Q-15

RAM-Q
INDUSTRIES

May 5, 1989

The Secretary of the Commission
US Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Subject: ECOTECH/RAM-Q COMMENTS TO ADVANCED NOTICE OF PROPOSED RULE MAKING (ANPR), "ACCEPTANCE OF PRODUCTS PURCHASED FOR USE IN NUCLEAR POWER PLANT STRUCTURES, SYSTEMS AND COMPONENTS", FEDERAL REGISTER VOL. 54, NO. 42, MONDAY MARCH 6, 1989

Gentlemen:

EcoTech Incorporated and RAM-q Industries is pleased to provide the enclosed comments and input to the subject Advanced Notice of Proposed Rule Making.

The comments are consistent with our mutual desire for a technically sound, cost-effective, licensing prudent, program for Engineered Procurement and Commercial Grade Item Dedication in the Nuclear Power Industry. For your convenience we are also enclosing our input on a standard diskette in ASCII format.

Should you have any questions, comments, or require our assistance in discussions, please advise either Larry Gradin or myself at (201) 662-0003.

Very truly yours

Cedric P. Szeglin
EcoTech/RAM-Q
Vice President

encl: Comments (26 pgs)
Diskette

ANPR-PE1.ltr

6702 Bergenline Avenue • West New York, NJ 07093 (201) 662-0376

EcoTech/RAM-Q COMMENTS
ADVANCED NOTICE OF PROPOSED RULE MAKING (ANPR),
"ACCEPTANCE OF PRODUCTS
PURCHASED FOR USE IN NUCLEAR POWER PLANT
STRUCTURES, SYSTEMS AND COMPONENTS", FEDERAL
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Section I Products Procured for Use in Safety-Related Structures, System, and Component Applications

1.1 General

1.1.1a In view of the problems that have been detected with substandard, counterfeit, or fraudulently marketed products, do the Commission's current regulations provide adequate criteria for ensuring the acceptability of purchased products?

Response/Comment. Yes, current regulations are adequate. More rigorous enforcement and inspection activities by the NRC is of value to industry. Assignment of Civil Penalties and Criminal Charges, as appropriate, is the prudent method to meet the goals of regulator and licensee. The current industry practice of attempting to retain the original design as "frozen" must be changed. This is causing users to seek a steadily reducing supply of obsolete parts, thereby leading to substantial monetary incentives for counterfeit. A technically sound, cost-effective, and licensing prudent Engineered Procurement and Commercial Grade Item Dedication Process will be the method to reduce risk of substandard and fraudulent equipment and parts.

1.1.1b If the current regulations are considered to provide adequate criteria, how should they be applied to ensure that substandard, counterfeit, and fraudulently marketed products are detected and precluded from use in nuclear power plants?

Response/Comment. See response/comment to 1.1.1(a). In addition, the NRC should be more rigorous in their efforts to prevent vendors who accept 10 CFR 21 and 10 CFR 50, Appendix B from claiming proprietary data in violation of the intent of 10 CFR 2.790.

1.1.1c If the current regulations do not provide adequate criteria, should the Commission establish specific

requirements or performance-based requirements to ensure that products purchased for use in nuclear power plant structures, systems and components satisfy the operational requirements necessary to protect public health safety?

Response/Comment. Current regulations are adequate. Also refer to responses 1.1.1a and 1.1.1b.

1.1.2a What traceability requirements should be imposed for all products to be used in safety-related structures, systems and components?

Response/Comment. The terminology, "all products" is excessively broad. The reporting and assumed liability of vendors accepting safety related orders is reducing the number of vendors who will provide enhanced traceability. The solution may be an increase in the use of Commercial Grade Item Dedication Processes where the utility or their agent has greater access to important vendor information. Also see additional related comments in response/comment 1.1.2d.

1.1.2b Should material traceability through all intermediary contractors, subcontractors and processors be required?

Response/Comment. Yes, for any accepting 10 CFR 50, Appendix B or 10 CFR 21.

1.1.2c Should all critical characteristics, for example, materials, operations, functions, etc., be traceable?

Response/Comment. This question can not be readily answered since the term "all" and "traceability" must be interpreted. Critical characteristics truly necessary to complete a safety function must be verifiable with reasonable assurance as intended by 10 CFR 50 Appendix B.

1.1.2d Should there be any exceptions to the traceability requirements?

Response/Comment. Answer requires an understanding of the word traceable. The great majority of items are assembled, fabricated, composed of other smaller items or parts or compounds which are derived from raw materials. Does traceability start when a discernable action or property of interest (i.e. critical characteristic) can be measured? If traceability is defined as the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification (per paragraph 3.18.1 of ANSI/ASQC A3 - 1978) there should not be any exceptions. See comment to 1.1.2c.

