QCT, CCT, CMTD and CAT II.

The purpose of the Technician Certification Program is to insure technicians performing testing have a minimum level of knowledge in the area of certification.

Technician Certifications

Following is a summary of the approved Technician Certifications currently in place. Initial certification, in any discipline, will be valid for a 3-year period, except CSTT, which is valid for a 5-year period. After the initial 3-year certification period has expired, the certification renewal period will be 5 years for all certifications, except CSTT, CCT, CMTD and Cat-II. CSTT will be valid for a 5-year period and CCT and Cat-II will be valid for a 3-year period. Recertification for CMTD is required every 2 years following the initial 3-year certification.

Certified Aggregate Technician (CAgT):

A CAgT performs a variety of tests on soils and aggregates including; sieve analysis, fracture, sand equivalency, and other tests. A CAgT also performs other duties as required by current specifications for soils and aggregate materials.

Certified Embankment and Base Technician (CEBT):

The CEBT performs testing of soils and aggregates for establishing the relative maximum density and optimum moisture for use in compaction testing of sub grade soils and aggregate bases. A CEBT also determines the Specific Gravities of aggregate.

Certified Density Technician (CDT):

A CDT performs in-place density testing of soils, aggregates, and asphalt mixtures using the nuclear density gauge. In addition to certification, a CDT must possess a current Radiation Safety Card issued by an approved source. For soil, soil aggregate mixtures, and aggregates a CDT determines percentages of coarse and fine material, performs one point testing and related calculations.

Certified Asphalt Technician I (CAT-I):

A CAT-I performs sampling and testing for ACP and EAC mixtures including AC content, maximum specific gravity, sieve analysis, void measurements, and other tests and duties as required by current specifications.

Certified Asphalt Technician II (CAT-II):

A CAT-II is responsible for managing the volumetric properties of asphalt mixes by controlling plant operations, for troubleshooting ACP sampling and testing processes, and for making appropriate adjustments to ACP production and lay down procedures. **Certification at CAT-II level is contingent on having successfully completed the CAT-I certification phase at least once.**

Certified Mix Design Technician (CMDT):

A CMDT is responsible for preparing ACP and EAC Mix Designs, including all material testing and data analysis necessary to properly complete a design. A CMDT prepares designs for both dense and open graded mixtures.

Quality Control Technician (QCT):

A QCT performs testing of fresh Portland cement concrete including sampling, concrete temperature, slump, unit weight, air content, and fabrication of specimens for strength testing and performs other duties including calculating cement content and water-cement ratio as required by specifications. QCT certification is obtained through the ACI Concrete Field Testing Technician - Grade 1 certification program, with the Oregon written Supplemental test, conducted by the Oregon Concrete and Aggregate Producers Association (OCAPA).

Concrete Control Technician (CCT):

A CCT is responsible for preparing concrete mix designs. Proportioning concrete mixtures to meet job requirements, and for making adjustments to the mix design as necessary to provide a concrete mixture of the quality required by specifications. A CCT certification is obtained through a training program conducted by OCAPA.

Concrete Strength Testing Technician (CSTT):

A CSTT is responsible for testing the compressive or flexural strength of hardened concrete cylinders or beams. The duties of a CSTT include proper capping of specimens (bonded and unbonded), correct operation of breaking device and visual evaluation of broken specimens. Also, the CSTT is responsible to insure the proper handling, mold removal, logging and curing of field fabricated samples upon arrival at the laboratory. A CSTT certification may be obtained through a program conducted by Oregon Chapter of the American Concrete Institute.

Who Must Be Certified?

All personnel responsible for sampling, performing testing, and reviewing test reports, required on projects, which the ODOT Quality Assurance Program applies must be certified. This requirement applies to project personnel working as technicians or fulfilling the role of a Quality Control Compliance Specialist for the State, Contractors, or Consultants on such projects.

