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REQUIREMENT 1	REQUIREMENT 1	REQUIREMENT 1
100 BASIC	100 GENERAL	100 GENERAL
Responsibilities for the establishment	Responsibilities for the establishment	Responsibilities for the establishment and
and implementation of the quality	and implementation of the quality	implementation of the quality assurance
assurance program shall be defined.	assurance program shall be defined.	program shall be defined.
The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.	The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.	The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.
200 STRUCTURE AND RESPONSIBILITY 201 General The organizational structure and responsibility assignments shall be such that	200 STRUCTURE AND RESPONSIBILITY 201 General The organizational structure and responsibility assignments shall be such that	200 STRUCTURE AND RESPONSIBILITY 201 General The organizational structure and responsibility assignments shall be such that
(a) senior management establishes	(a) senior management establishes	(a) senior management establishes overall
overall expectations for effective	overall expectations for effective	expectations for effective implementation
implementation of the quality	implementation of the quality	of the quality assurance program and is
assurance program and is responsible	assurance program and is responsible	responsible for obtaining the desired end
for obtaining the desired end result	for obtaining the desired end result	result
(b) quality is achieved and maintained	(b) quality is achieved and maintained	(b) quality is achieved and maintained by
by those assigned responsibility for	by those assigned responsibility for	those assigned responsibility for
performing work	performing work	performing work
(c) quality achievement is verified by	(c) quality achievement is verified by	(c) quality achievement is verified by those
those not directly responsible for	those not directly responsible for	not directly responsible for performing the
performing the work	performing the work	work
(d) those responsible for assuring that	(d) those responsible for assuring that	(d) those responsible for assuring that an
an appropriate quality assurance	an appropriate quality assurance	appropriate quality assurance program has
program has been established and	program has been established and	been established and those verifying
those verifying activities affecting	those verifying activities affecting	activities affecting quality have sufficient
quality have sufficient authority,	quality have sufficient authority,	authority, direct access to responsible
direct access to responsible levels of	direct access to responsible levels of	levels of management, organizational
management, organizational	management, organizational	freedom, and access to work to perform
freedom, and access to work to	freedom, and access to work to	this function, including sufficient
perform this function, including	perform this function, including	independence from cost and schedule
sufficient independence from cost	sufficient independence from cost	when opposed to safety function
and schedule when opposed to safety	and schedule when opposed to safety	considerations. These verification functions
function considerations. These	function considerations. These	include the
verification functions include the	verification functions include the	following:
following:	following:	(1) identifying quality problems
(1) identifying quality problems	(1) identifying quality problems	(2) initiating, recommending, or providing
(2) initiating, recommending, or	(2) initiating, recommending, or	solutions to quality problems through
providing solutions to quality	providing solutions to quality	designated channels
problems through designated	problems through designated	(3) verifying implementation of solutions
channels	channels	(4) assuring that further processing,
(3) verifying implementation of solutions(4) assuring that further processing, delivery, installation, or use is controlled until	 (3) verifying implementation of solutions (4) assuring that further processing, delivery, installation, or use is controlled until 	delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

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proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.	proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.	
202 Delegation of Work	202 Delegation of Work	202 Delegation of Work
The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any	The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any	The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain
or all of the work to others but shall retain	or all of the work to others but shall retain	responsibility therefor.
responsibility therefor.	responsibility therefor.	
300 INTERFACE CONTROL	300 INTERFACE CONTROL	300 INTERFACE CONTROL
Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.	Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.	Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.
The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.
REQUIREMENT 2	REQUIREMENT 2	REQUIREMENT 2
Quality Assurance Program 100 BASIC	Quality Assurance Program 100 GENERAL	Quality Assurance Program 100 GENERAL
(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof.	(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof.	(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof.
The program shall identify the activities and items to which it applies.	The program shall identify the activities and items to which it applies.	The program shall identify the activities and items to which it applies.
The program shall provide control over activities affecting quality to an extent consistent with their importance.	The program shall provide control over activities affecting quality to an extent consistent with their importance.	The program shall provide control over activities affecting quality to an extent consistent with their importance.
The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.	The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.	The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.
The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.	The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.	The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.
The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions.	The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions.	The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions.
Controlled conditions include the use	Controlled conditions include the use	Controlled conditions include the use of

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of appropriate equipment, suitable environmental conditions for	of appropriate equipment, suitable environmental conditions for	appropriate equipment, suitable environmental conditions for
accomplishing the activity, and	accomplishing the activity, and	accomplishing the activity, and assurance
assurance that prerequisites for the	assurance that prerequisites for the	that prerequisites for the given activity have been satisfied.
given activity have been satisfied.	given activity have been satisfied.	
The program shall provide for any	The program shall provide for any	The program shall provide for any special
special controls, processes, test	special controls, processes, test	controls, processes, test equipment, tools,
equipment, tools, and skills to attain the required quality of activities and	equipment, tools, and skills to attain the required quality of activities and	and skills to attain the required quality of activities and items and for verification of
items and for verification of that	items and for verification of that	
quality.	quality.	that quality.
The organization shall establish and	The organization shall establish and	The organization shall establish and
implement processes to detect and	implement processes to detect and	implement processes to detect and correct
correct quality problems.	correct quality problems.	quality problems.
(b) The program shall provide for	(b) The program shall provide for	(b) The program shall provide for
indoctrination, training, and	indoctrination, training, and	indoctrination, training, and qualification as
qualification as necessary of	qualification as necessary of	necessary of personnel performing or
personnel performing or managing	personnel performing or managing	managing activities affecting quality to
activities affecting quality to ensure	activities affecting quality to ensure	ensure that suitable proficiency is achieved
that suitable proficiency is achieved	that suitable proficiency is achieved	and maintained.
and maintained.	and maintained.	
(c) Management shall regularly assess	(c) Management shall regularly assess	(c) Management shall regularly assess the
the adequacy and effective	the adequacy and effective	adequacy and effective implementation of
implementation of the quality	implementation of the quality	the quality assurance program.
assurance program.	assurance program.	
200 INDOCTRINATION AND TRAINING	200 INDOCTRINATION AND TRAINING	200 INDOCTRINATION AND TRAINING
Indoctrination and training shall be	Indoctrination and training shall be	Indoctrination and training shall be commensurate with scope, complexity,
commensurate with scope,	commensurate with scope,	importance of the activities, and the
complexity, importance of the	complexity, importance of the	education, experience, and proficiency of
activities, and the education,	activities, and the education,	the person.
	experience, and proficiency of the	
experience, and proficiency of the		
experience, and proficiency of the person.		
	person. 201 Indoctrination	201 Indoctrination
person. 201 Indoctrination	person. 201 Indoctrination	201 Indoctrination Personnel performing or managing
person. 201 Indoctrination Personnel performing or managing	person.	Personnel performing or managing
person. 201 Indoctrination	person. 201 Indoctrination Personnel performing or managing	
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall	Personnel performing or managing activities affecting quality shall receive
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria,
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing
person.201 IndoctrinationPersonnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.202 Training The need for a formal training program for personnel performing or managing activities affecting quality	person.201 IndoctrinationPersonnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.202 Training The need for a formal training program for personnel performing or managing activities affecting quality	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be
person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.
person.201 IndoctrinationPersonnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.Training shall be provided, if needed,	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.Training shall be provided, if needed,	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to
person.201 IndoctrinationPersonnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.Training shall be provided, if needed, to achieve initial proficiency, maintain	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.Training shall be provided, if needed, to achieve initial proficiency, maintain	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain
person.201 IndoctrinationPersonnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.Training shall be provided, if needed,	person. 201 Indoctrination Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined.Training shall be provided, if needed,	Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. 202 Training The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to

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responsibilities.	responsibilities.	responsibilities.
On-the-job training shall be used if	On-the-job training shall be used if	On-the-job training shall be used if direct
direct hands-on applications or	direct hands-on applications or	hands-on applications or experience is
experience is needed to achieve and	experience is needed to achieve and	needed to achieve and maintain
maintain proficiency.	maintain proficiency.	proficiency.
300 QUALIFICATION REQUIREMENTS	300 QUALIFICATION REQUIREMENTS	300 QUALIFICATION REQUIREMENTS
The responsible organization shall designate those activities that require	The responsible organization shall designate those activities that require	The responsible organization shall designate those activities that require
qualification of personnel and the	qualification of personnel and the	qualification of personnel and the
minimum requirements for such	minimum requirements for such	minimum requirements for such personnel.
personnel.	personnel.	
The responsible organization shall	The responsible organization shall	The responsible organization shall establish
establish written procedures for the	establish written procedures for the	written procedures for the qualification of
qualification of personnel, and for the	qualification of personnel, and for the	personnel, and for the assurance that only
assurance that only those personnel	assurance that only those personnel	those personnel who meet the
who meet the requirements are	who meet the requirements are	requirements are permitted to perform
permitted to perform these activities.	permitted to perform these activities.	these activities.
Specific qualification requirements for	Specific qualification requirements for	Specific qualification requirements for
personnel performing nondestructive	personnel performing nondestructive	personnel performing nondestructive
examination inspection and tests to	examination inspection and tests to	examination, inspection and tests to verify
verify quality and auditing are	verify quality and auditing are	quality, and auditing are specified in paras.
specified in paras. 301 through 304 of	specified in paras. 301 through 304 of	301 through 304 of this Requirement.
this Requirement.	this Requirement.	
301 Nondestructive Examination (NDE)	301 Nondestructive Examination (NDE)	301 Nondestructive Examination (NDE) This paragraph specifies requirements for
This section specifies requirements	This section specifies requirements	the qualification of personnel who perform
for the qualification of personnel who	for the qualification of personnel who	radiographic (RT), magnetic particle (MP),
perform radiographic (RT), magnetic	perform radiographic (RT), magnetic	ultrasonic (UT), liquid penetrant (PT),
particle (MP), ultrasonic (UT), liquid	particle (MP), ultrasonic (UT), liquid	electromagnetic (ET), neutron radiographic
penetrant (PT), electromagnetic (ET),	penetrant (PT), electromagnetic (ET),	(NR), leak testing (LT), acoustic emission
neutron radiographic (NR), leak	neutron radiographic (NR), leak	(AE), and visual testing (VT) to verify
testing (LT), acoustic emission (AE),	testing (LT), acoustic emission (AE),	conformance to the specified
and visual testing (VT) to verify	and visual testing (VT) to verify	requirements.
conformance to the specified	conformance to the specified	
requirements. The American Society of	requirements. The American Society of	The American Society of Nondestructive
Nondestructive	Nondestructive	Testing (ASNT) Recommended Practices or
Testing (ASNT) Recommended	Testing (ASNT) Recommended	Standards provide acceptable qualification
Practices or Standards	Practices or Standards	requirements for NDE personnel.
provide acceptable qualification	provide acceptable qualification	
requirements for NDE personnel.	requirements for NDE personnel.	
Applicable Codes and Standards or	Applicable Codes and Standards or	Applicable Codes and Standards or design
design criteria controlling the	design criteria controlling the	criteria controlling the qualification of NDE
design criteria controlling the qualification of NDE personnel shall	design criteria controlling the qualification of NDE personnel shall	personnel shall be utilized to establish the
design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable	design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable	personnel shall be utilized to establish the applicable ASNT qualification requirement
design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and	design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and	personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent
design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent	design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent	personnel shall be utilized to establish the applicable ASNT qualification requirement
design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and	design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and	personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent

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shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.	shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.	be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.
The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years.	The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years.	The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years.
Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 200 of this Requirement.	Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 200 of this Requirement.	Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 200 of this Requirement.
If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance	If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance	If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the
with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated.	with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated.	qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated.
Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated.	Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated.	Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated.
303 Lead Auditor The Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action.	303 Lead Auditor The Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action.	303 Lead Auditor The Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action.
An individual shall meet the requirements of paras. 303.1 through 303.6 of this Requirement prior to being designated a Lead Auditor.	An individual shall meet the requirements of paras. 303.1 through 303.6 of this Requirement prior to being designated a Lead Auditor.	An individual shall meet the requirements of paras. 303.1 through 303.4 of this Requirement prior to being designated a Lead Auditor.
		Lead Auditors shall maintain proficiency in accordance with the requirements of para. 303.5 or requalify in accordance with the requirements of para. 303.6, as applicable.
303.1 Communication Skills. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally.	303.1 Communication Skills. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally.	303.1 Communication Skills. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally.
These skills shall be attested to in writing by the Lead Auditor's employer.	These skills shall be attested to in writing by the Lead Auditor's employer.	These skills shall be attested to in writing by the Lead Auditor's employer.
303.2 Training. Prospective Lead Auditors shall receive training to the extent necessary to assure auditing	303.2 Training. Prospective Lead Auditors shall receive training to the extent necessary to assure auditing	303.2 Training. Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including

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competence including	competence including	
(a) knowledge and understanding of this Standard and other nuclear- related codes, standards, regulations, and regulatory guides, as applicable	(a) knowledge and understanding of this Standard and other nuclear- related codes, standards, regulations, and regulatory guides, as applicable	(a) knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable
(b) general structure of quality	(b) general structure of quality	(b) general structure of quality assurance
assurance programs as a whole and applicable elements as defined in this Standard	assurance programs as a whole and applicable elements as defined in this Standard	programs as a whole and applicable elements as defined in this Standard
(c) auditing techniques of examining, questioning,	 (c) auditing techniques of examining, questioning, 	(c) auditing techniques of examining, questioning,
evaluating, and reporting; methods of identifying and	evaluating, and reporting; methods of identifying and	evaluating, and reporting; methods of identifying and
following up on corrective action items; and closing out audit findings	following up on corrective action items; and closing out audit findings	following up on corrective action items; and closing out audit findings
(d) planning audits of activities affecting quality	(d) planning audits of activities affecting quality	(d) planning audits of activities affecting quality
(e) on-the-job training to include applicable elements of the audit program	<i>(e)</i> on-the-job training to include applicable elements of the audit program	<i>(e)</i> on-the-job training to include applicable elements of the audit program
303.3 Audit Participation.	303.3 Audit Participation.	303.3 Audit Participation. Prospective Lead
Prospective Lead Auditors	Prospective Lead Auditors	Auditors
shall participate in a minimum of five	shall participate in a minimum of five	shall participate in a minimum of five
quality assurance audits within a	quality assurance audits within a	quality assurance audits within a period of
period of time not to exceed 3 years	period of time not to exceed 3 years	time not to exceed 3 years prior to the date
prior to the date of qualification, one	prior to the date of qualification, one	of qualification, one audit of which shall be
audit of which shall be a nuclear	audit of which shall be a nuclear	a nuclear quality assurance audit within the
quality assurance audit within the	quality assurance audit within the	year prior to qualification.
year prior to qualification.	year prior to qualification.	
Participation in independent	Participation in independent	Participation in independent assessments
assessments including team assessment activities such as	assessments including team assessment activities such as	including team assessment activities such as operations readiness reviews and
operations readiness reviews and	operations readiness reviews and	regulatory inspections/surveys may be
regulatory inspections/surveys may	regulatory inspections/surveys may	used to satisfy up to four of the five
be used to satisfy up to four of the	be used to satisfy up to four of the	required quality assurance audits, provided
five required quality assurance audits,	five required quality assurance audits,	that the activities can demonstrate
provided that the activities can	provided that the activities can	the following:
demonstrate	demonstrate	
the following:	the following:	
(a) independence from the functional	(a) independence from the functional	(a) independence from the functional areas
areas being assessed	areas being assessed	being assessed
(b) planning that establishes the	(b) planning that establishes the	(b) planning that establishes the scope of
scope of the activities and associated	scope of the activities and associated	the activities and associated evaluation
evaluation criteria	evaluation criteria	criteria
(c) performance by technically	(c) performance by technically	(c) performance by technically qualified
qualified and experienced	qualified and experienced	and experienced
personnel	personnel	personnel
(d) results that are documented and reported to management	(d) results that are documented and	(d) results that are documented and
reported to management (e) appropriate corrective action	reported to management (e) appropriate corrective action	reported to management (e) appropriate corrective action initiated
initiated and tracked to resolution	initiated and tracked to resolution	and tracked to resolution
Such participation shall be subject to	Such participation shall be subject to	Such participation shall be subject to