1.1.2e What should the identification requirements be for traceability, for example, uniquely marking each part whenever possible, bagging, records, etc.?

Response/Comment. It is recommended that the approach utilized by Underwriters Laboratories (UL) be used. UL requires identification "on the smallest unit container in which the product is packaged or on the product, when size or shape permits...". Obviously, identification may be lost physically for installed items; however a record of item location is necessary.

1.1.3 Should product acceptances be restricted to inspections and tests or should product acceptance include, on a sample basis, destructive inspections and tests to verify chemical and physical characteristics?

Response/Comment. If inspection and tests alone are not able to provide reasonable assurance of quality, other more rigorous testing must be used. Also see response/comment to 1.1.4.

1.1.4 What types of inspections and tests (appropriate for the various types of products) should be required?

Response/Comment. This question is well answered in industry standards for more than 10 years. Refer to paragraph 10.3 of ANSI N45.2.13-1976.

1.1.5 Should licensees, contractors and subcontractors be encouraged to perform joint testing?

Response/Comment. What does encouraged mean? Instances have occurred where even NRC funded tests by national laboratories have not been accepted by NRC. Until NRC is willing to accept multiple use of a single effort there is no reasonable encouragement. Also see response/comments 1.1.16c and 1.1.16d.

1.1.6 If destructive inspections and tests are determined necessary, what should be the sampling basis (per vendor, per purchase order, per shipment, per lot, per container, etc.)?

Response/Comment. Sampling basis depends on margin in design and application expected, manufacturing tolerance, population, and other factors. All that can be reasonably stated is that an engineering produced reasonable sampling plan must be used not an arbitrary "force fit".

1.1.7 Should sample plan testing be permitted for testing or should such testing be on a 100 percent basis?

Response/Comment. If the sampling is a verification of a "previous 100% inspection or quality process" sampling is acceptable. Sampling as the primary means of quality verification will allow defective units/items through.

1.1.8 What sort of statistical sampling during product inspection is adequate to provide confidence that the product has the requisite assurance of quality?

Response/Comment. See comment 1.1.7.

1.1.9 What criteria should be used for allowing sample plan testing during product acceptance?

Response/Comment. See response/comment 1.1.7.

1.1.10 Should the shelf life of appropriate types of structures, systems and components be inspected and verified as acceptable during product acceptances?

Response/Comment. Question is unclear. Shelf life is an essentially non-measureable characteristic at site receipt. If question relates to stated shelf life in receiving records then the question relates to economic prudency - should an item with a small remaining life be accepted? Obviously, shelf life in plant or warehouse storage cannot be exceeded. If exceeded an acceptable processing to evaluate nonconformance with requirements must be used.

1.1.11 To what extent will an effective vendor audit program and maintenance of a qualified vendor list reduce the likelihood of questionable products being used in nuclear power plants?

Response/Comment. A program which is performance based with engineering support and a willingness to prosecute fraud will have a positive effect. However, such an effect is not readily quantifiable.

1.1.12 What are the essential elements, for example, team composition, depth of audits, and approach, that must be included in an effective vendor audit program?

Response/Comment. An industry wide program to develop guidelines under EPRI/NCIG sponsorship will address this. Our review of the draft effort to date indicates a quality effort is underway.

1.1.13 What reinspection or reaudit frequency is appropriate to maintain confidence in those vendors on a qualified vendor list?

Response/Comment. The present industry general guidance is adequate. If a single audit for all parties is performed then consideration must include risk of infrequent audits. Quality of audit function is not frequency dependent but is dependent on depth of coverage. Direction

towards performance based audits will improve results.

1.1.14 How do licensees ensure that Code Certificate holder and "N" stamp vendors are current?

Response/Comment. Library of Congress Publication 74-32554 - Companies Holding Nuclear Certificate of Authorization is used as a "reference" to determine the scope and currency of suppliers accepted by the ASME.

1.1.15 Is there an auditable method to demonstrate that licensees actually purchased the product from a qualified vendor, for example, the holder of an ASME Code stamp holder certification?

Response/Comment. Yes. Through the use of the above-noted publication and comparison with the licensee issued purchase orders. Additional efforts would be required to establish traceability through the prime vendor into the sub-vendor.

1.1.16a Should negative inspection, testing and audit results be shared with other parties?

Response/Comment. Yes, with careful controls on quality of the audit, release of claimed proprietary data, and NRC protection from litigation in the interest of public safety.

1.1.16b Is a Federal requirement necessary to permit this sharing of information?