Certification Requirements

To obtain any of the above certifications, the technician will be required to pass a written and/or a practical test demonstrating a knowledge and understanding of how to perform the specific tests and of specifications applying to the material being tested. All tests shall be administered and evaluated only by evaluators approved by the Certification Advisory Committee Chair, or their designated representative.

To apply for the certification, the applicant will register either for one of the approved training classes, where the exam will be administered as part of the class, or submit an application to challenge the exam. The challenge applications will be submitted through the approved training program to facilitate scheduling. Appropriate fees will be charged for the challenge exams to cover scheduling, overhead and facility use. Applicants will be scheduled for examination through a cooperative effort between ODOT and the appropriate training program service provider.

All certifications shall be contingent upon the technicians signing a rights and responsibilities agreement. This agreement outlines the technician's rights and responsibilities along with the possible consequences of the abuse and/or neglect of these responsibilities. The technician will submit a signed agreement at the time they take the certification examination.

Examination Process

The Asphalt Paving Association of Oregon (APAO) and Oregon Concrete Aggregate Producers Association (OCAPA) currently perform the instructional phase, while ODOT maintains the certification and administration of the written and practical exam processes. The certification system is made up of three phases. Phase one - WAQTC written exam, phase two - ODOT written exam and phase three - combined ODOT and WAQTC performance exam. During the exam process, only hand calculators are allowed, the use of computers is not permitted during any exam phase.

Challenge Process

A person may challenge the exam process if they feel that they have the knowledge and skills to be able to pass without attending formal training. If the person does not currently possess a certification for that specific discipline and fails any of the following mentioned examination events, then that person must attend the formal training for that certification. If the person currently possess a certification for that specific discipline and fails any of the following mentioned examination events, then that person may challenge the failed examination event for that certification a second time. If the person fails the challenged event a second time, then the person must attend formal training for that specific discipline.

WAQTC Written Examination

- a. Closed Book
- b. Consists of multiple modules, depending on the needed certification
- c. Each module consists of 5 questions with multiple choice, true or false, and required calculations.
- d. Written exam time lines vary depending on the needed certification. 1 to 1 ½ hours is given to complete the exam.

ODOT Written Examination:

- a. Open Book
- b. Consists of multiple choices, true or false, and essay questions related to test procedures as well as specifications and completion of various ODOT forms.
- c. Written exam time lines vary depending on the needed certification. 3 to 3 ½ hours is given to complete the exam.
- d. For CMDT certification, there are two written exams covering Dense and Open graded ACP, EAC and Aggregate Treatment applications. 4 hours is allowed for the Dense ACP exam and 2 hours for the Open ACP, EAC and Aggregate Treatment exam.

ODOT /WAQTC Combined Performance Examination

- a. Each participant will demonstrate proficiency in the designated test methods with prepared samples and will demonstrate the ability to apply specifications and ODOT specific requirements to the needed test and identify the quality of the material being tested.
- b. The exam is open book but the technician may not use the performance exam checklist.
- c. The performance examination for ODOT is performed in conjunction with the WAQTC performance exam. 4 ½ hours is given to complete the performance exam process with 4 hours actual lab time and ½ hour given to complete calculations. The performance exam answers are graded based on completion of the required tests, accuracy of computations, application of the correct specifications, and the results of computations meeting the parameters set forth in the Independent Assurance Parameters section of the Quality Assurance Program.
- d. During the performance exam the examinee may be asked to explain various steps of a procedure to reduce the full test time.

- e. The performance exam checklist consists of yes and no blocks. In order to complete the checklist successfully, all of the yes blocks must be filled out.

In the event, a participant fails the first attempt; a second attempt is given, if time permits, and after the exam proctor explains the correct procedure. Anyone failing a test method on the performance exam may repeat that trial during the day of the performance exam, depending on the timelines and the type of test. Repeat trials will be allowed in not more than 50% of the total test methods in that performance exam. If the participant fails on the second attempt the performance exam will stop and the participant will have to re-take the exam at the scheduling convenience of the Agency.

