Ohio Administrative Code

Rule 3701:1-54-04 Quality assurance.

Effective: April 15, 2013

(A) The purpose of this rule is to set quality assurance requirements for facilities licensed under Chapter 3701:1-54 of the Administrative Code. The quality assurance requirements of a licensee apply to the design, operation, and decommissioning, of a facility for items and activities that are important to safety. The quality assurance program must include the following elements: the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification of structures, systems, and components, that are important to safety. The quality assurance requirements also apply to the operational procedures for ensuring compliance with safety requirements.

(B) The quality assurance functions are to:

(1) Ensure that an appropriate quality assurance program is established and effectively executed;

(2) Verify, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed; and

(3) Ensure that the persons and organizations performing quality assurance functions have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

(C) The licensee, or applicant for a license, shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee shall retain responsibility for the program. The licensee, or applicant for a license, shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions and structures, systems, and components, which are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(D) A quality assurance program shall meet the following:

(1) The licensee, or applicant for a license, shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with these procedures throughout the period during which the facility is licensed. The licensee, or applicant for a license, shall identify the structures, systems, and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(2) The licensee, or applicant for a license, through their quality assurance programs, shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each facility.

(3) The licensee, or applicant for a license, shall base the requirements and procedures of their quality assurance program(s) on the following considerations concerning the complexity and proposed use of the structures, systems, or components:

(a) The impact of malfunction or failure of the item on safety;

(b) The design and fabrication complexity or uniqueness of the item;

(c) The need for special controls and surveillance over processes and equipment;

(d) The degree to which functional compliance can be demonstrated by inspection or test; and

(e) The quality history and degree of standardization of the item.

(4) The licensee, or applicant for a license, shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

(5) The licensee, or applicant for a license, shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must regularly review the status and adequacy of that part of the quality assurance program that they are executing.

(6) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these considerations are opposed to safety considerations, are provided. The individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct authority, freedom, and access to the levels of management necessary to perform this function.

(E) A quality assurance program shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license application for those structures, systems, and components to which this chapter applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(F) A quality assurance program shall establish requirements for:

(1) Procurement document control by establishing measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality or safety are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee, or by the licensee's contractors or subcontractors. To the extent necessary, the licensee, or applicant for a license, shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this rule.

(2) Instructions, procedures and drawings prescribing activities affecting quality or safety by documented instructions, procedures, or drawings of a type appropriate to the circumstances and

shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

(3) Document control by establishing measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality or safety. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.

(4) Control of purchased material, equipment, and services requirements:

(a) Establishing measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery;

(b) The licensee, or applicant for a license, shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use of the material and equipment. The licensee shall retain or have available this documentary evidence for the life of the facility. The licensee shall ensure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment; and

(c) The licensee, or applicant for a license, or a designee of either, shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

(5) Identification and control of materials, parts, and components by establishing measures for the identification and control of materials, parts, and components. These measures must ensure that identification of the item is maintained either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item. These identification and control

measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

(6) Control of special processes by establishing measures to ensure that special processes are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(7) Licensee inspection by establishing and executing a program for inspection of quality or safety related activities by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. Individuals other than those who performed the activity being inspected must perform the inspection. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products cannot be carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both.

(8) Test control by establishing a test program to ensure that all testing, required to demonstrate that the structures, systems, and components will perform satisfactorily in service, is identified and performed in accordance with written test procedures that incorporate the requirements of this chapter and the requirements and acceptance limits contained in the facility. The test procedures must include provisions to ensure that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, or applicant for a license, shall document and evaluate the test results to ensure that test requirements have been satisfied.

(9) Control of measuring and test equipment requirements, the licensee, or applicant for a license, shall establish measures to ensure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

(10) Handling, storage and shipping control by establishing measures to control, in accordance with work and inspection instructions, the handling, storage, shipping, cleaning, and preservation of

materials and equipment to prevent damage or deterioration.

(11) Inspection, test and operating status:

(a) Establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the facility. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of the inspections and tests.

(b) Establish measures to identify the operating status of structures, systems, and components of the facility, such as tagging valves and switches, to prevent inadvertent operation.

(12) Nonconforming materials, parts and components by establishing measures to control materials, parts, or components that do not conform to their requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

(13) Corrective action by establishing measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

(14) Record keeping requirements, the licensee, or applicant for a license, shall maintain sufficient records to furnish evidence of activities affecting quality. The records must include the following: design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records must include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records must, at a

minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any noted deficiencies. Records must be identifiable and retrievable. Records pertaining to the design, fabrication, erection, facility as built diagrams, testing, maintenance, and use of structures, systems, and components important to safety must be maintained by or under the control of the licensee until the director terminates the license.

(15) Auditing requirements by conducting a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

(16) Measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of the design.

(a) For verifying or checking processes, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization.

(b) Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking the processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse testing condition.

(c) The licensee, or applicant for a license, shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license requires prior approval by the director.