Response/Comment. Yes, see response/comment 1.1.16a.

1.1.16c Should procurement contracts be required to include a provision for public release of the results of audit of the vendor?

Response/Comment. This cannot be resolved until a mechanism of review of arbitrary or erroneous audit findings is established. The consequence of an incorrect negative assessment can be dramatic on users of vendor equipment, on

the financial viability of a vendor, on the public perception of nuclear plant safety, on the availability of misjudged - but adequate equipment.

1.1.16d Are there restraint of trade, antitrust concerns or liabilities associated with these actions?

Response/Comment. The NRC should establish regulations protecting the industry from antitrust or liabilities. As indicated in response/comment 1.1.16c, the potential negative impacts of erroneous assessments are very severe. A vendor could reasonably seek remedy under law for libel and slander.

1.1.17 Should licensees, contractors and subcontractors be encouraged to make joint procurements and to share inspection/ audit results of joint procurements to enhance the effectiveness of inspections/audits?

Response/Comment. The response/comment to 1.1.5 is appropriate to this question. Also refer to responses 1.1.16c and 1.1.16d regarding potential liability.

1.1.18 If joint procurements and inspections/audits are encouraged, should controls be imposed and, if so, what and how should these controls be imposed?

Response/Comment. See response/comment 1.1.17.

1.1.19 What audit and testing documentation should be required to provide traceability and give confidence to all participants in joint product acceptances?

Response/Comment. Unless the NRC "accepts" joint work, similar to topical reports, each participate must have equal and complete documentation.

1.1.20a Should the NRC establish and publish a list of approved vendors for various products?

Response/Comment. This may have significant merit, when and if demonstrated practicable. See response/comment 1.1.20b.

1.1.20b If a list of approved vendors is established, how should vendors be selected?

Response/Comment. The economic incentives for vendors to participate in an equivalent to an "Approved Products List" similar to the military system (or a system similar to UL Listing) may not be available in today's environment or for the foreseeable future. A single set of acceptance requirements to envelop all or at least most nuclear plants would be necessary. A single set of well trained individuals must do the inspection or audits. The process must be thorough with all users in agreement. Should the users actually select the vendors many legal concerns regarding basis for exclusion would be apparent. Any supplier should be eligible for list consideration; costs for review being borne by supplier. With the thousands of diverse parts now in use who pays for the turmoil necessary for the industry wide change to standard components. This may well be a good concept that is twenty-five years too late.

1.1.20c If a list of approved vendors is established, who should be responsible for maintaining this list?

Response/Comment. The list, if practicable, can not be second guessed by the NRC after millions, perhaps billions of dollars is expended in such an effort. For viability the list must include NRC active participation. The NRC position that they operate at "arms length" from industry must be changed prior to considering the establishment of an NRC "Approved Vendors List".

1.1.20d Should licensees be restricted to making procurements from this list of approved vendors?

Response/Comment. No. Such a list if at all possible would require many years to develop. Great danger exists in precluding use of vendors not on "current list" which can lead to obsolescence.

1.1.21 Should the use of a certificate, such as a Certificate of Conformance, in the procurement process be prohibited or, if allowed, be restricted to issue by the original equipment manufacturer for items that have remained under his direct control?

Response/Comment. Adherence to the guidelines of ANSI N45.2.13-1976, paragraph 10.2 provides reasonable validation of Certificates of Conformance.

The second half of the question implies a bias on behalf of the original equipment manufacturer which is unfounded. Most items supplied are assemblies of smaller parts each of which may not be manufactured by the OEM.

1.1.22 Should the furnishing of the original manufacturer's certificate, such as a Certified Material Test Report, be made mandatory for procurement of materials from intermediate vendors?

Response/Comment. All documentary evidence which may attest to quality should be equally treated and provided by any supplier. This may place extreme burden on all throughout the procurement chain.

1.1.23 Should the transcribing of an original manufacturer's test data by intermediate vendors onto the vendor's certification, for example, Certified Material Test Report, be forbidden?

Response/Comment. No, it should not be forbidden. Traceability to the fundamental CMTR must be available. Transcribing should not be done in a manner to defraud.

1.1.24 To what extent should licensees or their representatives be required to inspect the implementation of contractor product acceptance programs?

Response/Comment. To the same extent that all quality aspects are inspected and audited. Also see response/comment 1.2.1a

1.1.25 Should licensees be required to audit implementation of 10 CFR Part 21 by suppliers and vendors?

Response/Comment. As no physical product is produced by 10 CFR 21 (i.e this regulation is a reporting mechanism primarily) normal audit implementation methods may not be appropriate. However, the audit function may well check on the process associated with 10 CFR 21 and the knowledge of the 10 CFR 21 mechanism by workers on safety-related activities especially those pertaining to verification tasks. As 10 CFR 21 includes reporting aspects and the allowance for Commercial Grade Item procurement, both aspects are subject to audit and evaluation. Methods to assess deviations and non-conformance for reportability, as well as the Dedication Process, are the primary aspects for review.