review and		
acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.	review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.	review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.
303.4 Examination.	303.4 Examination.	303.4 Examination.
Prospective Lead Auditors shall pass an examination that shall evaluate comprehension of and ability to apply the body of knowledge identified above.	Prospective Lead Auditors shall pass an examination that shall evaluate comprehension of and ability to apply the body of knowledge identified above.	Prospective Lead Auditors shall pass an examination that shall evaluate comprehension of and ability to apply the body of knowledge identified above.
The examination may be oral, written,	The examination may be oral, written,	The examination may be oral, written,
practical, or any combination thereof.	practical, or any combination thereof.	practical, or any combination thereof.
303.5 Maintenance of Proficiency. Lead Auditors shall maintain their proficiency through one or more of the following:	303.5 Maintenance of Proficiency. Lead Auditors shall maintain their proficiency through one or more of the following:	303.5 Maintenance of Proficiency. Lead Auditors shall maintain their proficiency through one or more of the following:
(a) regular and active participation in the audit process	(a) regular and active participation in the audit process	(a) regular and active participation in the audit process
(b) review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing	(b) review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing	(b) review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing
		(c) participation in training program(s)
(c) participation in training program(s) Based on annual assessment, management may extend the qualification, require retraining, or require requalification.	 (c) participation in training program(s) Based on annual assessment, management may extend the qualification, require retraining, or require requalification. 	Based on annual assessment, management may extend the qualification, require retraining, or require requalification.
303.6 Requalification. Lead Auditors	303.6 Requalification. Lead Auditors	303.6 Regualification. Lead Auditors who
who fail to maintain their proficiency for a period of 2 years or more shall require requalification.	who fail to maintain their proficiency for a period of 2 years or more shall require requalification.	fail to maintain their proficiency for a period of 2 years or more shall require requalification.
Requalification shall include retraining	Requalification shall include retraining	Requalification shall include retraining in
in accordance with the requirements of para. 303.2 of this Requirement, reexamination in accordance with para. 303.4 of this Requirement, and participation as an Auditor in at least one nuclear quality assurance audit.	in accordance with the requirements of para. 303.2 of this Requirement, reexamination in accordance with para. 303.4 of this Requirement, and participation as an Auditor in at least one nuclear quality assurance audit.	accordance with the requirements of para. 303.2 of this Requirement, reexamination in accordance with para. 303.4 of this Requirement, and participation as an Auditor in at least one nuclear quality assurance audit.
304 Auditors	304 Auditors	304 Auditors
Auditors are participants in an audit.	Auditors are participants in an audit.	Auditors are participants in an audit.
Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for	Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for	Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for performance

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performance of the various auditing functions shall be developed by one or more of the following methods:	performance of the various auditing functions shall be developed by one or more of the following methods:	of the various auditing functions shall be developed by one or more of the following methods:
 (a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results. (b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific 	 (a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results. (b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific 	 (a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results. (b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit
audit items and methods of closing out audit findings. (c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor.	audit items and methods of closing out audit findings. (c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor.	findings. (c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor.
Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.	Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.	Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.
305 Technical Specialists The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.	305 Technical Specialists The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.	305 Technical Specialists The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.
400 RECORDS OF QUALIFICATION (a) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information: (1) employer's name (2) identification of person being	400 RECORDS OF QUALIFICATION (<i>a</i>) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information: (<i>1</i>) employer's name	 400 RECORDS OF QUALIFICATION (a) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information: (1) employer's name (2) identification of person being certified
(2) identification of person being certified (3) activities certified to perform (4) basis of qualification	 (2) identification of person being certified (3) activities certified to perform (4) basis of qualification 	(3) activities certified to perform (4) signature of employer's designated
(a) education, experience, indoctrination, and training	(a) education, experience, indoctrination, and training	representative
(b) test results, where applicable(c) capability demonstration results(5) results of periodic evaluation	(b) test results, where applicable(c) capability demonstration results(5) results of periodic evaluation	
(6) results of physical examinations,	(6) results of physical examinations,	

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when required	when required	
(7) signature of employer's	(7) signature of employer's	
designated representative	designated representative	
who is responsible for such	who is responsible for such	
certification	certification	
(8) date of certification or	(8) date of certification or	
recertification and certification	recertification and certification	
expiration	expiration	
(b) The responsible organization shall	(b) The responsible organization shall	
identify any special physical	identify any special physical	
characteristics needed in the	characteristics needed in the	
performance of each activity,	performance of each activity,	
including the need for initial and	including the need for initial and	
subsequent physical examination.	subsequent physical examination.	
		In addition to the requirements above,
		specific requirements for each
		qualification/certification that are to be
		certified in writing are specified in paras.
		401 and
		402 of this Requirement.
The employer may delegate	The employer may delegate	The employer may delegate qualification
qualification examination activities to	qualification examination activities to	examination activities to an independent
an independent certifying agency, but	an independent certifying agency, but	certifying agency but shall retain
shall retain responsibility for	shall retain responsibility for	responsibility for conformance of the
conformance of the examination and	conformance of the examination and	examination and its administration.
its administration.	its administration.	
Integrity of the examination shall be	Integrity of the examination shall be	Integrity of the examination shall be
maintained by the employer or	maintained by the employer or	maintained by the employer or certifying
certifying agency through appropriate	certifying agency through appropriate	agency through appropriate confidentiality
confidentiality of files and, where	confidentiality of files and, where	of files and, where applicable, proctoring of
applicable, proctoring of	applicable, proctoring of	examinations.
examinations.	examinations.	
Copies of the objective evidence	Copies of the objective evidence	Copies of the objective evidence regarding
regarding the type(s) and content of	regarding the type(s) and content of	the type(s) and content of the
the examination(s) shall be retained	the examination(s) shall be retained	examination(s) shall be retained by the
by the employer in accordance with	by the employer in accordance with	employer in accordance with the
the requirements of section 500 of	the requirements of section 500 of	requirements of section 500 of this
this Requirement.	this Requirement.	Requirement.
		401 Inspection and Test Personnel
		Additional requirements to those listed in
		para. 400 shall include the following:
		(a) education
		(b) work experience
		(c) training
		(d) demonstration of capabilities
		(e) date of certification/recertification
		(f) any special physical requirements
		needed in the performance of each activity,
		including the need for initial
		and subsequent physical examination
		(g) certification expiration
		402 Lead Auditor Personnel
		Additional requirements to those listed in

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		para. 400 shall include the following:
		(a) education
		(b) work experience
		(c) training
		(d) audit participation
		(e) examination results
		(f) date of certification/recertification
		(g) annual assessment of proficiency maintenance
500 RECORDS	500 RECORDS	500 RECORDS
Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.	Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.	
Records of indoctrination and training shall include one or more of the following:	Records of indoctrination and training shall include one or more of the following:	Records of indoctrination and training shall include one or more of the following:
(a) attendance sheets	(a) attendance sheets	(a) attendance sheets
(b) training logs	(b) training logs	(b) training logs
(c) personnel training records	(c) personnel training records	(c) personnel training records
The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.	The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.	The employer shall establish and maintain records for indoctrination and training; Auditor and Lead Auditor qualification and requalification; and inspection and test personnel qualification and requalification.
REQUIREMENT 3	REQUIREMENT 3	REQUIREMENT 3
Design Control 100 BASIC	Design Control 100 GENERAL	Design Control 100 GENERAL
The design shall be defined, controlled, and verified.	The design shall be defined, controlled, and verified.	The design shall be defined, controlled, and verified.
Design inputs shall be specified on a timely basis and translated into design documents.	Design inputs shall be specified on a timely basis and translated into design documents.	Design inputs shall be specified on a timely basis and translated into design documents.
Design interfaces shall be identified and controlled.	Design interfaces shall be identified and controlled.	Design interfaces shall be identified and controlled.
Design adequacy shall be verified by individuals other than those who designed the item or computer program.	Design adequacy shall be verified by individuals other than those who designed the item or computer program.	Design adequacy shall be verified by individuals other than those who designed the item or computer program.
Design changes shall be governed by control measures commensurate with those applied to the original design.	Design changes shall be governed by control measures commensurate with those applied to the original design.	Design changes shall be governed by control measures commensurate with those applied to the original design.
200 DESIGN INPUT Applicable design inputs shall be identified and documented, and their selection reviewed and approved.	200 DESIGN INPUT Applicable design inputs shall be identified and documented, and their selection reviewed and approved.	200 DESIGN INPUT Applicable design inputs shall be identified and documented, and their selection reviewed and approved.
The design input shall be specified to the level of detail	The design input shall be specified to the level of detail	The design input shall be specified to the level of detail

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necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.	necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.	necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.
300 DESIGN PROCESS (<i>a</i>) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.	300 DESIGN PROCESS (<i>a</i>) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.	300 DESIGN PROCESS (<i>a</i>) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements.
Design documents shall support facility design, construction, and operation.	Design documents shall support facility design, construction, and operation.	Design documents shall support facility design, construction, and operation.
Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. (b) The design methods, materials,	Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. (b) The design methods, materials,	Appropriate quality standards shall be identified and documented, and their selection reviewed and approved. (b) The design methods, materials, parts,
parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.	parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.	equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application.
Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.	Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.	Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.
 (c) The final design shall (1) be relatable to the design input by documentation in sufficient detail to permit design verification. 	<i>(c)</i> The final design shall <i>(1)</i> be relatable to the design input by documentation in sufficient detail to permit design verification.	(c) The final design shall (1) be relatable to the design input by documentation in sufficient detail to permit design verification.
 (2) specify required inspections and tests and include or reference appropriate acceptance criteria. (3) identify assemblies and/or 	 (2) specify required inspections and tests and include or reference appropriate acceptance criteria. (3) identify assemblies and/or 	 (2) specify required inspections and tests and include or reference appropriate acceptance criteria. (3) identify assemblies and/or components
components that are part of the item being designed. When such an assembly or	components that are part of the item being designed. When such an assembly or	that are part of the item being designed. When such an assembly or component part
component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented.	component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall meet the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.	is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall meet the requirements of Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services.

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Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended function.	Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended function.	Critical characteristics to be verified are those that provide reasonable assurance that the item will perform its intended function.
If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier 's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.	If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier 's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.	If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the Supplier 's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented definition of the difference.
400 DESIGN ANALYSES Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.	400 DESIGN ANALYSES Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.	400 DESIGN ANALYSES Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.
401 Use of Computer Programs	401 Use of Computer Programs	401 Use of Computer Programs
To the extent required in paras. 401(a) and (b) of this Requirement, computer program acceptability shall be preverified or the results verified with the design analysis for each application.	To the extent required in paras. 401(a) and (b) of this Requirement, computer program acceptability shall be preverified or the results verified with the design analysis for each application.	Each computer program used for design analysis shall be accepted for use and controlled by applying the applicable requirements of Parts I and II prior to use, or the computer program's results shall be independently verified with the design analysis for each application.
Preverified computer programs shall be controlled in accordance with the requirements of this Standard.	Preverified computer programs shall be controlled in accordance with the requirements of this Standard.	The acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements:
(a) The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.	(a) The computer program shall be verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.	(a) The computer program, or the verification method applied to the computer program results, shall be shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed.
(b) The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.	(b) The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.	(b) The applied mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.
402 Documentation of Design	402 Documentation of Design	402 Documentation of Design Analyses
Analyses Documentation of design analyses	Analyses Documentation of design analyses	Documentation of design analyses shall include the following:
shall include the following: (a) the objective of the analyses	shall include the following: (a) the objective of the analyses	(a) the objective of the analyses

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(c) results of literature searches or	(c) results of literature searches or	(c) results of literature searches or other
other applicable	other applicable	applicable
background data	background data	background data
(d) assumptions and indication of	(d) assumptions and indication of	(d) assumptions and indication of those
those assumptions that must be	those assumptions that must be	assumptions that must be verified as the
verified as the design proceeds	verified as the design proceeds	design proceeds
(e) identification of any computer	(e) identification of any computer	(e) identification of any computer
calculation, including	calculation, including	calculation, including
identification of the computer type,	identification of the computer type,	identification of the computer type,
computer program	computer program	computer program
name, and revision, inputs, outputs,	name, and revision, inputs, outputs,	name, and revision, inputs, outputs,
evidence of	evidence of	evidence of
or reference to computer program	or reference to computer program	or reference to computer program
verification, and the	verification, and the	verification, and the
bases (of reference thereto)	bases (of reference thereto)	bases (of reference thereto) supporting
supporting application of	supporting application of	application of
the computer program to the specific	the computer program to the specific	the computer program to the specific
physical problem	physical problem	physical problem
(f) review and approval	(f) review and approval	(f) review and approval
500 DESIGN VERIFICATION	500 DESIGN VERIFICATION	500 DESIGN VERIFICATION
(a) The responsible design	(a) The responsible design	(a) The responsible design organization
organization shall identify	organization shall identify	shall identify
and document the particular design	and document the particular design	and document the particular design
verification method(s) used.	verification method(s) used.	verification method(s) used.
The results of design verification shall	The results of design verification shall	The results of design verification shall be
be documented with the	be documented with the	documented with the identification of the
identification of the verifier clearly	identification of the verifier clearly	verifier clearly indicated.
indicated.	indicated.	
Design verification shall be performed	Design verification shall be performed	Design verification shall be performed by
by any competent individual(s) or	by any competent individual(s) or	any competent individual(s) or group(s)
group(s) other than those who	group(s) other than those who	other than those who performed the
performed the original design but	performed the original design but	original design but who may be from the
who may be from the same	who may be from the same	same organization.
organization.	organization.	
This verification may be	This verification may be	This verification may be
performed by the originator's	performed by the originator's	performed by the originator's supervisor,
supervisor, provided	supervisor, provided	provided
(1) the supervisor did not specify a	(1) the supervisor did not specify a	(1) the supervisor did not specify a singular
singular design	singular design	design
approach or rule out certain design	approach or rule out certain design	approach or rule out certain design
considerations and	considerations and	considerations and
did not establish the design inputs	did not establish the design inputs	did not establish the design inputs used in
used in the design; or	used in the design; or (2) the supervisor is the only	the design; or (2) the supervisor is the only individual in
(2) the supervisor is the only individual in the organization	(2) the supervisor is the only individual in the organization	the organization competent to perform the
competent to perform the	competent to perform the	verification.
verification.	verification.	
Cursory supervisory reviews do not	Cursory supervisory reviews do not	Cursory supervisory reviews do not satisfy
	satisfy the intent of this Standard.	the intent of this Standard.
satisfy the intent of this Standard	satisfy the intent of this Stanualu.	
satisfy the intent of this Standard.	(h) Design verification shall be	(h) Design verification shall be performed
(b) Design verification shall be	(b) Design verification shall be	(b) Design verification shall be performed
-	(b) Design verification shall be performed prior to releasing the design for procurement,	<i>(b)</i> Design verification shall be performed prior to releasing the design for procurement, manufacture, construction,

