ATTACHMENT

COMPARISON OF APPENDIX B TO ISO 9001-2000

10 CFR 50 APPENDIX B		ISO 9001-2000	REGULATORY IMPACT/COMPLIANCE
CRITERION I: ORGANIZATION			
I - Responsibility for establishing and executing of a quality assurance program			
	Allows delegation of responsibility for establishing and executing of the QA program to others as long as responsibility is retained by the applicant.	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. (4.1)	**Does not specify that responsibility is retained by the applicant.**
CRITERION II: QUALITY ASSURANCE PROGRAM			
II - Determination of appropriate quality requirements			
	Requires identification of items controlled by the program and control only to a degree consistent with the item's importance to safety.	Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. (5.4.1)	**No direct link to safety.**
II - Controlled conditions for activities affecting quality			
	Requires activities affecting quality to be accomplished under controlled conditions.	The organization shall determine and manage the work environment needed to achieve conformity to product requirements. (6.4)	**No direct link to safety.**

	Requires control of prerequisites.	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. (8.2.3)	**No direct requirement for the control of prerequisites.**
II - Indoctrination and training of personnel			
	Specifies extent as...suitable proficiency is achieved and maintained. (Implicitly requires a program for retraining or proficiency maintenance).	The organization shall e) maintain appropriate records of education, training, skills, and experience. (6.2.2)	**Does not address proficiency achievement and retraining**.
II - Management review of quality assurance program status and adequacy			
CRITERION III: DESIGN CONTROL			
III - Review of materials and processes for suitability			
	Limits the materials, parts, equipment, and processes selected for review to those that are essential to the safety-related function.	Does not imply that the review is limited to elements essential to the safety-related function.	**Does not imply that the review is limited to elements essential to the safety-related function.**
III - Control of design documents			
	Requires participating design organizations to have procedures.	During the design and development planning, the organization shall determine b) the review, verification, and validation that are appropriate to each design and development stage c) the responsibilities and authorities for design and development. (7.3.1)	**Does not directly state the requirement for procedures among participating design organizations.**

III - Independent verification of design adequacy			
	Requires verification and checking to be performed by individuals or groups other than those who performed the design.	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met design and development input requirements. (7.3.5)	**Does not include requirement for independent design verification.**
	Requires qualification testing of specific design features to be performed under the most adverse design conditions.	In planning product realization, the organization shall determine the following, as appropriate: c) required...testing activities specific to the product and the criteria for product acceptance. (7.1)	**Does not require testing under the most adverse design conditions.**
CRITERION IV: PROCUREMENT DOCUMENT CONTROL			
IV - Inclusion of all applicable requirements in procurement documents			
	Provides examples of regulatory and design bases requirements.	The type and extent of control applied to the ...purchase product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. (7.4.1)	**No direct examples of regulatory and design bases requirements.**
CRITERION VI: DOCUMENT CONTROL			
VI - Control of review and approval of changes to documents			
	Requires changes to be reviewed and approved by the same organizations that performed the original review and approval.	No direction given on who shall review documents.	**No direction given on who shall review documents.**
	Allows designation of another organization for the review and approval.	No direction given on who shall review documents.	**No direction given on who shall review documents.**

CRITERION VII: CONTROL of PURCHASED MATERIAL, EQUIPMENT, and SERVICES			
VII - Documented evidence of conformance prior to installation			
	Requires evidence of conformance to be at the site prior to the product being installed and used.	No direction given on having evidence of conformance to be at the site prior to installation.	**No direction given on having evidence of conformance at the site prior to installation. However, all documentation pertinent to the product is given over to the licensee.**
VII - Documented evidence of conformance after installation			
	Requires retention of evidence at the site.	No direction given for retention of evidence at the site.	**No direction given for retention of evidence at the site.**
CRITERION VIII: IDENTIFICATION and CONTROL of MATERIALS, PARTS, and COMPONENTS			
III - Lineage traceability and duration of identification control			
	Requires identification maintenance to continue throughout fabrication, erection, installation, and use of the item.	No direction requiring identification maintenance throughout fabrication, erection, installation, and use of the item.	**No direction requiring identification maintenance throughout fabrication, erection, installation, and use of the item.**
VIII - Prevention of use of incorrect items			
CRITERION X: INSPECTION			
X - Independence of inspection personnel			
	Requires inspection personnel to be independent of the performance of the activity being inspected.	No direction that inspection personnel be independent of the performance of the activity being inspected.	**No direction that inspection personnel be independent of the performance of the activity being inspected.**