1.1.26 In addition to the requirements of 10 CFR Part 21, should licensees be required to notify manufacturers, suppliers and vendors of licensee-identified problems with vendor-providing nonconforming products or programs?

Response/Comment. Yes. Expertise may exist at vendor levels for appropriate 10 CFR 21 review. Furthermore, other industries (aerospace) may not otherwise become aware of problems if manufacturers are not informed.

1.1.27 Should licensee participation in a national data system for reporting equipment/component failures by manufacturer and application be required?

Response/Comment. To some extent this now exists in the nuclear industry with LERs and the NPRDS data base. Major concern exists on the quality of the data entry into a national system. Proceeding to take action on incorrect, incomplete, misleading data is dangerous. A national system is not recommended.

1.1.28 Is there specific data that should be included in a national data system that would significantly enhance its usefulness in establishing equipment performance history?

Response/Comment. Do not agree with system need or prudency of establishing such a system.

1.1.29 What are the implications of any new Commission requirements on the Commission's endorsement of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code in 10 CFR 50.55a?

Response/Comment. The implication would be that the original endorsement of the ASME Boiler and Pressure Vessel Code as the code of authority for pressure boundary design, fabrication, installation and testing was incorrect. This is not the case as viewed by the industry.

1.1.30 What is the best way to coordinate any new requirements with the ASME Boiler and Pressure Vessel Code?

Response/Comment. The ASME Boiler and Pressure Vessel Code is prepared to be used as a "codified" document adopted in regulatory law. The only way that NRC new requirements should be established is through the rigorous public comment review process of regulations.

1.1.31 Should the new requirements that relate to areas covered by the ASME Boiler and Pressure Vessel Code (e.g., SA material specifications) be handled through the code committee system?

Response/Comment. If the NRC so desires to consider new requirements, they should be coordinated through code committees and be executed in accordance with the currently established process.

1.1.32 To what extent should items 1.1.1a through 1.1.31 be required for other than safety-related components?

Response/Comment. The economic incentive to have a reliable and available plant and the industry initiatives through NUMARC are adequate for non-safety related components.

Furthermore, the disincentives which these new requirements would lead to (as described in response/comment 2.5.3) would not be balanced by an improvement in safety or cost-effective performance.

Finally, the NRC staff presentation at the NRC Information Conference, Session 2,

"Substandard Material and Equipment", held in Washington, DC on April 18, 1989 clearly indicated that the NRC recognizes the positive contribution by industry. As stated by the NRC:

> *"The Nuclear Utilities Management and Resources Council (NUMARC) is also supporting these activities through working group efforts addressing specific and generic substandard and fraudulent product issues. These industry efforts are positive contributions to the overall objective that licensees and the NRC must pursue which is protection of the public health and safety".*

1.2 Metallic Products (e.g., fasteners, piping, pipe fittings, weld rod, castings, forging, bar stock, plate material, stampings, wire, cable, etc.).

1.2.1a Should chemical analyses of the products be required as part of product acceptances?

Response/Comment. The sound guidance of ANSI N45.2.13-1976 should be used for product acceptance.

1.2.1b Should these analyses of the products be performed by destructive or by nondestructive means?

Response/Comment. See 1.2.1a response/ comment.

1.2.2a Should tests of mechanical properties (e.g., hardness, tensile strength, impact, etc.) of the products be required as part of product acceptances?

Response/Comment. See 1.2.1a response/ comment.

1.2.2b Should tests of mechanical properties of the products be performed by destructive or by nondestructive means?

Response/Comment. See 1.2.1a response/ comment.

1.2.3 When destructive tests are required, are test coupons (when applicable) an acceptable source of test materials for the tests of chemical and mechanical properties or should material samples be removed from actual products?

Response/Comment. Specific analysis should be performed to validate use of test coupons as representative of the product and the application stresses as appropriate. An analysis should verify coupons may be used in the majority of cases.

1.3 Nonmetallic Products (e.g., lubricants, tape, elastomers, seals, paints, filters, etc.)

1.3.1a Should chemical analyses be required for lubricants, tape, elastomers, etc., during product acceptance?

Response/Comment. See 1.2.1a response/ comment.

1.3.1b Should these analyses be performed by destructive or by nondestructive means?

Response/Comment. See 1.2.1a response/ comment.