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another design organization, except where this timing cannot be met, such as when insufficient data exist.	another design organization, except where this timing cannot be met, such as when insufficient data exist.	except where this timing cannot be met, such as when insufficient data exist.
In those cases, the unverified portion of the design shall be identified and controlled.	In those cases, the unverified portion of the design shall be identified and controlled.	In those cases, the unverified portion of the design shall be identified and controlled.
In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.	In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.	In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.
(c) If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.	(c) If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.	(c) If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.
(d) Extent of Design Verification. The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization,	(d) Extent of Design Verification. The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization,	(d) Extent of Design Verification. The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and
the state of the art, and the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance	the state of the art, and the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance	the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance with this
with this Part (Part I), the verification process need not be duplicated for identical designs. However, the applicability of	with this Part (Part I), the verification process need not be duplicated for identical designs. However, the applicability of	Part (Part I), the verification process need not be duplicated for identical designs. However, the applicability of standardized
standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.	standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.	or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application.
Known problems affecting the standard or previously proved designs and their effects on other features shall be considered.	Known problems affecting the standard or previously proved designs and their effects on other features shall be considered.	Known problems affecting the standard or previously proved designs and their effects on other features shall be considered.
The original design and associated verification documentation shall be referenced in records of subsequent application of the design.	The original design and associated verification documentation shall be referenced in records of subsequent application of the design.	The original design and associated verification documentation shall be referenced in records of subsequent application of the design.
501 Methods Acceptable verification methods include, but are not limited to, any one or a combination of the following:	501 Methods Acceptable verification methods include, but are not limited to, any one or a combination of the following:	501 Methods Acceptable verification methods include, but are not limited to, any one or a combination of the following:
(a) design reviews (b) alternate calculations (c) qualification testing	(a) design reviews (b) alternate calculations (c) qualification testing	(a) design reviews (b) alternate calculations (c) qualification testing

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501.1 Design Reviews.	501.1 Design Reviews.	501.1 Design Reviews.
Design reviews shall provide	Design reviews shall provide	Design reviews shall provide assurance that
assurance that the final design is	assurance that the final design is	the final design is correct and satisfactory
correct and satisfactory by	correct and satisfactory by	by addressing, where applicable, paras.
addressing, where applicable, paras.	addressing, where applicable, paras.	501.1(a) through
501.1(a) through	501.1(a) through	(g) of this Requirement.
(g) of this Requirement.	(g) of this Requirement.	(a) Were the design inputs correctly
(a) Were the design inputs correctly	(a) Were the design inputs correctly	selected?
selected?	selected?	
(b) Are assumptions necessary to	(b) Are assumptions necessary to	(b) Are assumptions necessary to perform
perform the design activity	perform the design activity	the design activity adequately described
adequately described and	adequately described and	and reasonable?
reasonable?	reasonable?	
		Where percent are the assumptions
Where necessary, are the	Where necessary, are the	Where necessary, are the assumptions identified for subsequent reverifications
assumptions identified for	assumptions identified for subsequent reverifications when the	
subsequent reverifications when the	•	when the detailed design activities are
detailed design activities are	detailed design activities are completed?	completed?
completed?		
(c) Were appropriate design methods	(c) Were appropriate design methods	(c) Were appropriate design methods and
and computer programs used?	and computer programs used?	computer programs used?
(d) Were the design inputs correctly	(d) Were the design inputs correctly	(d) Were the design inputs correctly
incorporated into	incorporated into	incorporated into
the design?	the design?	the design?
(e) Is the design output reasonable	(e) Is the design output reasonable	(e) Is the design output reasonable
compared to design inputs?	compared to design inputs?	compared to design inputs?
(f) Are the necessary design inputs for	(f) Are the necessary design inputs for	(f) Are the necessary design inputs for
interfacing organizations specified in	interfacing organizations specified in	interfacing organizations specified in the
the design documents or in	the design documents or in	design documents or in supporting
supporting procedures or	supporting procedures or	procedures or instructions?
instructions?	instructions?	
(g) Have suitable materials, parts,	(g) Have suitable materials, parts,	(g) Have suitable materials, parts,
processes, and inspection and testing	processes, and inspection and testing	processes, and inspection and testing
criteria been specified?	criteria been specified?	criteria been specified?
501.2 Alternate Calculations.	501.2 Alternate Calculations.	501.2 Alternate Calculations. Alternate
Alternate calculations shall use	Alternate calculations shall use	calculations shall use alternate methods to
alternate methods to verify	alternate methods to verify	verify correctness of the original
correctness of the original	correctness of the original	calculations or analyses.
calculations or analyses.	calculations or analyses.	
The appropriateness of assumptions;	The appropriateness of assumptions;	The appropriateness of assumptions; input
input data used; and the computer	input data used; and the computer	data used; and the computer program, its
program, its associated computer	program, its associated computer	associated computer hardware and system
hardware and system software, or	hardware and system software, or	software, or other calculation method used
other calculation method used shall	other calculation method used shall	shall also be reviewed.
also be reviewed.	also be reviewed.	
501.3 Qualification Tests. Testing	501.3 Qualification Tests. Testing	501.3 Qualification Tests. Testing shall
shall demonstrate adequacy of	shall demonstrate adequacy of	demonstrate adequacy of performance
performance under conditions that	performance under conditions that	under conditions that simulate the most
simulate the most adverse design	simulate the most adverse design	adverse design conditions.
conditions.	conditions.	
Operating modes and environmental	Operating modes and environmental	Operating modes and environmental
conditions shall be considered in	conditions shall be considered in	conditions shall be considered in
determining the most adverse	determining the most adverse	determining the most adverse conditions.
conditions.	conditions.	

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Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.	Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.	Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.
When tests are being performed on models or mockups, scaling laws shall be established and verified.	When tests are being performed on models or mockups, scaling laws shall be established and verified.	When tests are being performed on models or mockups, scaling laws shall be established and verified.
The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.	The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.	The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.
600 CHANGE CONTROL (a) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design.	600 CHANGE CONTROL (<i>a</i>) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design.	600 CHANGE CONTROL (<i>a</i>) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design.
These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based.	These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based.	These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based.
The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.	The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.	The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.
Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents.	Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents.	Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents.
When the organization originally responsible for review and approval of the original design documents is no longer responsible, the owner or his designee shall have responsibility or designate a new responsible organization.	When the organization originally responsible for review and approval of the original design documents is no longer responsible, the owner or his designee shall have responsibility or designate a new responsible organization.	When the organization originally responsible for review and approval of the original design documents is no longer responsible, the owner or his designee shall have responsibility or designate a new responsible organization.
The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.	The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.
 (b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. (c) Where a significant design change 	 (b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. (c) Where a significant design change 	 (b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate. (c) Where a significant design change is

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is necessary because of an incorrect	is necessary because of an incorrect	necessary because of an incorrect design,
design, the design process and	design, the design process and	the design process and verification
verification procedure shall be	verification procedure shall be	procedure shall be reviewed and modified
reviewed and modified as necessary.	reviewed and modified as necessary.	as necessary.
601 Configuration Management of	601 Configuration Management of	601 Configuration Management of
Operating	Operating	Operating
Facilities	Facilities	Facilities
Procedures implementing	Procedures implementing	Procedures implementing configuration
configuration management	configuration management	management requirements shall be
requirements shall be established and	requirements shall be established and	established and documented at the earlies
documented at the earliest practical	documented at the earliest practical	practical time prior to facility operation.
time prior to facility operation.	time prior to facility operation.	
These procedures shall include the	These procedures shall include the	These procedures shall include the
responsibilities and authority	responsibilities and authority	responsibilities and authority
of the organizations whose functions	of the organizations whose functions	of the organizations whose functions affec
affect the configuration of the facility	affect the configuration of the facility	the configuration of the facility including
including activities such as operations,	including activities such as operations,	activities such as operations, design,
design, maintenance, construction,	design, maintenance, construction,	maintenance, construction, licensing, and
licensing, and procurement.	licensing, and procurement.	procurement.
601.1 Configuration management	601.1 Configuration management	601.1 Configuration management
requirements shall include measures	requirements shall include measures	requirements shall include measures to
to ensure changes that may affect the	to ensure changes that may affect the	ensure changes that may affect the
approved configuration are	approved configuration are	approved configuration are recognized and
recognized and processed.	recognized and processed.	processed.
601.2 The configuration shall be	601.2 The configuration shall be	601.2 The configuration shall be
established and approved at the	established and approved at the	established and approved at the earliest
earliest practical time prior to initial	earliest practical time prior to initial	practical time prior to initial operation of
operation of the facility, and	operation of the facility, and	the facility, and maintained for the life of
maintained for the life of the facility. 601.3 The configuration shall include,	maintained for the life of the facility. 601.3 The configuration shall include,	the facility. 601.3 The configuration shall include, as
as applicable,	as applicable,	applicable,
characteristics derived from	characteristics derived from	characteristics derived from regulatory
regulatory requirements	regulatory requirements	requirements
and commitments, calculations and	and commitments, calculations and	and commitments, calculations and
analyses, design	analyses, design	analyses, design
inputs, installation and test	inputs, installation and test	inputs, installation and test requirements,
requirements, supplier manuals	requirements, supplier manuals	supplier manuals
and instructions, operating and	and instructions, operating and	and instructions, operating and
maintenance requirements, and other	maintenance requirements, and other	maintenance requirements, and other
applicable sources.	applicable sources.	applicable sources.
601.4 Interface controls shall include	601.4 Interface controls shall include	601.4 Interface controls shall include the
the integration of activities of	the integration of activities of	integration of activities of organizations
organizations that can affect the	organizations that can affect the	that can affect the approved configuration
approved configuration.	approved configuration.	
601.5 Documentation shall identify	601.5 Documentation shall identify	601.5 Documentation shall identify the
, the design bases	the design bases	design bases
and the approved configuration for	and the approved configuration for	and the approved configuration for the
the approved modes of operation.	the approved modes of operation.	approved modes of operation.
601.6 Measures shall be established	601.6 Measures shall be established	601.6 Measures shall be established and
and implemented to ensure that	and implemented to ensure that	implemented to ensure that proposed
proposed changes to the	proposed changes to the	changes to the configuration are evaluated
configuration are evaluated for their	configuration are evaluated for their	for their conformance to the design bases.
conformance to the design bases.	conformance to the design bases.	_

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601.7 The implementation sequence for approved configuration changes shall be	601.7 The implementation sequence for approved configuration changes shall be	601.7 The implementation sequence for approved configuration changes shall be reviewed to
reviewed to determine that the	reviewed to determine that the	determine that the configuration conforms
configuration conforms to the design bases.	configuration conforms to the design bases.	to the design bases.
601.8 Approval by the design authority shall be required prior to implementation of a change to the design bases.	601.8 Approval by the design authority shall be required prior to implementation of a change to the design bases.	601.8 Approval by the design authority shall be required prior to implementation of a change to the design bases.
601.9 The configuration of the facility	601.9 The configuration of the facility	601.9 The configuration of the facility shall
shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility.	shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility.	be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility.
The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for	The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for	The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in
revision in support of operation.	revision in support of operation.	support of operation.
700 INTERFACE CONTROL	700 INTERFACE CONTROL	700 INTERFACE CONTROL
Interface controls shall include	Interface controls shall include	Interface controls shall include assignment
assignment of responsibility	assignment of responsibility	of responsibility
and establishment of procedures	and establishment of procedures	and establishment of procedures among
among participating design organizations for review, approval,	among participating design organizations for review, approval,	participating design organizations for review, approval, release, distribution, and
release, distribution, and revision of	release, distribution, and revision of	revision of documents involving design
documents involving design	documents involving design	interfaces.
interfaces.	interfaces.	
Design information transmitted	Design information transmitted	Design information transmitted across
across interfaces shall	across interfaces shall	interfaces shall
identify the status of the design	identify the status of the design	identify the status of the design
information or document	information or document	information or document
provided, and identify incomplete	provided, and identify incomplete	provided, and identify incomplete items
items that require further evaluation,	items that require further evaluation,	that require further evaluation, review, or
review, or approval.	review, or approval.	approval.
Where it is necessary to initially	Where it is necessary to initially	Where it is necessary to initially transmit
transmit design information orally or	transmit design information orally or	design information orally or by other
by other informal means, the	by other informal means, the	informal means, the transmittal shall be
transmittal shall be confirmed	transmittal shall be confirmed	confirmed promptly by a controlled
promptly by a controlled document.	promptly by a controlled document.	document.
800 SOFTWARE DESIGN CONTROL	800 SOFTWARE DESIGN CONTROL	800 SOFTWARE DESIGN CONTROL
The requirements of section 800 apply to computer software design	The requirements of section 800 apply to computer software design	The requirements of Part II, Subpart 2.7, Quality Assurance Requirements for
control and shall be used instead of	control and shall be used instead of	Computer Software for Nuclear Facility
section 200, Design Input; section	section 200, Design Input; section	Applications, apply to computer software
300, Design Process; section 500,	300, Design Process; section 500,	design control and shall be used instead of
Design Verification; and section 600,	Design Verification; and section 600,	section 200, Design Input; section 300,
Change	Change	Design Process; section 500, Design
Control. Part II, Subpart 2.7, Quality	Control. Part II, Subpart 2.7, Quality	Verification; and section 600, Change
Assurance Requirements for	Assurance Requirements for	Control.
Computer Software for Nuclear	Computer Software for Nuclear	

practice requirements to implement p	Facility Applications, provides work practice requirements to implement	
	the requirements of this paragraph.1	
	1 Regulatory Guides 1.152, Criteria for	
	Use of Computers in Safety Systems	
	of Nuclear Power Plants, and 1.168,	
	Verification, Validation, Reviews, and	
	Audits for Digital Computer Software	
	Jsed in Safety Systems of Nuclear	
	Power Plants, provide guidance	
	for nuclear power plant licensees and	
	their suppliers on acceptable	
	methods and techniques.	
-	801 Software Design Process	
	The software design process shall be	
•	documented, approved by the	
	responsible design organization, and	
	controlled.	
	This process shall include the	
-	activities described in paras. 801.1	
•	through 801.5 of this Requirement.	
	801.1 Identification of Software	
	Design Requirements.	
	Software design requirements shall	
	be identified and documented and	
	their selection reviewed and	
	approved.	
	The software requirements shall	
	dentify the operating system,	
	function, interfaces, performance	
-	requirements, installation	
	considerations, design inputs, and any	
	design constraints of the computer	
	program.	
	801.2 Software Design.	
-	The software design shall be	
-	documented and shall define the	
computational sequence necessary to c	computational sequence necessary to	
	meet the software requirements.	
-	The documentation shall include, as	
	applicable, numerical	
	methods, mathematical models,	
	ohysical models, control flow, control	
	ogic, data flow, process flow, data	
-	structures, process structures, and	
-	he applicable relationships between	
	data structures and process	
-	structures.	
This documentation may be T	This documentation may be	
-	combined with the	
	documentation of the software	
documentation of the software d		

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the computer program listings resulting from implementation of the software design.	the computer program listings resulting from implementation of the software design.	
801.3 Implementation of the	801.3 Implementation of the	
Software Design.	Software Design.	
The software design shall be	The software design shall be	
translated into computer program(s)	translated into computer program(s)	
using the programming organization's	using the programming organization's	
or design organization's programming	or design organization's programming	
standards and conventions.	standards and conventions.	-
801.4 Software Design Verification.	801.4 Software Design Verification.	
Software design verification shall be	Software design verification shall be	
performed by a competent	performed by a competent	
individual(s) or group(s) other than	individual(s) or group(s) other than	
those who developed and	those who developed and	
documented the original design, but	documented the original design, but	
who may be from the same	who may be from the same	
organization.	organization.	-
This verification may be performed by	This verification may be performed by	
the originator's supervisor, provided	the originator's supervisor, provided	
(a) the supervisor did not specify a	(a) the supervisor did not specify a	
singular design approach or rule out	singular design approach or rule out	
certain design considerations and did	certain design considerations and did	
not establish the design inputs used	not establish the design inputs used	
in the design, or	in the design, or	
(b) the supervisor is the only	(b) the supervisor is the only	
individual in the organization	individual in the organization	
competent to perform the	competent to perform the	
verification.	verification.	
Cursory supervisory reviews do not	Cursory supervisory reviews do not	
satisfy the intent of this Standard. The results of verification shall be	satisfy the intent of this Standard. The results of verification shall be	-
documented with the identification of	documented with the identification of	
the verifier indicated.	the verifier indicated.	
Software verification methods shall	Software verification methods shall	-
include any one or a combination of	include any one or a combination of	
design reviews, alternate calculations,	design reviews, alternate calculations,	
and tests performed during computer	and tests performed during computer	
program development.	program development.	
The extent of verification and the	The extent of verification and the	
methods chosen are a function	methods chosen are a function	
of	of	
the complexity of the software,	the complexity of the software,	
the degree of standardization,	the degree of standardization,	4
the similarity with previously proved	the similarity with previously proved	
software, and the importance to safety.	software, and the importance to safety.	4
801.5 Computer Program Testing.	801.5 Computer Program Testing.	1
Computer program testing shall be	Computer program testing shall be	
performed and shall be in accordance	performed and shall be in accordance	
with Requirement 11.	with Requirement 11.	
802 Software Configuration	802 Software Configuration	