X - Indirect inspection by monitoring			
	Specifies monitoring of processing methods, equipment, and personnel.	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. (8.2.4)	**There is no direct requirement to monitor personnel.**
X - Recognition of hold points			
	Defines hold points as points beyond which work may not proceed until inspections are completed.	No direction for hold points beyond which work may not proceed until inspections are completed.	**No direction for hold points beyond which work may not proceed until inspections are completed.**
	Requires indication of hold points in appropriate documents if hold points are used.	No direction for hold points in appropriate documents if hold points are used.	**No direction for hold points in appropriate documents if hold points are used.**
CRITERION XI: TEST CONTROL			
XI - Establishment and execution of test program			
	Requires establishment of a test program.	The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system [including]. c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1)	**No direct requirement to establish a test program, only to establish test requirements needed for the product.**

	Requires assurance that structures, systems, and components (SSCs) will perform satisfactorily in service.	The organization shall validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use... (7.5.2)	**No direct requirement to validate that SSCs will perform satisfactorily in service.**
	Requires test procedures to incorporate requirements and acceptance limits contained in design documents.	In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents... c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1)	**No direct requirement to incorporate requirements and acceptance limits contained in design documents.**
XI - Inclusion of test parameters in test documents			
	Requires test procedures to assure completion of test prerequisites.	In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents... c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1)	**No requirement for the documentation or completion of test prerequisites.**
	Requires testing to be performed under suitable environmental conditions.	In planning product realization, the organization shall determine the following, as appropriate: b) the need to establish processes, documents... c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1)	**No direct requirement that testing to be performed under suitable environmental conditions.**

CRITERION XIII: HANDLING, STORAGE, and SHIPPING			
XIII - Controls for handling, storage, shipping, cleaning, and preservation			
	Requires control in accordance with work and inspection instructions.	No direct requirements to have controls in accordance with work and inspection instructions.	**No direct requirements to have controls in accordance with work and inspection instructions.**
	Defines the purpose of controls as prevention of damage or deterioration.	No definition of the purpose of controls as prevention of damage or deterioration.	**No definition of the purpose of controls as prevention of damage or deterioration.**
XIII - Provisions for special product requirements			
	Provides examples of types of protective environments.	No examples given of types of protective environments.	**No examples given of types of protective environments.**
CRITERION XV: NONCONFORMING MATERIALS, PARTS, and COMPONENTS			
XV - Identification, documentation, segregation, and notification			
	Requires notification to affected organizations.	When nonconforming product is detected after delivery or after use has started, the organization shall take action as appropriate to the effects, or potential effects, of the nonconformity. (8.3)	**No requirement to inform licensees of potential deficiencies in defective equipment.**
CRITERION XVI: CORRECTIVE ACTION			
XVI - Identification and corrections of condition adverse to quality			
	Provides examples of applicable conditions, (e.g., failures, malfunction, deficiencies, deviations, defective material, and nonconformances).	No examples are given of applicable conditions, (e.g., failures, malfunction, deficiencies, deviations, defective material, and nonconformances).	**No examples are given of applicable conditions, (e.g., failures, malfunction, deficiencies, deviations, defective material, and nonconformances).**

XVI - Determination of causes and preclusion of repetition of adverse quality conditions			
	Requires determination of the cause of significant conditions adverse to quality.	A documented procedure shall be established to define requirements for d) determining and implementing action needed. (8.5.2)	**Does not segregate "significant conditions adverse to quality."**
XVI - Documentation and reporting of corrective action			
	Requires that the cause and the corrective action taken be reported to appropriate management levels.	No discussion on reporting cause and corrective action to appropriate management levels.	**No discussion on reporting cause and corrective action to appropriate management levels.**
CRITERION XVII: QUALITY ASSURANCE RECORDS			
XVII - Identification of record types			
	Lists the minimum types of records to be maintained.	A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention, time, and disposition of records. (4.2.4)	**Does not list the minimum types of records to be maintained.**
XVII - Special requirements for inspection and test records			
	Requires identification of the inspector, type of observation, inspection results, and acceptability.	No direct requirement to identify the inspector or type of observations. In planning product realization, the organization shall determine the following, as appropriate: c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance. (7.1)	**No direct requirement to identify the inspector or type of observations.**

XVII - Retention and retrievability of records			
CRITERION XVIII: AUDITS			
XVIII - Audit performance, documentation, and review			
	Requires trained auditors who are independent of the activity being audited.	No requirement for trained auditors who are independent of the activity being audited.	**No requirement for trained auditors who are independent of the activity being audited.**
XVIII - Audit follow-up requirements			
	Includes re-audit of deficient areas in followup actions.	No direction for re-audit of deficient areas.	**No direction for re-audit of deficient areas.**