1.3.2 Should physical property tests (e.g., viscosity for lubricants, hardness for elastomers, efficiency for filters, etc.) be required during product acceptances?

Response/Comment. See 1.2.1a response/ comment.

1.4 Components (e.g., pumps, valves, circuit breakers, controllers and electronic parts/assemblies and their replacement parts)

1.4.1 Should components be subjected to functional tests during product acceptance?

Response/Comment. See 1.2.1a response/ comment.

1.4.2a Should components be disassembled, if necessary during product acceptance, to verify dimensional characteristics?

Response/Comment. See 1.2.1a response/ comment.

1.4.2b If the components are not disassembled, what methods should be utilized to verify critical characteristics?

Response/Comment. See 1.2.1a response/ comment.

1.4.3a Should the chemical and physical properties of component materials be analyzed during product acceptance inspections?

Response/Comment. See 1.2.1a response/ comment.

1.4.3b If the chemical and physical properties of component materials are to be analyzed during product acceptance inspections, what means should be utilized?

Response/Comment. See 1.2.1a response/ comment.

2 Dedication of Commercial Grade Products for Use in Safety-Related Structure, System and component Applications.

The questions in this section are categorized in five subsections: General, Metallic Products, Nonmetallic Products, Components, and Other Questions.

2.1 General

2.1.1 Should the Commission establish specific requirements or performance-based requirements to ensure that commercial grade products being dedicated for use in safety-related nuclear power plant structures, systems and components satisfy the operational requirements necessary to protect public health and safety?

Response/Comment. No. The staff has already conditionally endorsed industry guidance (e.g. EPRI NP 4652) in Generic Letter 89-02. A whole series of comprehensive guidelines and evolving "acceptable" practice is in motion.

Finally, the NRC staff presentation at the NRC Information Conference, Session 2, "Substandard Material and Equipment", held in Washington, DC on April 18, 1989 clearly indicated that the NRC recognizes the positive contribution by industry. An actual quotation from a recent NRC dialog with industry is provided in response/comment 1.1.32.

2.1.2 Should NRC regulations be revised to endorse and incorporate by reference, the industry codes, standards, or guidance documents for dedication programs of commercial grade products for use in safety-related structure, system and component applications?

Response/Comment. Yes. Endorsement by NRC precludes the moving target of acceptability and differing interpretations inherent in "regulation by precedent". The NRC conditional endorsement of EPRI NP5652 (NCIG-07) in Generic Letter 89-02 should be the beginning. Only through a standard set of criteria and acceptable practice will the NRC and industry be cost-effectively and rapidly ferreting out poor performance and improve on overall industry performance.

2.1.3a What should the traceability requirements for all commercial products being upgraded for use in safety-related structures, systems and components?

Response/Comment. The traceability for Commercial Grade Items should begin concurrent with the point that it is determined to buy an item as a Commercial Grade Item in lieu of a Basic Component or Safety Related item. The procurement documents, engineering analysis, determination of critical characteristics, methods to verify critical characteristics are met, and acceptance are all traceable in addition to site receipt effort and documents. Also refer to response/comments 1.1.2a, 1.1.2b, 1.1.2c, 1.1.2d, and 1.1.2e.

2.1.3b If upgrading traceability provisions are necessary, what should these provisions include?

Response/Comment. The Dedication Process includes both the Technical evaluation and acceptance phase. This process is a safety related process which is under the provisions and control of 10 CFR 21 and 10 CFR 50, Appendix B. These provisions and controls, in conjunction with NUMARC initiative to adopt guidance of EPRI NP5652 (NCIG-07), are sufficient. No upgrading is necessary.

2.1.3c Should material traceability through all intermediary contracts, subcontractors and processors required?

Response/Comment. This question is similar in nature to 1.1.2b. The answer is the same. An intermediary accepting a safety-related order (10 CFR 21, 10 CFR 50, Appendix B) is performing a safety function. A supplier truly supplying a Commercial Grade Item can not be held accountable for special nuclear unique requirements in "manufacturing".

2.1.3d If item traceability is necessary, should there be any provisions for upgrading products whose traceability cannot be established?

Response/Comment. The context of the question is unclear. Traceability, as appropriate, is part of the reasonable assurance concepts used to assure quality. Is the question relating to existing equipment which has often been "qualified" on a lot basis with traceability to the "lot" qualified, not to the individual parts? If no traceability on the resistor, capacitor, etc. is available other than to the original "lot" itself when a replacement is necessary than critical characteristics are established with a Dedication Process assuring the new part is adequate. There should be no "need" to establish traceability on existing equipment which is considered adequate for the application as a "rule". However, establishing traceability may be one of the methods used to assure adequacy.