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Management	Management	
Software configuration management	Software configuration management	
includes, but is not limited to	includes, but is not limited to	
configuration identification, change	configuration identification, change	
control, and status control.	control, and status control.	
Configuration items shall be	Configuration items shall be	1
maintained under configuration	maintained under configuration	
management until the software is	management until the software is	
retired.	retired.	
802.1 Configuration Identification.	802.1 Configuration Identification.	1
A software baseline shall be	A software baseline shall be	
established at the completion of each	established at the completion of each	
activity of the software design	activity of the software design	
process.	process.	
Approved changes created	Approved changes created]
subsequent to a baseline shall be	subsequent to a baseline shall be	
added to the baseline.	added to the baseline.	
A baseline shall define the most	A baseline shall define the most]
recently approved software	recently approved software	
configuration.	configuration.	
A labeling system for configuration	A labeling system for configuration	
items shall be	items shall be	
implemented that	implemented that	
(a) uniquely identifies each	(a) uniquely identifies each	
configuration item	configuration item	
(b) identifies changes to configuration	(b) identifies changes to configuration	
items by	items by	
revision	revision	
(c) provides the ability to uniquely	(c) provides the ability to uniquely	
identify each configuration of the	identify each configuration of the	
revised software available for use	revised software available for use	_
802.2 Configuration Change Control.	802.2 Configuration Change Control.	
Changes to software shall be formally	Changes to software shall be formally	
documented.	documented.	
The documentation shall include	The documentation shall include	
(a) a description of the change	(a) a description of the change	
(b) the rationale for the change	<i>(b)</i> the rationale for the change	
(c) the identification of affected	(c) the identification of affected	
software baselines	software baselines	
The change shall be formally	The change shall be formally	
evaluated and approved by the	evaluated and approved by the	
organization responsible for the	organization responsible for the	
original design, unless an alternate	original design, unless an alternate	
organization has been given the	organization has been given the	
authority to approve the changes.	authority to approve the changes.	4
Only authorized changes shall be	Only authorized changes shall be	
made to software baselines.	made to software baselines.	4
Appropriate verification activities	Appropriate verification activities	
shall be performed for the change.	shall be performed for the change.	
The change shall be appropriately	The change shall be appropriately	
reflected in documentation, and	reflected in documentation, and	
traceability of the change to the	traceability of the change to the	
software design requirement shall be	software design requirement shall be	

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maintained.	maintained.	
Appropriate acceptance testing shall	Appropriate acceptance testing shall	
be performed for the change.	be performed for the change.	
802.3 Configuration Status Control.	802.3 Configuration Status Control.	
The status of configuration items	The status of configuration items	
resulting from software design shall	resulting from software design shall	
be maintained current.	be maintained current.	
Configuration item changes shall be	Configuration item changes shall be	
controlled until they are incorporated	controlled until they are incorporated	
into the approved product baseline.	into the approved product baseline.	
The controls shall include a process	The controls shall include a process	
for maintaining the status of changes	for maintaining the status of changes	
that are proposed and approved, but	that are proposed and approved, but	
not implemented.	not implemented.	
The controls shall also provide for	The controls shall also provide for	
notification of this information to	notification of this information to	
affected organizations.	affected organizations.	
900 DOCUMENTATION AND	900 DOCUMENTATION AND	900 DOCUMENTATION AND RECORDS
RECORDS	RECORDS	Design documentation and records shall
Design documentation and records	Design documentation and records	include not only final design documents,
shall include not	shall include not	such as drawings and specifications, and
only final design documents, such as	only final design documents, such as	revisions to those documents, but also
drawings and specifications, and	drawings and specifications, and	documentation that identifies the
revisions to those documents, but	revisions to those documents, but	important steps in the design process,
also	also	including sources of design inputs that
documentation that identifies the	documentation that identifies the	support the final design.
important steps in the	important steps in the	
design process, including sources of	design process, including sources of	
design inputs that support the final	design inputs that support the final	
design.	design.	
REQUIREMENT 4	REQUIREMENT 4	REQUIREMENT 4
Procurement Document Control 100 BASIC	Procurement Document Control 100 GENERAL	Procurement Document Control 100 GENERAL
Applicable design bases and other	Applicable design bases and other	Applicable design bases and other
requirements necessary to assure	requirements necessary to assure	requirements necessary to assure adequate
adequate quality shall be included or	adequate quality shall be included or	quality shall be included or referenced in
referenced in documents for	referenced in documents for	documents for procurement of items and
procurement of items and services.	procurement of items and services.	services.
To the extent necessary, procurement	To the extent necessary, procurement	To the extent necessary, procurement
documents shall require Suppliers to	documents shall require Suppliers to	documents shall require Suppliers to have a
have a quality assurance program	have a quality assurance program	quality assurance program consistent with
consistent with the applicable	consistent with the applicable	the applicable requirements of this
requirements of this Standard.	requirements of this Standard.	Standard.
200 CONTENT OF THE	200 CONTENT OF THE	200 CONTENT OF THE PROCUREMENT
PROCUREMENT	PROCUREMENT	DOCUMENTS
DOCUMENTS	DOCUMENTS	Procurement documents issued at all tiers
Procurement documents issued at all	Procurement documents issued at all	of procurement shall include provisions for
tiers of procurement shall include	tiers of procurement shall include	the following, as deemed necessary by the
provisions for the following, as	provisions for the following, as	Purchaser.
deemed necessary by the Purchaser.	deemed necessary by the Purchaser.	
201 Scope of Work	201 Scope of Work	201 Scope of Work
Procurement documents shall include	Procurement documents shall include	Procurement documents shall include a
a statement of the scope of the work	a statement of the scope of the work	statement of the scope of the work to be

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to be performed by the Supplier.	to be performed by the Supplier.	performed by the Supplier.
202 Technical Requirements	202 Technical Requirements	202 Technical Requirements
Technical requirements shall be	Technical requirements shall be	Technical requirements shall be specified in
specified in the procurement	specified in the procurement	the procurement documents.
documents.	documents.	
These requirements shall be	These requirements shall be	These requirements shall be specified, as
specified, as appropriate by reference	specified, as appropriate by reference	appropriate by reference to specific
to specific drawings, specifications,	to specific drawings, specifications,	drawings, specifications, codes, standards,
codes, standards, regulations,	codes, standards, regulations,	regulations, procedures, or instructions,
procedures, or instructions, including	procedures, or instructions, including	including revisions thereto that describe
revisions thereto that describe the	revisions thereto that describe the	the items or services to be furnished.
items or services to be furnished.	items or services to be furnished.	
The procurement documents shall	The procurement documents shall	The procurement documents shall identify
identify appropriate test, inspection,	identify appropriate test, inspection,	appropriate test, inspection, and
and acceptance criteria for	and acceptance criteria for	acceptance criteria for determining
determining acceptability of the item	determining acceptability of the item	acceptability of the item or service.
or service.	or service.	
203 Quality Assurance Program	203 Quality Assurance Program	203 Quality Assurance Program
Requirements	Requirements	Requirements
Quality assurance program	Quality assurance program	Quality assurance program requirements
requirements shall be specified in the	requirements shall be specified in the	shall be specified in the procurement
procurement documents.	procurement documents.	documents.
These requirements shall be	These requirements shall be	These requirements shall be consistent
consistent with importance and/or	consistent with importance and/or	with importance and/or complexity of the
complexity of the item or service	complexity of the item or service	item or service being procured.
being procured.	being procured.	
The procurement documents shall	The procurement documents shall	The procurement documents shall require
require the Supplier to incorporate	require the Supplier to incorporate	the Supplier to incorporate appropriate
appropriate quality assurance	appropriate quality assurance	quality assurance program requirements in
program requirements in subtier	program requirements in subtier	subtier procurement documents.
procurement documents.	procurement documents.	
204 Right of Access	204 Right of Access	204 Right of Access
The procurement documents shall	The procurement documents shall	The procurement documents shall provide
provide for access to the Supplier's	provide for access to the Supplier's	for access to the Supplier's and subtier
and subtier Supplier's facilities and	and subtier Supplier's facilities and	Supplier's facilities and records for
records for surveillance, inspection, or	records for surveillance, inspection, or	surveillance, inspection, or audit by the
audit by the Purchaser, its designated	audit by the Purchaser, its designated	Purchaser, its designated representative,
representative, and others authorized	representative, and others authorized	and others authorized by the Purchaser.
by the Purchaser.	by the Purchaser.	
205 Documentation Requirements	205 Documentation Requirements	205 Documentation Requirements
The procurement documents shall	The procurement documents shall	The procurement documents shall identify
identify the documentation required	identify the documentation required	the documentation required to be
to be submitted for information,	to be submitted for information,	submitted for information, review, or
review, or approval by the Purchaser.	review, or approval by the Purchaser.	approval by the Purchaser.
The time of submittal shall also be	The time of submittal shall also be	The time of submittal shall also be
established.	established.	established.
When the Purchaser requires the	When the Purchaser requires the	When the Purchaser requires the Supplier
Supplier to maintain specific records,	Supplier to maintain specific records,	to maintain specific records, the retention
the retention times and disposition	the retention times and disposition	times and disposition requirements shall be
requirements shall be prescribed.	requirements shall be prescribed.	prescribed.
206 Nonconformances	206 Nonconformances	206 Nonconformances
The procurement documents shall	The procurement documents shall	The procurement documents shall specify
specify the Purchaser's requirements	specify the Purchaser's requirements	the Purchaser's requirements for the

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for the Supplier's reporting of nonconformances.	for the Supplier's reporting of nonconformances.	Supplier's reporting of nonconformances.
207 Spare and Replacement Parts	207 Spare and Replacement Parts	207 Spare and Replacement Parts
The procurement documents shall	The procurement documents shall	The procurement documents shall specify
specify the Supplier's requirements to	specify the Supplier's requirements to	the Supplier's requirements to identify
identify spare and replacement parts	identify spare and replacement parts	spare and replacement parts or assemblies
or assemblies and the related data	or assemblies and the related data	and the related data required for ordering
required for ordering these parts or	required for ordering these parts or	these parts or assemblies.
assemblies.	assemblies.	
300 PROCUREMENT DOCUMENT	300 PROCUREMENT DOCUMENT	300 PROCUREMENT DOCUMENT REVIEW
REVIEW	REVIEW	A review of the procurement documents,
A review of the procurement	A review of the procurement	and changes thereto, shall be made and
documents, and changes thereto,	documents, and changes thereto,	documented prior to award to assure that
shall be made and documented prior	shall be made and documented prior	documents transmitted to prospective
to award to assure that documents	to award to assure that documents	Supplier(s) include appropriate provisions
transmitted to prospective Supplier(s)	transmitted to prospective Supplier(s)	to assure that items or services will meet
include appropriate provisions to	include appropriate provisions to	the specified requirements.
assure that items or services will meet	assure that items or services will meet	
the specified requirements.	the specified requirements.	
Technical or quality assurance	Technical or quality assurance	Technical or quality assurance program
program changes made as a result of	program changes made as a result of	changes made as a result of bid evaluations
bid evaluations or negotiations shall	bid evaluations or negotiations shall	or negotiations shall be incorporated into
be incorporated into the procurement	be incorporated into the procurement	the procurement documents prior to their
documents prior to their issuance to	documents prior to their issuance to	issuance to the Supplier.
the Supplier.	the Supplier.	
Procurement document review shall	Procurement document review shall	Procurement document review shall be
be performed by	be performed by	performed by
personnel who have access to	personnel who have access to	personnel who have access to pertinent
pertinent information and who have	pertinent information and who have	information and who have an adequate
an adequate understanding of the	an adequate understanding of the	understanding of the requirements and
requirements and intent of the	requirements and intent of the	intent of the procurement documents.
procurement documents.	procurement documents.	
400 PROCUREMENT DOCUMENT	400 PROCUREMENT DOCUMENT	400 PROCUREMENT DOCUMENT CHANGES
CHANGES	CHANGES	Procurement document changes affecting
Procurement document changes	Procurement document changes	the technical or quality assurance program
affecting the technical or quality	affecting the technical or quality	requirements shall be subject to the same
assurance program requirements	assurance program requirements	degree of control as utilized in the
shall be subject to the same degree of	shall be subject to the same degree of	preparation of the original documents.
control as utilized in the preparation	control as utilized in the preparation	
of the original documents.	of the original documents.	
REQUIREMENT 5	REQUIREMENT 5	REQUIREMENT 5
	Instructions, Procedures, and	Instructions, Procedures, and Drawings
Instructions, Procedures, and		
Drawings	Drawings	100 GENERAL
Drawings 100 BASIC	Drawings 100 GENERAL	100 GENERAL
Drawings 100 BASIC Activities affecting quality and	Drawings 100 GENERAL Activities affecting quality and	100 GENERAL Activities affecting quality and services shall
Drawings 100 BASIC Activities affecting quality and services shall be prescribed by and	Drawings 100 GENERAL Activities affecting quality and services shall be prescribed by and	100 GENERAL Activities affecting quality and services shall be prescribed by and performed in
Drawings 100 BASIC Activities affecting quality and services shall be prescribed by and performed in accordance with	Drawings 100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with	100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions,
Drawings 100 BASIC Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures,	Drawings 100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures,	100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or
Drawings 100 BASIC Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference	Drawings 100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference	100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or
Drawings 100 BASIC Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or	Drawings 100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or	100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for
Drawings 100 BASIC Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference	Drawings 100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference	100 GENERAL Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or

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accomplished.	accomplished.	
The activity shall be described to a	The activity shall be described to a	The activity shall be described to a level of
level of detail commensurate with the	level of detail commensurate with the	detail commensurate with the complexity
complexity of the activity and the	complexity of the activity and the	of the activity and the need to assure
need to assure consistent and	need to assure consistent and	consistent and acceptable results.
acceptable results.	acceptable results.	
The need for, and level of detail in,	The need for, and level of detail in,	The need for, and level of detail in, written
written procedures or instructions	written procedures or instructions	procedures or instructions shall be
shall be determined based upon	shall be determined based upon	determined based upon complexity of the
complexity of the task, the	complexity of the task, the	task, the significance of the item or activity,
significance of the item or activity,	significance of the item or activity,	work environment,
work environment,	work environment,	and worker proficiency and capability
and worker proficiency and capability	and worker proficiency and capability	(education, training, experience).
(education, training, experience).	(education, training, experience).	
REQUIREMENT 6	REQUIREMENT 6	REQUIREMENT 6
Document Control	Document Control	Document Control
100 BASIC	100 GENERAL	100 GENERAL
The preparation, issue, and change of	The preparation, issue, and change of	The preparation, issue, and change of
documents that specify quality	documents that specify quality	documents that specify quality
requirements or prescribe activities	requirements or prescribe activities	requirements or prescribe activities
affecting quality such as instructions,	affecting quality such as instructions,	affecting quality such as instructions,
procedures, and drawings shall be	procedures, and drawings shall be	procedures, and drawings shall be
controlled to ensure that correct	controlled to ensure that correct	controlled to ensure that correct
documents are being employed.	documents are being employed.	documents are being employed.
Such documents, including changes	Such documents, including changes	Such documents, including changes
thereto, shall be reviewed for	thereto, shall be reviewed for	thereto, shall be reviewed for adequacy
adequacy and approved for release by	adequacy and approved for release by	and approved for release by authorized
authorized personnel.	authorized personnel.	personnel.
200 DOCUMENT CONTROL	200 DOCUMENT CONTROL	200 DOCUMENT CONTROL
The following controls shall be	The following controls shall be	The following controls shall be applied to
applied to documents and changes	applied to documents and changes	documents and changes thereto:
thereto:	thereto:	(a) the identification of controlled
(a) the identification of controlled	(a) the identification of controlled	documents
documents	documents	
		(b) the specified distribution of controlled
(b) the specified distribution of	(b) the specified distribution of	documents for use at the appropriate
controlled documents for use at the	controlled documents for use at the	location
appropriate location	appropriate location	
		(c) the identification of individuals
(c) the identification of individuals	(c) the identification of individuals	responsible for the
responsible for the	responsible for the	preparation, review, approval, and
preparation, review, approval, and	preparation, review, approval, and	distribution of controlled
distribution of controlled	distribution of controlled	documents
documents	documents	
		(d) the review of controlled documents for
(d) the review of controlled	(d) the review of controlled	adequacy,
documents for adequacy,	documents for adequacy,	completeness, and approval prior to
completeness, and approval prior to	completeness, and approval prior to	distribution
distribution	distribution	(e) a method to ensure the correct
(e) a method to ensure the correct	(e) a method to ensure the correct	documents are being used
documents are being used	documents are being used	
300 DOCUMENT CHANGES	300 DOCUMENT CHANGES	300 DOCUMENT CHANGES
301 Major Changes	301 Major Changes	301 Major Changes