Passing Score – Written

- a. Initial exam (first attempt) WAQTC: An overall score of 70% with a minimum of 60% on any one-test method.
- b. Re-exam (second attempt) WAQTC: An initial exam overall score below 70% will require a re-exam on all test methods. An initial exam score above 70% overall, but below 60% on one or more test methods, will require a re-exam on only those test methods. In the case of one test method comprising the re-exam, the examinee must receive a score of 70%. In the case of more than one test method comprising the re-exam, the examinee must receive an overall score of 70% with a minimum of 60% on any one-test method.
- c. Initial exam (first attempt and second attempt) ODOT: An overall score of 70% is required to successfully complete the exam requirement.
- d. Initial exam (first attempt) for the QCT ODOT supplemental exam: An overall score of 80% is required to successfully complete the exam requirement. For the CCT and CMDT certification exams, an overall score of 75% is required to successfully complete the exam requirement.
- e. Re-exam (second attempt) for the ODOT QCT and CCT exam the participant must meet the same criteria as the Initial exam (first attempt).

Passing Score – Performance

- a. All performance checklists must have 100% yes blanks checked and each test method must be performed within the designated time limit. Each examinee is allowed two attempts to complete procedures if time allows.
- b. First attempt: Performing all the required tests, application of correct specifications and meeting the Independent Assurance Parameters is required to receive a pass rating. The grading is based on pass/fail of all associated tests performed under the desired certification.
- c. Second attempt: The same criteria as the Initial exam must be met.
- d. For CMDT, an acceptable Level 2, 3 or 4 ACP design must be submitted along with verification materials, as described in Section 6 of the most recent edition of the “Contractor Mix Design Guidelines for Asphalt Concrete”. A six-month period will be allowed for the mix design submittal from the date of the written exam.

Re-examination Policy – Written/Performance

Failure of any exam phase a second attempt will require attendance of the course for that qualification and passing the exam element failed on the second attempt if certification is still desired. In addition, on the date the certification exam was first taken a technician will have 120 days to complete the exam requirements for the desired certification. If the exam requirements are not met within the 120-day period and certification is still desired the technician will be required to perform the entire exam process again.

Applicants with Disabilities or Special Needs

Applicants with a disability or those having special needs should notify the Certification Advisory Committee Chair, or their designee, at the time application is made of what appropriate accommodations need to be made so that these can be planned for.

Disclaimer

Certification of an individual by the ODOT Technician Certification Program indicates only that the individual has demonstrated a certain level of competence on a written and/or practical examination in a selected field of activity. ODOT may require this certification of individuals performing activities specified in work contracts or other activities. ODOT and the Certification Advisory Committee make no claims regarding the abilities or competence of certified individuals. Each individual or organization utilizing certified individuals must make its own independent judgment of the competence of certified individuals. ODOT specifically disclaims any responsibility for the actions, or the failure to act, of individuals who have been certified through the ODOT Technician Certification Program.

To obtain certification may involve hazardous materials, operations and equipment. This program does not purport to address all safety or regulation concerns associated with the use of the procedures used. It is the responsibility of the users to use and establish appropriate safety and health practices and determine the applicability of regulatory limitations.

Documentation of Certification

Upon the successful completion of the examination(s), the participant's name, home address, and/or company affiliation is registered in the official registry of certified technicians for the appropriate certification. ODOT Construction Section maintains the official registry. It is accessible on the internet at the following address:

<http://highway.odot.state.or.us/cf/techcertDynamic/Index1.cfm>.

It is anticipated that many technicians will hold multiple certifications. An official letter(s) indicating certifications(s) held will be provided after successful completion of the certification process. A certified technician may request a laminated wallet-size identification card, which indicates all areas of certification.

Recertification

To remain current, a Certified Technician must obtain recertification before the expiration date of the certification. Recertification may only be obtained by passing the written and/or practical test required for that particular certification. A Certified Technician must apply for the individual certification for which they want to remain certified. The Certified Technician is responsible for scheduling his/her own written and/or practical comprehensive examination.