Either traceability is established to original acceptable configuration or a new configuration with appropriate traceability must be established.

2.1.3e Should the upgrading traceability provisions be any different if the products are heat/lot identified or not?

Response/Comment. See response/comment 2.1.3d. Also see 2.1.10a and 2.1.10b.

2.1.3f What should the identification requirements be for traceability, for example, marking, bagging and records?

Response/Comment. When the dedication process is complete and a Commercial Grade Item is "converted" or "transformed" or "identified" as a Safety Related or Basic component than identification appropriate to Safety Related items is used. The term "upgraded" is being used by the NRC repeatedly. This is unfortunate as it implies a lesser quality in Commercial Grade Items. The quality is typically built into the item with the Dedication Process demonstrating and documenting the quality only. In fact, the Statements of Consideration for 10 CFR 21 correctly point out a Commercial Grade Item may be of superior quality to a basic component. As stated by 21-SC-3:

> *"The use of this meaning of basic component has not improved the quality of such items and, therefore, has not enhanced safety. Instead it is causing cost increases and inability to obtain needed supplies. To the extent that the purchaser is unable to obtain a needed item from the most qualified supplier and must turn to other less qualified suppliers, defining basic component to include such an item may to some extent detract from safety".*

2.1.4 How should products intended for use in applications to meet specific standards be inspected to verify that all critical characteristics are satisfied?

Response/Comment. It is assumed that the specific standards which are mentioned are non-

nuclear industrial standards. Certain aspects of a Commercial Grade Items' Critical Characteristics may not be verified by inspection, if inspection is meant to be receipt inspection. Receipt Inspection usually can not confirm functional capability under operating or accident conditions (i.e. flow, pressure retaining capability, environmental qualification, etc). EPRI NP5652, conditionally endorsed by Generic Letter 89-02, includes Source Verification and Commercial Grade Survey methods. In addition, certain aspects of Critical Characteristics may be readily verified by validation of the independent inspections of the under Underwriters Laboratories, under the Canadian Standards Association, etc. Also refer to response/comment 2.5.1a.

2.1.5 Should the shelf life of appropriate types of products be inspected and verified as acceptances as part of the upgrade inspection process?

Response/Comment. This is essentially the same question as 1.1.10. The response/comment remains the same regardless of the initial classification and purchase of an item as a CGI to be converted to a Basic Component or classification and purchase of an item as a Basic Component.

2.1.6 What types of shelf life controls should be imposed on products that are being upgraded for use in safety-related structures, systems and components?

Response/Comment. Requirements for shelf life controls are independent of the procurement as either CGI or Basic Components. Should a non-safety related item in storage be investigated for consideration as a CGI for Basic Component conversion, then shelf life consequences must be carefully evaluated and considered.

2.1.7 Should all upgrade inspections be restricted to inspections and tests or should they include, on a sample basis, destructive inspections and tests to verify chemical and physical characteristics?

Response/Comment. This is essentially the same question as 1.1.3. The response/comment

nuclear industrial standards. Certain aspects of a Commercial Grade Items' Critical Characteristics may not be verified by inspection, if inspection is meant to be receipt inspection. Receipt Inspection usually can not confirm functional capability under operating or accident conditions (i.e. flow, pressure retaining capability, environmental qualification, etc). EPRI NP5552, conditionally endorsed by Generic Letter 89-02, includes Source Verification and Commercial Grade Survey methods. In addition, certain aspects of Critical Characteristics may be readily verified by validation of the independent inspections of the under Underwriters Laboratories, under the Canadian Standards Association, etc. Also refer to response/comment 2.5.1a.

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Response/Comment. This is essentially the same question as 1.1.3. The response/comment

remains the same regardless of the initial classification and purchase of an item as a CGI to be converted to a Basic Component or classification and purchase of an item as a Basic Component.

2.1.8 What types of inspections and tests (appropriate for the various types of products) should be required?

Response/Comment. This is essentially the same question as 1.1.4. The response/comment remains essentially the same regardless of the initial classification and purchase of an item as a CGI to be converted to a Basic Component or classification and purchase of an item as a Basic Component. Users should utilize EPRI NP5652.

2.1.9 How should inspections verify all critical characteristics (for example, chemistry, physical properties, dimensions, special processes, etc.)?

Response/Comment. This is essentially the same question as 1.1.5. The response/comment remains essentially the same regardless of the initial classification and purchase of an item as a CGI to be converted to a Basic Component or classification and purchase of an item as a Basic Component. Users should utilize EPRI NP5652.