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Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.	Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.	Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated.
The reviewing organization shall have access to pertinent background data or information upon which to base their approval.	The reviewing organization shall have access to pertinent background data or information upon which to base their approval.	The reviewing organization shall have access to pertinent background data or information upon which to base their approval.
302 Minor Changes Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.	302 Minor Changes Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.	302 Minor Changes Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.
To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.	To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.	To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.
REQUIREMENT 7 Control of Purchased Items and Services 100 BASIC	REQUIREMENT 7 Control of Purchased Items and Services 100 GENERAL	REQUIREMENT 7 Control of Purchased Items and Services 100 GENERAL
The procurement of items and services shall be controlled to ensure conformance with specified requirements.	The procurement of items and services shall be controlled to ensure conformance with specified requirements.	The procurement of items and services shall be controlled to ensure conformance with specified requirements.
Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.	Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.	Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.
200 SUPPLIER EVALUATION AND SELECTION Prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents.	200 SUPPLIER EVALUATION AND SELECTION Prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents.	200 SUPPLIER EVALUATION AND SELECTION Prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents.
Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:	Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:	Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:

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(a) Supplier's history of providing an	(<i>a</i>) Supplier's history of providing an	<i>(a)</i> Supplier's history of providing an identical or similar product that performs
identical or similar product that	identical or similar product that	satisfactorily in actual use. The Supplier's
performs satisfactorily in actual use.	performs satisfactorily in actual use.	history shall reflect current capability.
The Supplier's history shall reflect	The Supplier's history shall reflect	
current capability.	current capability.	(b) Supplier's current quality records
		supported by documented qualitative and
(b) Supplier's current quality records	(b) Supplier's current quality records	quantitative information that can be
supported by	supported by	objectively evaluated and may include
documented qualitative and	documented qualitative and	current third party certificates that
quantitative information that can be	quantitative information that can be	recognize the Supplier's quality assurance
objectively evaluated.	objectively evaluated.	program (QAP) or other technical
		certification.
(c) Supplier's technical and quality	(c) Supplier's technical and quality	
capability as determined by a direct	capability as determined by a direct	(c) Supplier's technical and quality
evaluation of the facilities, personnel,	evaluation of the facilities, personnel,	capability as determined by a direct
and the implementation of the	and the implementation of the	evaluation of the facilities, personnel, and
Supplier's quality assurance program.	Supplier's quality assurance program.	the implementation of the Supplier's QAP.
300 BID EVALUATION	300 BID EVALUATION	300 BID EVALUATION
If bids are solicited, the bid evaluation	If bids are solicited, the bid evaluation	If bids are solicited, the bid evaluation shall
shall include a determination of the	shall include a determination of the	include a determination of the Supplier's
Supplier's capability to conform to the	Supplier's capability to conform to the	capability to conform to the technical and
technical and quality assurance	technical and quality assurance	quality assurance requirements.
requirements.	requirements.	
Prior to the award of the contract,	Prior to the award of the contract,	Prior to the award of the contract, the
the Purchaser shall	the Purchaser shall	Purchaser shall
resolve or obtain commitments to	resolve or obtain commitments to	resolve or obtain commitments to resolve
resolve unacceptable technical and	resolve unacceptable technical and	unacceptable technical and quality
quality assurance conditions resulting	quality assurance conditions resulting	assurance conditions resulting from the bid
from the bid evaluation.	from the bid evaluation.	evaluation.
400 CONTROL OF SUPPLIER-	400 CONTROL OF SUPPLIER-	400 CONTROL OF SUPPLIER-GENERATED
GENERATED	GENERATED	DOCUMENTS
DOCUMENTS	DOCUMENTS	Controls shall be implemented to ensure
Controls shall be implemented to	Controls shall be implemented to	that the submittal and evaluation of
ensure that the submittal and	ensure that the submittal and	Supplier-generated documents and
evaluation of Supplier-generated	evaluation of Supplier-generated	changes are accomplished in accordance
documents and changes are	documents and changes are	with the procurement document
accomplished in accordance with the	accomplished in accordance with the	requirements.
procurement document	procurement document	
requirements.	requirements.	
These controls shall provide for the	These controls shall provide for the	These controls shall provide for the
acquisition, processing, and	acquisition, processing, and	acquisition, processing, and
recorded evaluation of the quality	recorded evaluation of the quality	recorded evaluation of the quality
assurance, technical, inspection, and	assurance, technical, inspection, and	assurance, technical, inspection, and test
test documentation or data against	test documentation or data against	documentation or data against acceptance
acceptance criteria.	acceptance criteria.	criteria.
500 ACCEPTANCE OF ITEM OR	500 ACCEPTANCE OF ITEM OR	500 ACCEPTANCE OF ITEM OR SERVICE
SERVICE	SERVICE	501 General
501 General	501 General	Prior to offering the item or service for
Prior to offering the item or service	Prior to offering the item or service	acceptance, the Supplier shall verify that
for acceptance, the Supplier shall	for acceptance, the Supplier shall	the item or service being furnished
verify that the item or service being	verify that the item or service being	complies with the procurement
furnished complies with the	furnished complies with the	requirements.

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procurement requirements.	procurement requirements.	
The extent of the verification	The extent of the verification	The extent of the verification activities by
activities by the Purchaser shall be a	activities by the Purchaser shall be a	the Purchaser shall be a function of the
function of the relative importance,	function of the relative importance,	relative importance, complexity, and
complexity, and quantity of the item	complexity, and quantity of the item	quantity of the item or services procured
or services procured and the	or services procured and the	and the Supplier's quality performance.
Supplier's quality performance.	Supplier's quality performance.	
Where required by code, regulation,	Where required by code, regulation,	Where required by code, regulation, or
or contract requirement,	or contract requirement,	contract requirement, documentary
documentary evidence that items	documentary evidence that items	evidence that items conform to
conform to procurement	conform to procurement	procurement requirements shall be
requirements shall be available at the	requirements shall be available at the	available at the nuclear facility site prior to
nuclear facility site prior to	nuclear facility site prior to	installation or use.
installation or use.	installation or use.	
502 Methods of Acceptance	502 Methods of Acceptance	502 Methods of Acceptance
Purchaser methods used to accept an	Purchaser methods used to accept an	Purchaser methods used to accept an item
item or service	item or service	or service
from a Supplier shall be a Supplier	from a Supplier shall be a Supplier	from a Supplier shall be a Supplier
Certificate of	Certificate of Conformance, source verification,	Certificate of
Conformance, source verification,		Conformance, source verification, receiving inspection, or postinstallation test at the
receiving inspection, or postinstallation test at the nuclear	receiving inspection, or postinstallation test at the nuclear	nuclear facility site, or a combination of
facility site, or a combination of these	facility site, or a combination of these	these methods.
methods.	methods.	these methods.
503 Certificate of Conformance	503 Certificate of Conformance	503 Certificate of Conformance
When a Certificate of Conformance is	When a Certificate of Conformance is	When a Certificate of Conformance is
used, the minimum criteria of paras.	used, the minimum criteria of paras.	used, the minimum criteria of paras. 503(a)
503(a) through (f) of this	503(a) through (f) of this	through (f) of this
Requirement shall be met.	Requirement shall be met.	Requirement shall be met.
(a) The certificate shall identify the	(a) The certificate shall identify the	(a) The certificate shall identify the
purchased material or equipment,	purchased material or equipment,	purchased material or equipment, such as
such as by the purchase order	such as by the purchase order	by the purchase order number.
number.	number.	
		(b) The certificate shall identify the specific
(b) The certificate shall identify the	(b) The certificate shall identify the	procurement requirements met by the
specific procurement requirements	specific procurement requirements	purchased material or equipment, such as
met by the purchased material or	met by the purchased material or	codes, standards, and other specifications.
equipment, such as codes, standards,	equipment, such as codes, standards,	This may be accomplished by including a
and other specifications. This may be	and other specifications. This may be	list of the specific requirements or by
accomplished by including a list of the	accomplished by including a list of the	providing, on-site, a copy of the purchase
specific requirements or by providing,	specific requirements or by providing,	order and the procurement specifications
on-site, a copy of the purchase order	on-site, a copy of the purchase order	or drawings, together with a suitable
and the procurement specifications or	and the procurement specifications or	certificate. The procurement requirements
drawings, together with a suitable	drawings, together with a suitable	identified shall include any approved
certificate. The procurement	certificate. The procurement	changes, waivers, or deviations applicable
requirements identified shall include	requirements identified shall include	to the subject material or equipment.
any approved changes, waivers, or	any approved changes, waivers, or	(a) The contificate shall identify any
deviations applicable to the subject	deviations applicable to the subject	(c) The certificate shall identify any
material or equipment.	material or equipment.	procurement requirements that have not been met, together with an explanation
(c) The certificate shall identify any	(c) The certificate shall identify any	and the means for resolving the
procurement requirements that have	procurement requirements that have	nonconformances.
procurement requirements that have	procurement requirements that lidve	noncomormances.

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not been met, together with an explanation and the means for	not been met, together with an explanation and the means for	(d) The certificate shall be signed or
resolving the nonconformances.	resolving the nonconformances.	otherwise authenticated by a person who is
 (d) The certificate shall be signed or otherwise authenticated by a person who is 	 (d) The certificate shall be signed or otherwise authenticated by a person who is 	responsible for this quality assurance function and whose function and position are described in the Purchaser's or
responsible for this quality assurance function and whose function and	responsible for this quality assurance function and whose function and	Supplier's quality assurance program.
position are described in the Purchaser's or Supplier's quality	position are described in the Purchaser's or Supplier's quality	<i>(e)</i> The certification system, including the procedures to be followed in filling out a
assurance program.	assurance program.	certificate and the administrative procedures for review and approval of the
<i>(e)</i> The certification system, including the procedures to be followed in filling out a certificate and the	<i>(e)</i> The certification system, including the procedures to be followed in filling out a certificate and the	certificates, shall be described in the Purchaser's or Supplier's quality assurance program.
administrative procedures for review and approval	administrative procedures for review and approval	<i>(f)</i> Means shall be provided to verify the
of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.	of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.	validity of Supplier certificates and the effectiveness of the certification
(f) Means shall be provided to verify the validity of	(f) Means shall be provided to verify the validity of	system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such
Supplier certificates and the effectiveness of the certification system, such as during the	Supplier certificates and the effectiveness of the certification system, such as during the	verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.
performance of audits of the Supplier or independent inspection or test of	performance of audits of the Supplier or independent inspection or test of	
the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.	the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.	
504 Source Verification	504 Source Verification	504 Source Verification
When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities.	When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities.	When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities.
Source verification shall be implemented in accordance with plans to perform inspections,	Source verification shall be implemented in accordance with plans to perform inspections,	Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at
examinations, or tests at predetermined points.	examinations, or tests at predetermined points.	predetermined points.
Upon Purchaser acceptance of source verification, documented evidence of	Upon Purchaser acceptance of source verification, documented evidence of	Upon Purchaser acceptance of source verification, documented evidence of
acceptance shall be furnished to the receiving destination of the item, to	acceptance shall be furnished to the receiving destination of the item, to	acceptance shall be furnished to the receiving destination of the item, to the
the Purchaser, and to the Supplier. 505 Receiving Inspection	the Purchaser, and to the Supplier. 505 Receiving Inspection	Purchaser, and to the Supplier. 505 Receiving Inspection
When receiving inspection is used,	When receiving inspection is used,	When receiving inspection is used,

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purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier.	purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier.	purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier.
Receiving inspection shall verify by objective evidence such features as (a) configuration (b) identification (c) dimensional, physical, and other characteristics (d) freedom from shipping damage	Receiving inspection shall verify by objective evidence such features as (a) configuration (b) identification (c) dimensional, physical, and other characteristics (d) freedom from shipping damage	Receiving inspection shall verify by objective evidence such features as (a) configuration (b) identification (c) dimensional, physical, and other characteristics (d) freedom from shipping damage
(e) cleanliness Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.	(e) cleanliness Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.	(e) cleanliness Receiving inspection shall be coordinated with review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.
506 Postinstallation Testing When postinstallation testing is used, postinstallation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.	506 Postinstallation Testing When postinstallation testing is used, postinstallation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.	506 Postinstallation Testing When postinstallation testing is used, postinstallation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.
507 Acceptance of Services Only In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:	507 Acceptance of Services Only In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:	507 Acceptance of Services Only In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:
(a) technical verification of data produced (b) surveillance and/or audit of the	(a) technical verification of data produced (b) surveillance and/or audit of the	(a) technical verification of data produced (b) surveillance and/or audit of the activity
activity (c) review of objective evidence for conformance to the procurement document	activity (c) review of objective evidence for conformance to the procurement document	<i>(c)</i> review of objective evidence for conformance to the procurement document requirements
requirements 600 CONTROL OF SUPPLIER NONCONFORMANCES Methods for control and disposition of Supplier nonconformances for items and services that do not meet	requirements 600 CONTROL OF SUPPLIER NONCONFORMANCES Methods for control and disposition of Supplier nonconformances for items and services that do not meet	600 CONTROL OF SUPPLIER NONCONFORMANCES Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement

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procurement document requirements	procurement document requirements	document requirements shall include
shall include paras. 600(a) through (e)	shall include paras. 600(a) through (e)	paras. 600(a) through (e) of this
of this Requirement:	of this Requirement:	Requirement:
(a) evaluation of nonconforming items.	(a) evaluation of nonconforming items.	(a) evaluation of nonconforming items.
		(b) submittal of nonconformance notice to
(b) submittal of nonconformance	(b) submittal of nonconformance	Purchaser by Supplier as directed by the
notice to Purchaser by Supplier as	notice to Purchaser by Supplier as	Purchaser. These submittals shall include
directed by the Purchaser. These	directed by the Purchaser. These	Supplier-recommended disposition (e.g.,
submittals shall include Supplier-	submittals shall include Supplier-	use-as-is or repair) and technical
recommended disposition (e.g., use-	recommended disposition (e.g., use-	justification. Nonconformances
as-is or repair) and technical	as-is or repair) and technical	to the procurement requirements or
justification. Nonconformances	justification. Nonconformances	Purchaser-approved documents, which
to the procurement requirements or	to the procurement requirements or	consist of one or more of the following,
Purchaser-approved documents,	Purchaser-approved documents,	shall be submitted to the Purchaser for
which consist of one or more of the	which consist of one or more of the	approval of the recommended disposition:
following, shall be submitted to the	following, shall be submitted to the	(1) technical or material requirement is
Purchaser for approval of the	Purchaser for approval of the	violated (2) requirement in Supplier documents,
recommended disposition:	recommended disposition:	
 technical or material requirement violated 	(1) technical or material requirement is violated	which has been approved by the Purchaser, is violated
(2) requirement in Supplier	(2) requirement in Supplier	(3) nonconformance cannot be corrected
documents, which has been approved	documents, which has been approved	by continuation of the original
by the Purchaser, is violated	by the Purchaser, is violated	manufacturing process or by rework
(3) nonconformance cannot be	(3) nonconformance cannot be	(4) the item does not conform to the
corrected by continuation of the	corrected by continuation of the	original requirement even though the item
original manufacturing process or by	original manufacturing process or by	can be restored to a condition such that the
rework	rework	capability of the item to function
(4) the item does not conform to the	(4) the item does not conform to the	is unimpaired
original requirement even though the	original requirement even though the	
item can be restored to a condition	item can be restored to a condition	(c) Purchaser disposition of Supplier
such that the capability of the item to	such that the capability of the item to	recommendation.
function	function	
is unimpaired	is unimpaired	(d) verification of the implementation of
		the disposition.
(c) Purchaser disposition of Supplier	(c) Purchaser disposition of Supplier	
recommendation.	recommendation.	(e) maintenance of records of Supplier-
		submitted
(d) verification of the implementation	(d) verification of the implementation	nonconformances.
of the disposition.	of the disposition.	
(e) maintenance of records of	(e) maintenance of records of	
Supplier-submitted	Supplier-submitted	
nonconformances.	nonconformances.	
700 COMMERCIAL GRADE ITEMS	700 COMMERCIAL GRADE ITEMS AND	700 COMMERCIAL GRADE ITEMS AND
AND SERVICES1	SERVICES	SERVICES
701 General	When commercial grade items or	When commercial grade items or services
1 The U.S. Nuclear Regulatory	services are utilized, the requirements	are utilized, the requirements of Part II,
Commission issued Generic Letter	of Part II, Subpart 2.14, Quality	Subpart 2.14, Quality Assurance
89-02 and Generic Letter 91-05 to	Assurance Requirements for	Requirements for Commercial Grade Items
licenses of nuclear power plants	Commercial Grade Items and Services,	and Services, shall apply and are an
pursuant to 10 CFR Part 50, Appendix	shall apply and are an acceptable	acceptable alternative to sections 200

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B. These generic letters conditionally endorse the guidelines contained in EPRI, NP-5652, <i>Guidelines for the Commercial Grade</i> <i>Items in Safety-Related Applications</i> (<i>NCIG-07</i>). These documents subsequently contributed to the development of the 10 CFR Part 21 related <i>commercial grade item</i> definitions. These sources were utilized in the development of the criteria in section 700 of Requirement 7. 10 CFR Part 21, <i>Reporting of Defects</i> <i>and Noncompliance</i> , is applicable to facilities per 10 CFR Parts 30, 40, 50, 60, 61, 70, and 72, unless specifically provided otherwise in the regulations. 10 CFR Part 21, Definitions, §21.3, are pursuant to all identified 10 CFR Parts, unless a specific 10 CFR Part is identified in the definition. 10 CFR Part 21, Definitions, §21.3 contains two definitions related to <i>commercial</i> <i>grade items</i> . One definition relates to nuclear power plants licensed pursuant to 10 CFR S0 and the second relates to other facilities, per the applicable 10 CFR Parts. Additionally, other definitions in 10 CFR Part 21 have criteria that are only applicable to licensed nuclear power plants pursuant to 10 CFR Part 50. Section 700 of Requirement 7, Commercial Grade Items and Services, contains criteria applicable to 10 CFR Part 50 for nuclear power plants but provides sufficient quality criteria for the facilities identified in Part 1, Introduction, section 200, Applicability. Facilities other than 10 CFR 50 nuclear power plants utilizing this section may establish other commercial grade criteria for the applicable 10 CFR Part facility, per the definitions contained in 10 CFR Part 21 and other applicable regulations.	alternative to sections 200 through 600 of this Requirement, except that Supplier evaluation and selection, where determined necessary by the Purchaser, shall be in accordance with section 200 of this Requirement.	through 600 of this Requirement, except that Supplier evaluation and selection, where determined necessary by the Purchaser, shall be in accordance with section 200 of this Requirement.
services are utilized,		

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the dedicating entity can utilize the		
requirements of this section for		
procurement and acceptance of items		
or services as an acceptable		
alternative to sections 200 through		
600 of this Requirement, except that		
Supplier evaluation and selection,		
where determined necessary by the		
Purchaser, shall be in accordance with		
section 200 of this Requirement. The		
applicable requirements of this		
Standard shall apply to dedication		
activities for acceptance.		
When section 700 of this		
Requirement is applied		
to nuclear power plants licensed		
pursuant to 10 CFR Part 50 or 10 CFR		
Part 52 and their suppliers, Part II,		
Subpart 2.14, Quality Assurance		
Requirements for Commercial Grade		
Items and Services, provides		
requirements for dedication activities		
for acceptance that are required by		
10 CFR Part 21.		
702 Utilization]	
(a) The utilization of commercial		
grade items or services		
shall include the following:		
(1) technical evaluation to determine		
that the item or service performs a		
safety function		
(2) confirmation that the item or		
service meets the commercial grade		
definition criteria		
(3) identification of the critical		
characteristics,		
including acceptance criteria		
(4) selection, performance, and		
documentation of the dedication		
method(s) for determining		
compliance with acceptance criteria		
(b) When one or more critical		
characteristics for acceptance cannot		
be verified by the dedication		
methods, the requirements of this		
section shall not be utilized to		
procure and accept the commercial		
grade item or service.	4	
703 Critical Characteristics		
Critical characteristic selection for		
acceptance shall address the		
following:		
(a) identifiable and measurable		

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attributes or variables		
appropriate for the safety function		
(b) criteria related to the location of		
the item in the		
facility or criteria addressing the most		
severe location of the item in the		
facility, unless controls are in place to		
prevent usage in undesignated		
locations		
704 Dedication		
(a) The dedicating entity shall provide		
reasonable assurance that the		
commercial grade item or service		
meets the acceptance criteria for the		
identified critical characteristics by		
inspections, tests, or analyses		
performed after delivery,		
supplemented as necessary by one or		
more of the following:		
(1) commercial grade survey of the		
Supplier		
(2) source verification of the item or		
service		
(3) acceptable Supplier/item		
performance record		
(b) Prior to acceptance of the		
commercial grade item		
or service, the dedicating entity shall		
determine the following, as		
applicable:		
(1) damage was not sustained during shipment		
(2) the item or service has satisfied		
the specified		
acceptance criteria for the identified		
critical characteristics		
(3) specified documentation was		
received and is acceptable		
704.1 Commercial Grade Survey		
(a) A commercial grade survey is		
performed in accordance		
with a checklist or plan at the		
Supplier's facility and includes or		
addresses the following:		
(1) identification of the item(s), or		
product line, or service included		
within the scope of the survey		
(2) identification of the critical		
characteristics to be controlled by the		
Supplier		
(3) verification of the Supplier 's processes and quality program		
processes and quality program	1	

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controls are effectively implemented			
for control of the critical			
characteristics			
(4) identification of the survey			
methods or verification			
activities performed with results			
obtained			
(5) documentation of the adequacy of			
the Supplier's processes and controls			
(b) A commercial grade survey shall			
not be employed			
as a supplemental basis for accepting			
commercial grade			
items or services from Suppliers with			
undocumented quality programs or			
with programs that do not effectively			
implement the Supplier's own			
specified processes and controls.			
After a Supplier's processes and			
controls have been determined to be			
adequate, the dedicating entity shall			
invoke or reference the verified			
processes and controls as a part of			
the purchase order or control			
requirements for the commercial			
grade item or service and require the			
Supplier to provide a Certificate of			
Conformance attesting to the			
implementation of the identified			
processes and controls.			
(c) The dedicating entity shall			
establish the survey frequency for			
reconfirming the previous survey			
information for application to			
additional purchases.			
704.2 Source Verification. Source			
verification is only applicable to the			
actual item(s) or service(s) that are			
verified at the Supplier's facility or			
other applicable location.			
Source verification shall be performed			
in accordance with para. 504 of this			
Requirement, including a checklist or			
plan with the documented evidence			
of the source verification furnished to			
the dedicating entity and shall include			
or address the following:			
(a) identification of the item(s) or			
service(s) included within the scope of			
the source verification			
(b) identification of the critical			
characteristics, including			
acceptance criteria, to be controlled			

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by the Supplier		
(c) verification of the Supplier's		
processes and controls are effectively		
implemented for the identified critical		
characteristics		
(d) identification of the activities		
witnessed during the source		
verification and the results obtained		
(e) documentation of the adequacy of		
the Supplier's processes and controls		
704.3 Acceptable Supplier/Item		
Services Performance		
Records		
(a) An acceptable		
Supplier/item/service performance		
record shall include the following:		
(1) identification of the		
supplier/item/service being evaluated		
(2) identification of previously		
established critical		
characteristics specific to the		
Supplier/item/service		
(3) identification of industry data		
examined to evaluate the		
Supplier/item/service		
(4) identification of basis for		
determining that industry data		
substantiates acceptability of the		
Supplier/item/service		
(5) documentation of the adequacy		
and acceptance of the		
Supplier/item/service performance		
record		
<i>(b)</i> An acceptable		
Supplier/item/service performance		
record shall not be employed unless		
(1) the established historical record is		
based on		
industry-wide performance data that		
is directly applicable to the critical		
characteristics and the intended		
facility application, i.e., a single		
source of information is not adequate		
to demonstrate satisfactory performance		
(2) the manufacturer/Supplier's		
measures for the control of applicable		
design, process, and material change		
have been accepted by the dedicating		
entity		
(c) Continued application of an		
acceptable Supplier/item/service		
performance record shall include a		

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documented periodic update and		
review to assure the		
Supplier/item/service maintains an		
acceptable performance record.		
705 Supplier Deficiency Correction		
Deficiencies identified in the		
Supplier's processes and controls		
identified in the dedication process		
shall be corrected by the Supplier and		
verified by the dedicating entity, if the		
specified dedication process is to be		
used to verify an identified critical		
characteristic.		
800 RECORDS	800 RECORDS	800 RECORDS
Records shall be established and	Records shall be established and	Records shall be established and
maintained to indicate the	maintained to indicate the	maintained to indicate the performance of
performance of the following	performance of the following	the following functions:
functions:	functions:	(a) supplier evaluation and selection
(a) supplier evaluation and selection	(a) supplier evaluation and selection	(b) acceptance of items or services
(b) acceptance of items or services	(b) acceptance of items or services	(c) supplier nonconformances to
(c) supplier nonconformances to	(c) supplier nonconformances to	procurement document requirements,
procurement document requirements, including their	procurement document requirements, including their	including their evaluation and disposition
evaluation and disposition	evaluation and disposition	
(d) utilization and acceptance of		
commercial grade items		
REQUIREMENT 8	REQUIREMENT 8	REQUIREMENT 8
Identification and Control of Items	Identification and Control of Items	Identification and Control of Items
100 BASIC	100 GENERAL	100 GENERAL
Controls shall be established to assure	Controls shall be established to assure	Controls shall be established to assure that
that only correct and accepted items	that only correct and accepted items	only correct and accepted items are used
are used or installed.	are used or installed.	or installed.
Identification shall be maintained on	Identification shall be maintained on	Identification shall be maintained on the
the items or in documents traceable	the items or in documents traceable	items or in documents traceable to the
to the items, or in a manner that	to the items, or in a manner that	items, or in a manner that assures that
assures that identification is	assures that identification is	identification is established and
established and maintained.	established and maintained.	maintained.
200 IDENTIFICATION METHODS	200 IDENTIFICATION METHODS	200 IDENTIFICATION METHODS
201 Item Identification	201 Item Identification	201 Item Identification
Items of production (batch, lot,	Items of production (batch, lot,	Items of production (batch, lot,
component, part) shall be identified	component, part) shall be identified	component, part) shall be identified from
from the initial receipt and fabrication	from the initial receipt and fabrication	the initial receipt and fabrication of items
of items up to and including	of items up to and including	up to and including installation and use.
installation and use.	installation and use.	milteteleventfreent i i i i voor
This identification shall relate an item	This identification shall relate an item	This identification shall relate an item to an
to an applicable design or other	to an applicable design or other	applicable design or other pertinent
nortinont chocituing document	pertinent specifying document.	specifying document.
pertinent specifying document.	202 Dhycical Identification	
202 Physical Identification	202 Physical Identification	202 Physical Identification
202 Physical Identification Physical identification shall be used to	Physical identification shall be used to	Physical identification shall be used to the
202 Physical Identification Physical identification shall be used to the maximum extent possible.	Physical identification shall be used to the maximum extent possible.	Physical identification shall be used to the maximum extent possible.
202 Physical Identification Physical identification shall be used to	Physical identification shall be used to	Physical identification shall be used to the

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procedural control, or other appropriate means shall be	procedural control, or other appropriate means shall be	appropriate means shall be employed.
employed.	employed.	Identification markings shall be applied
Identification markings shall be	Identification markings shall be	Identification markings shall be applied
applied using materials and methods	applied using materials and methods	using materials and methods that provide a
that provide a clear and legible	that provide a clear and legible	clear and legible identification and do not
identification and do not degrade the function or service life of the item.	identification and do not degrade the function or service life of the item.	degrade the function or service life of the item.
Markings shall be transferred to each	Markings shall be transferred to each	Markings shall be transferred to each part
part of an identified item when	part of an identified item when	of an identified item when subdivided and
subdivided and shall not be	subdivided and shall not be	shall not be obliterated or hidden by
		surface treatment or coating unless other
obliterated or hidden by surface	obliterated or hidden by surface	means of identification are substituted.
treatment or coating unless other means of identification are	treatment or coating unless other means of identification are	means of identification are substituted.
substituted.	substituted.	
300 SPECIFIC REQUIREMENTS	300 SPECIFIC REQUIREMENTS	300 SPECIFIC REQUIREMENTS
301 Identification and Traceability of	301 Identification and Traceability of	301 Identification and Traceability of
Items	Items	Items
When codes, standards, or	When codes, standards, or	When codes, standards, or specifications
specifications include specific	specifications include specific	include specific
identification or traceability	identification or traceability	identification or traceability requirements
requirements (such as	requirements (such as	(such as
identification or traceability of the	identification or traceability of the	identification or traceability of the item to
item to applicable	item to applicable	applicable
specification and grade of material;	specification and grade of material;	specification and grade of material; heat,
heat, batch, lot, part,	heat, batch, lot, part,	batch, lot, part,
or serial number; or specified	or serial number; or specified	or serial number; or specified inspection,
inspection, test, or other records), the	inspection, test, or other records), the	test, or other records), the program shall
program shall provide such	program shall provide such	provide such identification and traceability
identification and traceability control.	identification and traceability control.	control.
302 Limited Life Items	302 Limited Life Items	302 Limited Life Items
Items having limited calendar or	Items having limited calendar or	Items having limited calendar or operating
operating life or cycles shall be	operating life or cycles shall be	life or cycles shall be identified and
identified and controlled to preclude	identified and controlled to preclude	controlled to preclude use of items whose
use of items whose shelf life or	use of items whose shelf life or	shelf life or operating life has expired.
operating life has expired.	operating life has expired.	
303 Maintaining Identification of	303 Maintaining Identification of	303 Maintaining Identification of Stored
Stored Items	Stored Items	Items
Provisions shall be made for the	Provisions shall be made for the	Provisions shall be made for the control of
control of item identification	control of item identification	item identification consistent with the
consistent with the planned duration	consistent with the planned duration	planned duration and conditions of
and conditions of storage, such as	and conditions of storage, such as	storage, such as
(a) provisions for maintenance or	(a) provisions for maintenance or	(a) provisions for maintenance or
replacement of markings and	replacement of markings and	replacement of markings and identification
identification records due to damage	identification records due to damage	records due to damage during handling or
during handling or aging (h) protection of identifications on	during handling or aging	aging
(b) protection of identifications on	(b) protection of identifications on items subject to excessive	(b) protection of identifications on items subject to excessive deterioration due to
	-	environmental exposure
items subject to excessive deterioration due to environmental	deterioration due to environmental	
deterioration due to environmental	deterioration due to environmental	-
deterioration due to environmental exposure	exposure	(c) provisions for updating existing plant
deterioration due to environmental		-