It should be noted that should a technician fail to successfully complete a Certification renewal in a specialty area, the technician will be considered disqualified in that area, only, until the requirements for Certification renewal have been successfully met, subject to the limitations set forth in this document.

Note: A certification extension may be provided upon written request to the QAE. The request should contain the reason for the extension, desired certification, and proof of future class attendance or challenge process through a registration of the training provider.

The length and conditions of any extension will vary and are at the discretion of ODOT.

Revocation or Suspension of Certification

The Certification Advisory Committee Chair for just cause may revoke technician Certifications at any time. Proposed revocations are sent to the individual in writing along with the individual's right to appeal the proposed revocation. A proposed revocation is effective upon receipt by the technician and will be affirmed, modified, or vacated following any appeal.

The reasons that certified technicians will be subject to revocation or suspension of their certifications are *negligence* or *abuse* of their responsibilities. The Certification Advisory Committee (CAC) may disqualify certified technicians for other reasons of just cause, which may or may not be specifically defined herein following the due process procedures outlined herein.

Negligence is unintentional deviations from approved procedures that may or may not cause erroneous results. The following penalties are guidelines for findings of *negligence*: The first finding of *negligence* will result in a letter of reprimand being sent to both the employee and the employer. Depending on the nature of the incident, the CAC could impose up to a 30 day suspension. The second significant incident during the certification period will result in the Quality Assurance Engineer (QAE) discussing the issue with the individual and their employer to establish a corrective action plan. Depending on the nature of the incident, the CAC could impose up to a 180 day suspension. The QAE will also notify the entire ODOT Quality Assurance staff of the issue. A third instance of neglect may result in permanent revocation of the Certification.

Abuse is knowingly deviating from approved procedures or when the technician should have known they were deviating from approved procedures. There are two levels of severity for *abuse*.

For level 1 *abuse*: The first finding may result in up to a 180-day suspension all of the Certifications of the individual. A second instance (within the certification period) would result in a minimum of 180-day suspension of all certifications.

For level 2 *abuse*: the first finding will result in a 1-year suspension of all Certifications of that individual. A second finding will result in permanent revocation of all Certifications.

Revocations or suspensions for *abuse* or *negligence* in one Certification area are considered revocations or suspensions in all Certifications held by the technician.

Allegations of *negligence* or *abuse* are made to the Quality Assurance Engineer (QAE) in writing. The allegations will contain the name, address, and signature of the individual(s) making the allegation. The QAE will investigate all allegations. The QAE will decide if the incident is significant to warrant review by the Certification Advisory Committee (CAC). If the incident is given to the CAC for review, then the accused and the individual(s) making the allegation are given the opportunity to appear before the CAC to present any appropriate information. Within a 60 day period, all involved parties will receive a report of the findings in writing. Any warranted penalties will be imposed in accordance with guidance contained herein and according to the guidelines outlined under the Technician Compliant Process. Decisions regarding allegations of *negligence* or *abuse* may be appealed in writing to the Committee Chair. The Committee Chair will independently consider such written appeals but may rely on the advice and counsel of the Committee.

In all cases, the CAC will conduct the investigation into the allegations and make a recommendation to the ODOT Construction Engineer as to appropriate sanctions against the technician. All final decisions regarding suspension of certifications will be up to the ODOT Construction Engineer.

Because ODOT is a member of the Western Alliance for Quality Transportation Construction, the Certifications are honored by other member states. The Certification Advisory Committee will notify the other members of the WAQTC, or other participants in the TTQP, of anyone having a Certification revoked or suspended.

TECHNICIAN COMPLAINT PROCESS

The Oregon Department of Transportation’s Technician Certification program is intended to assure qualified personnel are performing all materials testing for ODOT construction projects. In addition to certified technicians, the department needs a means to address concerns that are raised regarding those technicians not following approved procedures. The Technician Complaint Process will provide guidance on how to deal with these concerns. It should be understood that the intent of the process is to resolve differences of opinion on appropriate procedures at the lowest possible level. Technicians are encouraged to work together to resolve any differences they might have. Only when those issues cannot be resolved at the project level should they be raised to the level of filing an official complaint. It should be understood that in no way is the formal complaint process intended to remove any authority the Project Manager may have under an existing contract.