2.1.10a If destructive inspections and tests are determined to be necessary, how should samples be selected if products are heat/lot identified?

Response/Comment. The response/comment to this question is provided in response/comment 2.1.3d and 2.1.3e. It must be pointed out that heat/lot control may not adequately assure all (e.g. heat/lot control may not adequate assure consistent dimensions) critical characteristics of each item is reproducible throughout the heat/lot batch.

2.1.10b How should samples be selected if products are not heat/lot identified?

Response/Comment. This question is unclear. Samples for acceptance are different than samples

to demonstrate application (e.g. EQ, seismic, flow, electrical short circuit withstand ability) acceptability. For verification that ordered item and received item is the same (Acceptance Process) the response/comment to the question 1.1.7 is appropriate. For samples selected for application verification acceptability (especially where unit is tested to failure) the use of margin as considered in 10 CFR 50.49 is used. Margin is meant to compensate for reasonable uncertainty in products. Even the best acceptance verification process does not result in 100% exactness. Testing may be destructive resulting in no products for use under 100% test/inspection programs.

2.1.11 Should sample plan testing be permitted for nondestructive testing or should such testing be on a 100 percent basis?

Response/Comment. Refer to response/comment 2.1.10b and 1.1.7.

2.1.12 What criteria are appropriate for allowing sample plan testing during upgrade inspections?

Response/Comment. Refer to response/comment 2.1.10b and 1.1.7.

2.2 Metallic Products

2.2.1a Are chemical analyses of the products appropriate as part of upgrade inspections?

Response/Comment. Refer to response/comment 1.2.1a. A CGI which is to be used (after conversion to a Basic Component) for safety must include the appropriate methods to reasonably assure adequacy.

2.2.1b Should these analyses be performed by destructive or by nondestructive means?

Response/Comment. Refer to response/comment 2.1.8. A CGI which is to be used (after conversion to a Basic Component) for safety must

include the appropriate methods to reasonably assure adequacy.

2.2.2a Are tests of mechanical properties (e.g., hardness, tensile strength, impact etc.) appropriate as part of upgrade inspections?

Response/Comment. Refer to response/comment 2.1.8. A CGI which is to be used (after conversion to a Basic Component) for safety must include the appropriate methods to reasonably assure adequacy.

2.2.2b Should these tests be performed by destructive or by nondestructive means?

Response/Comment. Refer to response/comment 2.1.8. A CGI which is to be used (after conversion to a Basic Component) for safety must include the appropriate methods to reasonably assure adequacy.

2.2.3 If the product is heat/lot traceable, is sample inspection (destructive and nondestructive) adequate for confirmation of critical characteristics?

Response/Comment. Perhaps for acceptance when adequacy of heat/lot controls is reasonably verifiable. For application adequacy analysis and testing, if used, would include reasonable margin to account for deviations in a product. Also refer to response/comment 2.1.10b.

2.2.4 If the product is not heat/lot traceable, is it necessary to either sample or 100 percent test, for example, hardness, to establish uniformity and then destructively analyses, tensile tested, impact tested, etc.) to determine acceptability?

Response/Comment. See response/comment 2.1.10b and 1.1.7.

2.2.5 Should requirements in addition to those included in industry standards (e.g., additional samples, etc.) be required?

Response/Comment. Industry standards must be reviewed and validated as adequate for the application. Additional requirements may or may not be determined based on engineering technical evaluations.

2.2.6 When destructive tests are required, are test coupons (when available) an acceptable source of test materials for chemical and mechanical properties tests or should material samples be removed from actual products?

Response/Comment. response/comment to question 1.2.3 remains unchanged regardless of CGI or Basic Component classification.

2.3 Nonmetallic Products

2.3.1a Are chemical analyses necessary to establish critical characteristics for lubricants, tape, elastomers, etc., proposed for upgrading for use in safety-related systems?

Response/Comment. Response/comment to question 1.3.1a remains essentially unchanged regardless of CGI or Basic Component classification. Also refer to 2.1.8.

2.3.1b Should these analyses be performed by destructive or by nondestructive means?

Response/Comment. Response/comment to question 1.3.1b remains essentially unchanged regardless of CGI or Basic Component classification. Also refer to 2.1.8.

2.3.2 Are physical property tests (e.g., viscosity for lubricants, hardness for elastomers, efficiency for filters, etc.) necessary for upgrading these products?

Response/Comment. Response/comment to question 1.2.1a remains essentially unchanged regardless of CGI or Basic Component classification.

2.3.3 May critical characteristics be inspected by samples or is 100 percent inspection necessary to verify these characteristics?

Response/Comment. Response/comment to question 1.1.7 remains essentially unchanged regardless of CGI or Basic Component classification. Also refer to response/comment 2.1.10b.