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Control of Special Processes	Control of Special Processes	Control of Special Processes
100 BASIC	100 GENERAL	100 GENERAL
Special processes that control or	Special processes that control or	Special processes that control or verify
verify quality, such as those used in	verify quality, such as those used in	quality, such as those used in welding, heat
welding, heat treating, and	welding, heat treating, and	treating, and nondestructive examination,
nondestructive examination, shall be	nondestructive examination, shall be	shall be performed by qualified personnel
performed by qualified personnel	performed by qualified personnel	using qualified procedures in accordance
using qualified procedures in	using qualified procedures in	with specified requirements.
accordance with specified	accordance with specified	
requirements.	requirements.	
200 PROCESS CONTROL	200 PROCESS CONTROL	200 PROCESS CONTROL
201 Special Processes	201 Special Processes	201 Special Processes
Special processes shall be controlled	Special processes shall be controlled	Special processes shall be controlled by
by instructions, procedures, drawings,	by instructions, procedures, drawings,	instructions, procedures, drawings,
checklists, travelers, or other	checklists, travelers, or other	checklists, travelers, or other appropriate
appropriate means.	appropriate means.	means.
Special process instructions shall	Special process instructions shall	Special process instructions shall include or
include or reference procedure,	include or reference procedure,	reference procedure, personnel, and
personnel, and equipment	personnel, and equipment	equipment qualification requirements.
qualification requirements.	qualification requirements.	
Conditions necessary for	Conditions necessary for	Conditions necessary for accomplishment
accomplishment of the process shall	accomplishment of the process shall	of the process shall be included.
be included.	be included.	
These conditions shall include proper	These conditions shall include proper	These conditions shall include proper
equipment, controlled parameters of	equipment, controlled parameters of	equipment, controlled parameters of the
the process, specified environment,	the process, specified environment,	process, specified environment, and
and calibration requirements.	and calibration requirements.	calibration requirements.
202 Acceptance Criteria	202 Acceptance Criteria	202 Acceptance Criteria
The requirements of applicable codes	The requirements of applicable codes	The requirements of applicable codes and
and standards, including acceptance	and standards, including acceptance	standards, including acceptance criteria for
criteria for the process, shall be	criteria for the process, shall be	the process, shall be specified or
specified or referenced in procedures	specified or referenced in procedures	referenced in procedures or instructions.
or instructions.	or instructions.	·
203 Special Requirements	203 Special Requirements	203 Special Requirements
For special processes not covered by	For special processes not covered by	For special processes not covered by
existing codes and standards or	existing codes and standards or	existing codes and standards or where
where quality requirements specified	where quality requirements specified	quality requirements specified exceed
exceed those of existing codes or	exceed those of existing codes or	those of existing codes or standards, the
standards, the necessary	standards, the necessary	necessary requirements for qualifications
requirements for qualifications of	requirements for qualifications of	of personnel, procedures, or equipment
personnel, procedures, or equipment	personnel, procedures, or equipment	shall be specified or referenced in
shall be specified or referenced in	shall be specified or referenced in	procedures or instructions.
procedures or instructions.	procedures or instructions.	
300 RESPONSIBILITY	300 RESPONSIBILITY	300 RESPONSIBILITY
It is the responsibility of the	It is the responsibility of the	It is the responsibility of the organization
organization performing the special	organization performing the special	performing the special process to adhere to
process to adhere to the approved	process to adhere to the approved	the approved procedures and processes.
procedures and processes.	procedures and processes.	The second s
400 RECORDS	400 RECORDS	400 RECORDS
Records shall be maintained as	Records shall be maintained as	Records shall be maintained as appropriate
appropriate for the currently qualified	appropriate for the currently qualified	for the currently qualified personnel,
personnel, processes, and equipment	personnel, processes, and equipment	processes, and equipment of each special
personnel, processes, and equipment		

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REQUIREMENT 10	REQUIREMENT 10	REQUIREMENT 10
Inspection	Inspection	Inspection
100 BASIC	100 GENERAL	100 GENERAL
Inspections required to verify	Inspections required to verify	Inspections required to verify conformance
conformance of an item or activity to	conformance of an item or activity to	of an item or activity to specified
specified requirements or continued	specified requirements or continued	requirements or continued acceptability of
acceptability of items in service shall	acceptability of items in service shall	items in service shall be planned and
be planned and executed.	be planned and executed.	executed.
Characteristics subject to inspection	Characteristics subject to inspection	Characteristics subject to inspection and
and inspection methods shall be	and inspection methods shall be	inspection methods shall be specified.
specified.	specified.	
Inspection results shall be	Inspection results shall be	Inspection results shall be documented.
documented.	documented.	
Inspection for acceptance shall be	Inspection for acceptance shall be	Inspection for acceptance shall be
performed by qualified persons other	performed by qualified persons other	performed by qualified persons other than
than those who performed or directly	than those who performed or directly	those who performed or directly
supervised the work being inspected.	supervised the work being inspected.	supervised the work being inspected.
200 INSPECTION REQUIREMENTS	200 INSPECTION REQUIREMENTS	200 INSPECTION REQUIREMENTS
Inspection requirements and	Inspection requirements and	Inspection requirements and acceptance
acceptance criteria shall	acceptance criteria shall	criteria shall
include specified requirements	include specified requirements	include specified requirements contained
contained in the applicable design	contained in the applicable design	in the applicable design documents or
documents or other pertinent	documents or other pertinent	other pertinent technical documents
technical documents approved by the	technical documents approved by the	approved by the responsible design
responsible design organization.	responsible design organization.	organization.
300 INSPECTION HOLD POINTS	300 INSPECTION HOLD POINTS	300 INSPECTION HOLD POINTS
If mandatory inspection hold points	If mandatory inspection hold points	If mandatory inspection hold points are
are required beyond which work shall	are required beyond which work shall	required beyond which work shall not
not proceed without the specific	not proceed without the specific	proceed without the specific consent of the
consent of the designated	consent of the designated	designated representative, the specific hold
representative, the specific hold	representative, the specific hold	points shall be indicated in appropriate
points shall be indicated in	points shall be indicated in	documents.
appropriate documents.	appropriate documents.	
Consent to waive specified hold	Consent to waive specified hold	Consent to waive specified hold points shall
points shall be recorded prior to	points shall be recorded prior to	be recorded prior to continuation of work
continuation of work beyond the	continuation of work beyond the	beyond the designated hold point.
designated hold point.	designated hold point.	
400 INSPECTION PLANNING	400 INSPECTION PLANNING	400 INSPECTION PLANNING
401 Planning	401 Planning	401 Planning
401 Planning Characteristics to be inspected,	401 Planning Characteristics to be inspected,	401 Planning Characteristics to be inspected, methods of
401 Planning Characteristics to be inspected, methods of inspection, and	401 Planning Characteristics to be inspected, methods of inspection, and	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.	401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.
 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling
 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval.	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval.
401 PlanningCharacteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval.500 IN-PROCESS INSPECTION	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION Inspection of items under	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION Inspection of items under 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION Inspection of items under construction or
401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION 	 401 Planning Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process. 402 Sampling Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval. 500 IN-PROCESS INSPECTION

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necessary to verify quality.	necessary to verify quality.	to verify quality.
If inspection of processed items is	If inspection of processed items is	If inspection of processed items is
impossible or disadvantageous,	impossible or disadvantageous,	impossible or disadvantageous, indirect
indirect control by monitoring of	indirect control by monitoring of	control by monitoring of processing
processing methods, equipment, and	processing methods, equipment, and	methods, equipment, and personnel shall
personnel shall be provided.	personnel shall be provided.	be provided.
Process monitoring shall be	Process monitoring shall be	Process monitoring shall be performed by
performed by qualified personnel or	performed by qualified personnel or	qualified personnel or qualified automated
qualified automated means.	qualified automated means.	means.
Both inspection and process	Both inspection and process	Both inspection and process monitoring
monitoring shall be provided when	monitoring shall be provided when	shall be provided when control is
control is inadequate without both.	control is inadequate without both.	inadequate without both.
600 FINAL INSPECTIONS	600 FINAL INSPECTIONS	600 FINAL INSPECTIONS
601 Resolution of Nonconformances	601 Resolution of Nonconformances	601 Resolution of Nonconformances
Final inspections shall include a	Final inspections shall include a	Final inspections shall include a records
records review of the results and	records review of the results and	review of the results and resolution of
resolution of nonconformances	resolution of nonconformances	nonconformances identified by prior
identified by prior inspections.	identified by prior inspections.	inspections.
602 Inspection Requirements	602 Inspection Requirements	602 Inspection Requirements
Completed items shall be inspected	Completed items shall be inspected	Completed items shall be inspected for
for completeness, markings,	for completeness, markings,	completeness, markings, calibration,
calibration, adjustments, protection	calibration, adjustments, protection	adjustments, protection from damage, or
from damage, or other characteristics	from damage, or other characteristics	other characteristics as required to verify
as required to verify the quality and	as required to verify the quality and	the quality and conformance of the item to
conformance of the item to specified	conformance of the item to specified	specified requirements.
requirements.	requirements.	
hud Madutications Banairs or		
603 Modifications, Repairs, or Replacements	603 Modifications, Repairs, or Replacements	603 Modifications, Repairs, or Replacements
Replacements	Replacements	Replacements
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Replacements Any modifications, repairs, or replacements of items performed subsequent to final inspection shall	Replacements Any modifications, repairs, or replacements of items performed subsequent to final inspection shall	Replacements Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or
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(f) reference to information on action taken in connection with nonconformances	<i>(f)</i> reference to information on action taken in connection with nonconformances	(f) reference to information on action taken in connection with nonconformances
REQUIREMENT 11 Test Control 100 BASIC	REQUIREMENT 11 Test Control 100 GENERAL	REQUIREMENT 11 Test Control 100 GENERAL
Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed.	Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed.	Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed.
Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.	Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.	Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.
200 TEST REQUIREMENTS (<i>a</i>) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization.	200 TEST REQUIREMENTS (<i>a</i>) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization.	200 TEST REQUIREMENTS (<i>a</i>) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization.
Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, operational tests, and computer program tests such as software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled.	Required tests (other than for computer programs) including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled.	Required tests (other than for computer programs) including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled.
Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.	Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.	Computer program tests including, as appropriate, software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.
The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.	The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.	The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.
(b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable	(b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable	(b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable

NQA-1-2008	NQA-1a-2009	NQA-1-2017
design documents, or other pertinent technical documents that provide approved requirements.	design documents, or other pertinent technical documents that provide approved requirements.	design documents or other pertinent technical documents that provide approved requirements.
(c) If temporary changes to the	(c) If temporary changes to the	(c) If temporary changes to the approved
approved configuration of a facility	approved configuration of a facility	configuration of a facility are required for
are required for testing purposes,	are required for testing purposes,	testing purposes, approval by the design
approval by the design authority is	approval by the design authority is	authority is required prior to performing
required prior to performing the test.	required prior to performing the test.	the test.
	(d) Test requirements and acceptance	No (d) paragraph in 2017 edition
	criteria for computer programs shall	
	be provided by the organization	
	responsible for the use of the	
	computer program and shall include	
	the following, as applicable:	
	(1) Software design verification	
	testing shall demonstrate the	
	capability of the computer program(s)	
	to provide valid results for test	
	problems encompassing the range of	
	documented permitted usage.	
	(2) Computer program acceptance testing shall consist of the process of	
	exercising or evaluating a system or	
	system component by manual or	
	automated means to ensure that it	
	satisfies the specified requirements	
	and to identify differences between	
	expected and actual results in the	
	operating environment.	
	(3) In-use computer programs testing	
	shall demonstrate required	
	performance over the range of	
	operation of the controlled function	
· · · · · · · · · · · · · · · · · · ·	or process.	
300 TEST PROCEDURES (OTHER THAN	300 TEST PROCEDURES (OTHER THAN	300 TEST PROCEDURES (OTHER THAN FOR
FOR COMPUTER PROGRAMS)	FOR COMPUTER PROGRAMS)	COMPUTER PROGRAMS) (a) Test procedures shall include or
(a) Test procedures shall include or	(a) Test procedures shall include or	reference the test configuration and test
reference the test configuration and	reference the test configuration and	objectives.
test objectives.	test objectives.	objectives.
Test procedures shall also include	Test procedures shall also include	Test procedures shall also include
provisions for assuring that	provisions for assuring that	provisions for assuring that prerequisites
prerequisites and suitable	prerequisites and suitable	and suitable environmental conditions are
environmental conditions are met,	environmental conditions are met,	met, adequate instrumentation is available
adequate instrumentation is available	adequate instrumentation is available	and used, appropriate tests and equipment
and used, appropriate tests and	and used, appropriate tests and	are used, and necessary monitoring is
equipment are used, and necessary	equipment are used, and necessary	performed.
monitoring is performed.	monitoring is performed.	-
Prerequisites shall include the	Prerequisites shall include the	Prerequisites shall include the following, as
following, as applicable:	following, as applicable:	applicable:
(1) calibrated instrumentation	(1) calibrated instrumentation	(1) calibrated instrumentation
(2) appropriate equipment	(2) appropriate equipment	(2) appropriate equipment
(3) trained personnel	(3) trained personnel	(3) trained personnel

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(4) condition of test equipment and the item to be tested	(4) condition of test equipment and the item to be tested	(4) condition of test equipment and the item to be tested
(5) suitable environmental conditions	(5) suitable environmental conditions	(5) suitable environmental conditions
(6) provisions for data acquisition	(6) provisions for data acquisition	(6) provisions for data acquisition
(b) As an alternative to para. 300(a) of	(b) As an alternative to para. 300(a) of	(b) As an alternative to para. 300(a) of this
this Requirement, appropriate	this Requirement, appropriate	Requirement, appropriate sections of
sections of related documents, such	sections of related documents, such	related documents, such as ASTM methods,
as ASTM methods, Supplier manuals,	as ASTM methods, Supplier manuals,	Supplier manuals, equipment maintenance
equipment maintenance instructions,	equipment maintenance instructions,	instructions, or approved drawings or
or approved drawings or travelers	or approved drawings or travelers	travelers with acceptance criteria, may be
with acceptance criteria, may be	with acceptance criteria, may be	used.
used.	used.	
Such documents shall include or be	Such documents shall include or be	Such documents shall include or be
supplemented with appropriate	supplemented with appropriate	supplemented with appropriate criteria
criteria from para. 300(a) to assure	criteria from para. 300(a) to assure	from para. 300(a) to assure adequate
adequate procedures for the test.	adequate procedures for the test.	procedures for the test.
400 COMPUTER PROGRAM TEST	400 COMPUTER PROGRAM TEST	400 COMPUTER PROGRAM TEST
PROCEDURES	PROCEDURES	PROCEDURES
The requirements of section 400 of	The requirements of section 400 of	Requirements for computer program test
Requirement 11 apply, instead of	Requirement 11 apply, instead of	procedures are defined in Subpart 2.7,
section 300, Test Procedures, to testing of computer programs, and as	section 300, Test Procedures, to testing of computer programs, and as	Quality Assurance Requirements for Computer Software for Nuclear
appropriate, the computer hardware	appropriate, the computer hardware	Facility Applications.
and operating system.	and operating system.	
(a) Computer program test	(a) Computer program test	
procedures shall provide for	procedures shall provide for	
demonstrating the adherence of the	demonstrating the adherence of the	
computer program to documented	computer program to documented	
requirements. For those computer	requirements. For those computer	
programs used in design activities,	programs used in design activities,	
computer program test procedures	computer program test procedures	
shall provide for assuring that the	shall provide for assuring that the	
computer program produces correct	computer program produces correct	
results. For those computer programs	results. For those computer programs	
used for operational control,	used for operational control,	
computer program test procedures	computer program test procedures	
shall provide for demonstrating	shall provide for demonstrating	
required performance over the range	required performance over the range	
of operation of the controlled function or process. The procedures	of operation of the controlled function or process. The procedures	
shall also provide for evaluating	shall also provide for evaluating	
technical adequacy through	technical adequacy through	
comparison of test results from	comparison of test results from	
alternative methods such as hand	alternative methods such as hand	
calculations, calculations using	calculations, calculations using	
comparable proven programs, or	comparable proven programs, or	
empirical data and information from	empirical data and information from	
technical literature.	technical literature.	
(b) In-use test procedures shall be	(b) In-use test procedures shall be	
developed and documented to permit	developed and documented to permit	
confirmation of acceptable	confirmation of acceptable	
performance of the computer	performance of the computer	
program in the operating system. In-	program in the operating system. In-	

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use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.	use test procedures shall be performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance. (c) Test procedures or plans shall specify the following, as applicable: (1) required tests and test sequence (2) required ranges of input parameters (3) identification of the stages at which testing is required (4) criteria for establishing test cases (5) requirements for testing logic branches (6) requirements for hardware integration (7) anticipated output values (8) acceptance criteria (9) reports, records, standard formatting, and conventions	
500 TEST RESULTS Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied.	500 TEST RESULTS Test results shall be documented and maintained.	500 TEST RESULTS Test results shall be documented and maintained.
Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization.	Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.	Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.
600 TEST RECORDS Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.	600 TEST RECORDS Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.	600 TEST RECORDS Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements.
Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602.	Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602.	Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum, for the specified application identified in paras. 601 and 602.