Any individual may file a complaint regarding testing procedures or practices. The first step when filing a complaint is to decide whether the issue is a case of “Neglect” or “Abuse”. “Neglect” is unintentional deviations from approved procedures. “Abuse” Abuse is knowingly deviating from approved procedures or when the technician should have known they were deviating from approved procedures. The appropriate process for dealing with the issue is followed after a decision is made on the type of offence. The following pages outline the process for dealing with both Neglect and Abuse:

Complaint Process for Neglect

Again, neglect is much less severe than abuse and individuals are encouraged to resolve their differences at the project level so the project can continue forward in a positive fashion. The complaint process for neglect is intended primarily to allow a means of tracking the types of problems being encountered and also to look out for technicians who seem to have repeated instances of neglect.

Step 1: When an individual discovers a significant problem with a technician’s procedures or testing process, that individual will personally point out the concern to the technician. The two individuals will work together to try to resolve the issue. They may need to refer to the Manual of Field Test Procedures or other contract documents to verify proper procedures.

If the two can agree on corrective action, the issue can be resolved at their level. If not, the Region QAC should be contacted for clarification. If discrepancies on correct procedures still exist, the issue will be brought to the ODOT Quality Assurance Engineer (QAE) for resolution.

Step 2: Once the problem is resolved, the individual who discovered the problem will send a short memo to the QAE describing the issue and the resolution.

The QAE will maintain a file of these incidents. Depending on the severity of the issue, the QAE may send a letter of reprimand to the technician and their employer and the CAC could impose up to a 30 day suspension.

Step 3: If a second significant incident is reported within the certification period for a specific technician, the QAE will discuss the issues with the technician and their employer and establish a corrective action plan to help the technician avoid further complaints. Depending on the nature of the incident, the CAC could impose up to a 180 day suspension. In addition, the CAC could require the technician to attend additional training and retake the particular certification exam before reinstatement as a certified technician. The QAE will also send out notice to all ODOT Quality Assurance staff of the issue. This notification is intended to help put ODOT staff on notice of particular problems being encountered.

Step 4: If a third instance of neglect is reported within the certification period, the specific technician and his/her employer must meet with representatives from the Certification Advisory Committee (CAC) to discuss the issues. The technician will be responsible for providing a plan of how they will correct their deficiencies and assure no further instances will occur. The CAC may gather further information to substantiate the claims. The CAC will review the information and could impose up to permanent revocation of the certification in question.

It should be noted that because of the potential for repeated offences of neglect, the CAC could at any point in the process make a determination that the successive instances no longer fit as neglect, but because of the repeated nature of an offense, may become an instance of abuse. If this occurs, the issue would be dealt with through the complaint process for abuse.

Complaint Process for Abuse

Because abuse is defined as intentional, the process for dealing with instances of abuse will be more formal and penalties more severe than for instances of neglect.

Step 1: If abuse is suspected, the issue shall be raised immediately to the ODOT Quality Assurance Engineer (QAE). The QAE will investigate the issue and make a preliminary determination on whether it actually is abuse or neglect. If the issue is determined to be abuse, move to step 2 below. If it is determined to actually be a case of neglect, move to step 1 of the process for dealing with neglect.

Step 2: The QAE will gather information regarding the incident from both the technician involved as well as the individual filing the complaint. The QAE will review the information and determine whether the incident is significant to warrant review by the Certification Advisory Committee (CAC). This review will be completed within 60 day of receipt of the complaint. If the incident is determined to be “significant” the issue will be put on the agenda for the next CAC meeting.

Both the technician and the individual filing the complaint will be invited to attend the meeting to present any appropriate information. Insignificant issues will be handled directly by the QAE and a summary of the incident will be submitted to the CAC for their review.