2.4 Components

2.4.1 Must each critical characteristic be inspected before the component is acceptable for use in safety-related systems?

Response/Comment. This question seems to indicate a critical characteristic can always be verified at receipt inspection -- it cannot. See response/comment 2.1.10. Also see response/comment 1.1.4.

2.4.2 How should the chemical and physical properties of component materials be analyzed during upgrade inspections?

Response/Comment. See response/comment 2.4.1.

2.4.3 If critical characteristics cannot be inspected on each component piece, should it be acceptable to establish heat/lot traceability, establish uniformity of lot by sample inspection and thereby accept the lot?

Response/Comment. See response/comment 2.2.3.

2.4.4a Must components be 100 percent functionally tested or may they be subjected to functional tests on a sampling basis?

Response/Comment. Refer to response/comment 2.1.10b.

2.4.4b Inspected by sample, what is the basis for performing only sample inspection?

Response/Comment. Refer to response/comment 2.1.10b.

2.4.5a Should disassembly of components be required to verify critical characteristics?

Response/Comment. Refer to response/comment 2.1.10b.

2.4.5b May verification of critical characteristics be done on a sampling basis or are 100 percent inspections necessary?

Response/Comment. See response/comment 1.4.2a and 1.4.2b.

2.4.5c What is the basis for performing only sample inspections?

Response/Comment. See response/comment 2.1.10b.

2.4.5d If components are not disassembled to verify dimensions, what methods can be utilized to verify dimensions?

Response/Comment. See responses 1.4.2a, 1.4.2b, and 2.1.10b.

2.5 Other Questions

2.5.1a Are there any other agency/organization standards or programs there should be adopted for use in upgrading commercial grade products for use in safety related systems?

Response/Comment. Yes. Many organizations world wide perform actual periodic performance evaluation verification of many critical characteristics. Whereas the orientation towards 10 CFR 50, Appendix B has been a paper review, non-US nuclear industries an non-nuclear industries concentrate on actual performance verification. Although certain aspects, such as radiation withstand, may not be verified, many truly meaningful critical characteristics are.

For example, Underwriter's Laboratories performs frequent periodic follow-up for UL listed or recognized components as evidenced by the discussions and background to NRCB 88-10. Likewise, generally similar efforts are undertaken by the Swedish Institute of Testing and Approvals of Electrical Equipment (SEMKO), the Canadian Standards Association (CSA), the US Military as part of the APL process, British Standards Institute (BSI) and the German Approval Agency (VDE).

A careful review of the independence and thoroughness of these agencies can be used to accept certain critical characteristics which can not reasonably be verified otherwise.

2.5.1b Should these standards or programs be endorsed by NRC regulations?

Response/Comment. Ultimately, endorsement (as appropriate) would be of value. As a minimum, the NRC inspectors and industry should be apprised of the "quality" that such independent agencies actually provide.

2.5.2 Are there other alternatives that could provide the necessary assurances?

Response/Comment. In recent years we have all seen a return to the realization that engineering involvement is necessary and appropriate. A "cook-book" or "fill-in the blanks" approach is not adequate, prudent, or a basis to ensure technical adequacy. This trend back to reasonable engineering must be encouraged by recognizing application driven engineering differences exist. The review, whether NRC or industry, must be performance based to preclude not "punishing" engineering, which may be excellent, on the basis that it does not fit some one's checklist.

In addition, the implication that the 10 CFR 50 Appendix B vendor which has a product which is superior in quality to a non 10 CFR 50 Appendix B vendor must be corrected. A utility may and should be encouraged to select the best technical product, using a thorough Commercial Grade Item Dedication Process, to demonstrate adequacy.

This places control in the hands of the licensees and will minimize (although obviously not completely prevent) fraudulent and counterfeit products provided by a supplier hiding behind a 10 CFR 50 Appendix B, 10 CFR 21, and "Proprietary" programs.

2.5.3 To what extent should any existing controls or any additional controls being contemplated in the ANPR be extended to nonsafety-related applications in "balance of plant" structures, systems and components?

Response/Comment. The drive to meet the Performance Indicators promulgated by both Industry and NRC and a greater emphasis on engineered solutions to problems will lead to improvements in balance of plant. The addition of regulations to Balance of Plant would lead to disincentive due to:

- *Increased complexity and perceived personal risk to make improvements requiring regulatory oversite driven review.*
- *Increased costs and resultant incentive for producers to provide fraudulent and counterfeit products.*
- *Diffusion of accountability and responsibility*
- *Potential for the economic ruin of the nuclear power plant option in the US.*