Step 3: The CAC will determine the merits of the complaint and also the severity level of the abuse. Abuse will be identified as one of two different levels of severity.

Level 1 being identified as the least severe form of abuse. This level is identified as knowingly deviating from approved procedures or when the technician should have known they were deviating from approved procedures. The key component for Level 1 Abuse is there is no misrepresentation the quality of material being incorporated in the project. This level of abuse could result in up to a 180 day suspension of all certifications held by the technician. The exact duration of the suspension will be set by the CAC depending on the circumstances encountered. A second instance (within the certification period) of Level 1 abuse would result in a minimum 180 day suspension of all certifications.

Level 2 abuse is much more severe. The distinguishing component of Level 2 Abuse is misrepresentation of the quality of material being tested. This level of abuse will be dealt with by a 1-year suspension of all certifications for the technician. A second instance of level 2 abuse will result in permanent revocation of all certifications.

V. QUALITY ASSURANCE LABORATORY PROFICIENCY SAMPLE PROGRAM

OREGON DEPARTMENT OF TRANSPORTATION CONSTRUCTION SECTION

Proficiency sample testing is an additional factor used to evaluate the performance of a Quality Assurance (QA) laboratory and the Quality Assurance (QA) laboratory technicians. It provides information not otherwise available from the on-site laboratory inspection (Section III, Pg. 9) and a means of continued monitoring of testing personnel and testing equipment. The ODOT Construction Section requires QA Laboratories and QA laboratory technicians to participate in this Proficiency Sample-testing Program. Participation includes testing all applicable samples, which are to be distributed and completed within the specified time frame. The resulting data is analyzed by the ODOT Quality Assurance Engineer.

Proficiency samples are distributed by Construction Section at annual intervals as outlined in the Proficiency Sample Testing Plan in Table 1 of this Section. The Construction Section will distribute a minimum of one set of samples from each material test method listed in Table 1 for each of the QA laboratory technicians. The ODOT Central Laboratory and the QA laboratory technicians will perform the required testing listed in Table 1 on each set of samples. The distribution of proficiency samples is not intended to coincide with the on-site laboratory inspection. Proficiency Sample test results will be submitted to the Quality Assurance Engineer within 30 days of receipt of the sample. The results will tabulate all of the testing results from the ODOT Central Laboratory and the QA laboratory technicians and statistically evaluate if any of the technician results are more than two standard deviations beyond the grand average value for each test method.

When a QA laboratory technician results are beyond two standard deviations of the grand average values, the Quality Assurance Coordinator (QAC) shall investigate the reason for the discrepancies and report the findings and actions taken to the ODOT Quality Assurance Engineer (QAE) within thirty days of issuance of a final report. The QAE will determine whether or not the findings warrant further action to address the testing deviations and identify steps that need to be taken to ensure that the technician is correctly performing the test. The QAE will be responsible for monitoring the technician testing results until there is confidence that the technician is following approved procedures.

When an ODOT Central Lab technician results are beyond two standard deviations of the grand average values, the ODOT Laboratory Services Manager shall investigate the reason for the discrepancies and report the findings and actions taken to the ODOT Quality Assurance Engineer (QAE) within thirty days of issuance of a final report. The QAE will address the testing deviations, identify steps to be taken, and be responsible for monitoring results in the same manner as for a QA laboratory technician.

If a QA laboratory technician or ODOT Central Lab technician exceeds the two standard deviation limit on the next year's Proficiency Samples for the same material test method and is not able to provide the QAE with a satisfactory explanation for exceeding the limits; the technician will immediately perform a backup proficiency sample witnessed by the QAE or designated representative. The QAE will review the process that was followed from the previous year's investigation findings and make a determination if the technician is not following approved procedures. If the QAE finds that the technician is not following approved procedures the QAE will immediately suspend the technician from performing any QA project work or third party dispute resolution work involving the test method that has been identified. The QAE will identify what steps are necessary to allow the technician to resume testing for the failing test method.

TABLE 1 – PROFICIENCY SAMPLE TESTING PLAN

January Distribution

TEST METHOD
SOIL & Aggregate Sample
Bulk Specific Gravity – AASHTO T 85
Coarse Particle correction – AASHTO T 99
Max. Density – AASHTO T 99 Aggregate Base
Max. Density – AASHTO T 99 Soil
Sieve Analysis – AASHTO T 27/11
Sand Equivalent – AASHTO T 176
Fracture – AASHTO T 335
Wood Particles – ODOT TM 225
Elongated Pieces – ODOT TM 229
ACP Mixture Sample
Bulk Specific Gravity – AASHTO T 166, Method A
Max. Specific Gravity – AASHTO T 209
AC Content by Incinerator – AASHTO T 308
Mechanical Analysis of Extracted Aggregate- AASHTO T30
Fabrication of Gyratory Specimen – ODOT TM 326

A laboratory may obtain additional information on the Construction Section's proficiency-testing program by contacting the Construction Section at the following address:

Oregon Department of Transportation
 Construction Section, Materials Laboratory
 Attn: Quality Assurance Engineer
 800 Airport Road S.E.
 Salem, OR 97301
 Telephone (503) 986-3061

VI. PRODUCT SPECIFIC QC/QA TESTING PLAN

The Quality Assurance Program consists of three distinct sub-programs. The Quality Control Program, the Verification Program and the Independent Assurance Program. This Section provides specific details on how these programs work together to assure specification materials are incorporated into ODOT projects. It also provides details on specific requirements of each of the programs for each of the materials, which are utilized on ODOT projects.

In general, contractor's quality control tests are obtained at the highest frequency. Agency verification tests are run usually on a minimum frequency of 10%, of subplot quantities identified in section 4(D) of the MFTP. While the Independent Assurance program takes steps to assure the quality of both the QC and the verification test results.

ODOT will accept materials based on the contractors QC test results only if verified by the Agency verification testing. Verification of QC test results will require all of the following conditions to be met:

1. The Department's testing results show that the material meets the specified quality.
2. The split samples meet Independent Assurance parameters.
3. The Department's Verification test results compare reasonably to the ongoing Quality Control data.

If any of the above conditions are not met, an investigation will be conducted by the Project Managers office to determine whether to reject the material or if the material is suitable for the intended purpose according to section 150.25 and also what price adjustment might be applied. See Investigation Criteria for details and requirements.

Step 2 in the above conditions compares the contractor's test results on the split IA sample to the agency results. The Independent Assurance Parameters to be used for the comparison are listed in Table 1 of this Section.

The following pages detail the Investigation Criteria, Quality Control, Verification and Independent Assurance requirements for each of the specific materials used on ODOT projects.

Investigation Criteria

The intent of the investigation is to determine reasonable cause for the discrepancy and provide supporting documentation of materials failing to meet the conditions outlined for Verification, Independent Assurance and prior Quality Control testing. An investigation is required for all materials failing to meet these conditions because of the potential impact on the quality of the material produced or incorporated into the project.

Several resources are available to assist with the troubleshooting process and data collection. Appendix C, Pg. 49 (Troubleshooting Guide) provides some guidance through the evaluation phase based on material discipline and the associated tests. The guide is an evaluation tool and is not necessarily a complete listing of all potential areas to be investigated and the assistance of the Region QAC, QAE or other technical resources is encouraged.

The investigation and the resolution of the discrepancy shall be documented on form (734-4040) and at a minimum will contain the following information:

- Clearly explain the issue under investigation. Provide the bid item number, material description, test procedure or process in question, associated Quality Assurance testing reference's and date or timelines of the testing issue.
- Describe the steps taken to resolve the discrepancy and the associated information or test results gathered to support the findings.
- Provide a conclusion based on the findings.
- Describe recommendations or actions to be taken.
- Provide written notification to the QAC and Quality Control entity upon completion of the investigation. Ensure a copy of the investigation is maintained in the project files.