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601 Test Records	601 Test Records	601 Test Records
(a) item tested	(a) item tested	(a) item tested
(b) date of test	(b) date of test	(b) date of test
(c) tester or data recorder	(c) tester or data recorder	(c) tester or data recorder
(d) type of observation	(d) type of observation	(d) type of observation
(e) results and acceptability	(e) results and acceptability	(e) results and acceptability
(f) action taken in connection with	(f) action taken in connection with	(f) action taken in connection with any
any deviations	any deviations	deviations
(g) person evaluating test results	(g) person evaluating test results	(g) person evaluating test results
602 Computer Program Test Records	602 Computer Program Test Records	602 Computer Program Test Records
(a) Verification Test Records	(a) computer program tested	Requirements for computer program test
(1) computer program tested	including system software used	records are defined in Subpart 2.7, Quality
(2) computer hardware tested	(b) computer hardware used	Assurance Requirements for Computer
(3) test equipment and calibrations,	(c) test equipment and calibrations,	Software for Nuclear Facility Applications.
where applicable	where applicable	
(4) date of test	(d) date of test	
(5) tester or data recorder	(e) tester or data recorder	
(6) simulation models used, where	(f) simulation models used, where	
applicable	applicable	
(7) test problems	(g) test problems	
(8) results and applicability	(h) results and applicability	
(9) action taken in connection with	(i) action taken in connection with any	
any deviations noted	deviations noted	
(10) person evaluating test results	(j) person evaluating test results	
(b) In-Use Test Records	(k) acceptability	
(1) computer program tested		
(2) computer hardware tested		
(3) test equipment and calibrations,		
where applicable		
(4) date of test		
(5) tester or data recorder		
(6) acceptability		
REQUIREMENT 12	REQUIREMENT 12	REQUIREMENT 12
Control of Measuring and Test	Control of Measuring and Test	Control of Measuring and Test Equipment
Equipment	Equipment	100 GENERAL
100 BASIC	100 GENERAL	
Tools, gages, instruments, and other	Tools, gages, instruments, and other	Tools, gages, instruments, and other
measuring and test equipment used	measuring and test equipment used	measuring and test equipment used for
for activities affecting quality shall be	for activities affecting quality shall be	activities affecting quality shall be
controlled, calibrated at specific	controlled, calibrated at specific	controlled, calibrated at specific periods,
periods, adjusted, and maintained to	periods, adjusted, and maintained to	adjusted, and maintained to required
required accuracy limits.	required accuracy limits.	accuracy limits.
200 SELECTION	200 SELECTION	200 SELECTION
Selection of measuring and test	Selection of measuring and test	Selection of measuring and test equipment
equipment shall be based on the	equipment shall be based on the	shall be based on the type, range, accuracy,
type, range, accuracy, and tolerance needed to accomplish the required	type, range, accuracy, and tolerance needed to accomplish the required	and tolerance needed to accomplish the required measurements for determining
measurements for determining	measurements for determining	conformance to specified requirements.
conformance to specified	conformance to specified	· · · · · · · · · · · · · · · · · · ·
requirements.	requirements.	
300 CALIBRATION AND CONTROL	300 CALIBRATION AND CONTROL	300 CALIBRATION AND CONTROL
301 Calibration	301 Calibration	301 Calibration
Measuring and test equipment shall	Measuring and test equipment shall	Measuring and test equipment shall be

intervals and whenever the accuracy of the measuring and test equipment is suspect.intervals and whenever the accuracy of the measuring and test equipment is suspect.and when measuring is suspect.Calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards.Calibration reference standards known to be equivalent to and verified against corresponding nationally recognized standards.Calibration having kn nationally recognized standards known to be equivalent to and verified against corresponding nationally recognized standards.Where no such standards exist, the basis for calibration shall be defined.Where no such standards exist, the basis for calibration shall be defined.Where no such standards exist, the basis for calibration shall be defined.302 Reference Standards measuring and test302 Reference Standards accuracy four times greater than that of the measuring and test302 Reference Standards measuring and test302 Reference standards accuracy302 Reference standards accuracyWhere this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be shall define methods and frequencyWhere this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be shall define methods and frequency303 Control303 ControlCalibration procedures shall identify or reference required accuracy.Calibration method and interval of checking accuracy.Calibration metho	d, at prescribed times or intervals hever the accuracy of the g and test equipment is suspect. In shall be against and traceable to equipment or reference standards own valid relationships to
Calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards.Calibration shall be against and traceable to certified equipment or reference standards, or to international standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized 	equipment or reference standards own valid relationships to
basis for calibration shall be defined.basis for calibration shall be defined.for calibration302 Reference Standards302 Reference Standards302 ReferenceReference standards shall have aReference standards shall have aReferenceminimum accuracyminimum accuracyaccuracyfour times greater than that of themeasuring and testmeasuring and testequipment being calibrated to ensureequipment being calibrated to ensurethat the reference standardsthat the reference standardsthat the reference standardsthe referecontribute no more than one-fourthof the allowable calibration tolerance.calibrationWhere this 4:1 ratio cannot beWhere this 4:1 ratio cannot beWhere this 4:1 ratio cannot bemaintained, the basis for selection ofthe standard in question shall betechnically justified.303 Control303 Control303 ControlCalibration procedures shall identifyor reference required accuracy andreferenceshall define methods and frequencyof checking accuracy.of checking accuracy.The calibration shall be based on thetype of equipment, stabilitytype of equipment, stabilitytype of equipment, stabilitycalibration shall be based on thetype of equipment, stabilitythe calibration shall be based on thetype of equipment, stabilityequipmentcalibration shall be based on thetype of equipment, stabilitycalibration shall be based on thecalibrationthe calibration shall be based on thetype of equipment, stabilityequipment </td <td></td>	
Reference standards shall have a minimum accuracy four times greater than that of the measuring and testReference standards shall have a 	o such standards exist, the basis ation shall be defined.
of calibration shall be based on the type of equipment, stabilityof calibration shall be based on the type of equipment, stabilitycalibration equipmentcharacteristics, required accuracy, intended use, and other conditionscharacteristics, required accuracy, intended use, and other conditionsconditions	n procedures shall identify or required accuracy and shall ethods and frequency of checking
	ration method and interval of n shall be based on the type of nt, stability characteristics, accuracy, intended use, and other s affecting performance.
is overdue for calibration or found to be out-of-calibration, shall be tagged and/or segregated, or removed from be out-of-calibration, shall be tagged and/or segregated, or removed from	g and test equipment, which is
Measuring or test equipment consistently found to be out-of calibration shall be repaired or replaced.Measuring or test equipment consistently found to be out-of calibration shall be repaired or replaced.Measuring or test equipment found to be out-of calibration shall be repaired or replaced.Measuring or test equipment found to be out-of replaced. 303.1 Application. Measuring and 303.1 Application. Measuring and 303.1 Application.	or calibration or found to be out- tion, shall be tagged and/or d, or removed from service, and until it has been recalibrated.

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test equipment shall be traceable to	test equipment shall be traceable to	equipment shall be traceable to its
its application and use.	its application and use.	application and use.
303.2 Corrective Action.	303.2 Corrective Action.	303.2 Corrective Action.
When measuring and test equipment	When measuring and test equipment	When measuring and test equipment is
is lost, damaged, or found to be out-	is lost, damaged, or found to be out-	lost, damaged, or found to be out-of
of calibration, the validity of previous	of calibration, the validity of previous	calibration, the validity of previous
measurement, inspection, or test	measurement, inspection, or test	measurement, inspection, or test results,
results, and the acceptability of items	results, and the acceptability of items	and the acceptability of items previously
previously inspected or tested shall	previously inspected or tested shall	inspected or tested shall be evaluated.
be evaluated.	be evaluated.	
This evaluation shall be from at least	This evaluation shall be from at least	This evaluation shall be from at least the
the last acceptable calibration of the	the last acceptable calibration of the	last acceptable calibration of the M&TE.
M&TE.	M&TE.	
The evaluation and resulting actions	The evaluation and resulting actions	The evaluation and resulting actions shall
shall be commensurate with the	shall be commensurate with the	be commensurate with the significance of
significance of the condition.	significance of the condition.	the condition.
303.3 Handling and Storage.	303.3 Handling and Storage.	303.3 Handling and Storage. Measuring
Measuring and test equipment shall	Measuring and test equipment shall	and test equipment shall be properly
be properly handled and stored to	be properly handled and stored to	handled and stored to maintain accuracy.
maintain accuracy.	maintain accuracy.	
303.4 Environmental Controls.	303.4 Environmental Controls.	303.4 Environmental Controls. Measuring
Measuring and test equipment shall	Measuring and test equipment shall	and test equipment shall be used and
be used and calibrated in	be used and calibrated in	calibrated in environments that are
environments that are controlled to	environments that are controlled to	controlled to the extent necessary to
the extent necessary to ensure that	the extent necessary to ensure that	ensure that the required accuracy and
the required accuracy and precision	the required accuracy and precision	precision are maintained.
are maintained.	are maintained.	
303.5 Precalibration Checks.	303.5 Precalibration Checks.	303.5 Precalibration Checks. Measuring
Measuring and test equipment and	Measuring and test equipment and	and test equipment and reference
reference standards submitted for	reference standards submitted for	standards submitted for calibration shall be
calibration shall be checked and the	calibration shall be checked and the	checked and the results recorded before
results recorded before any required	results recorded before any required	any required adjustments or repairs are
adjustments or repairs are made.	adjustments or repairs are made.	made.
303.6 Status Indication. Measuring	303.6 Status Indication. Measuring	303.6 Status Indication. Measuring and
and test equipment	and test equipment	test equipment
shall be suitably marked, tagged,	shall be suitably marked, tagged,	shall be suitably marked, tagged, labeled,
labeled, or otherwise identified to	labeled, or otherwise identified to	or otherwise identified to indicate
indicate calibration status and	indicate calibration status and	calibration status and establish traceability
establish traceability to calibration	establish traceability to calibration	to calibration records.
records.	records.	
304 Commercial Devices	304 Commercial Devices	304 Commercial Devices
Calibration and control measures are	Calibration and control measures are	Calibration and control measures are not
not required for commercial	not required for commercial	required for commercial equipment such as
equipment such as rulers, tape	equipment such as rulers, tape	rulers, tape measures, levels, etc., if such
measures, levels, etc., if such	measures, levels, etc., if such	equipment provides the required accuracy.
equipment provides the required	equipment provides the required	
accuracy.	accuracy. 400 RECORDS	
400 RECORDS 401 General	400 RECORDS 401 General	400 RECORDS 401 General
Records shall be established and	Records shall be established and	Records shall be established and
maintained to indicate calibration	maintained to indicate calibration	maintained to indicate calibration status
status and the capability of measuring	status and the capability of measuring	and the capability of measuring and test
status una the capability of measuring	status and the capability of measuring	and the capability of measuring and test

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and test equipment to satisfactorily	and test equipment to satisfactorily	equipment to satisfactorily perform its
perform its intended function.	perform its intended function.	intended function.
402 Reports and Certificates	402 Reports and Certificates	402 Reports and Certificates
Calibration reports and certificates	Calibration reports and certificates	Calibration reports and certificates
reporting the results of calibrations	reporting the results of calibrations	reporting the results of calibrations shall
shall include the information and data	shall include the information and data	include the information and data necessary
necessary for interpretation of the	necessary for interpretation of the	for interpretation of the calibration results
calibration results and verification of	calibration results and verification of	and verification of conformance to
conformance to applicable	conformance to applicable	applicable requirements.
requirements.	requirements.	
REQUIREMENT 13	REQUIREMENT 13	REQUIREMENT 13
Handling, Storage, and Shipping	Handling, Storage, and Shipping	Handling, Storage, and Shipping
100 BASIC	100 GENERAL	100 GENERAL
Handling, storage, cleaning,	Handling, storage, cleaning,	Handling, storage, cleaning, packaging,
packaging, shipping, and preservation	packaging, shipping, and preservation	shipping, and preservation of items shall be
of items shall be controlled to prevent	of items shall be controlled to prevent	controlled to prevent damage or loss and
damage or loss and to minimize	damage or loss and to minimize	to minimize deterioration.
deterioration.	deterioration.	
These activities shall be conducted in	These activities shall be conducted in	These activities shall be conducted in
accordance with established work and	accordance with established work and	accordance with established work and
inspection instructions, drawings,	inspection instructions, drawings,	inspection instructions, drawings,
specifications, shipment instructions,	specifications, shipment instructions,	specifications, shipment instructions, or
or other pertinent documents or	or other pertinent documents or	other pertinent documents or procedures
procedures specified for use in	procedures specified for use in	specified for use in conducting the activity.
conducting the activity.	conducting the activity.	
200 SPECIAL REQUIREMENTS	200 SPECIAL REQUIREMENTS	200 SPECIAL REQUIREMENTS
When required, special equipment	When required, special equipment	When required, special equipment (such as
(such as containers, shock absorbers,	(such as containers, shock absorbers,	containers, shock absorbers, and
and accelerometers) and special	and accelerometers) and special	accelerometers) and special protective
protective environments (such as inert gas atmosphere, specific	protective environments (such as inert gas atmosphere, specific	environments (such as inert gas atmosphere, specific moisture content
moisture content levels, and	moisture content levels, and	levels, and temperature levels) shall be
temperature levels) shall be specified	temperature levels) shall be specified	specified and provided and their existence
and provided and their existence	and provided and their existence	verified.
verified.	verified.	vermea.
300 PROCEDURES	300 PROCEDURES	300 PROCEDURES
When required for critical, sensitive,	When required for critical, sensitive,	When required for critical, sensitive,
When required for critical, sensitive, perishable, or	When required for critical, sensitive, perishable, or	When required for critical, sensitive, perishable, or
When required for critical, sensitive, perishable, or high-value items, specific procedures	When required for critical, sensitive, perishable, or high-value items, specific procedures	When required for critical, sensitive, perishable, or high-value items, specific procedures for
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging,	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging,	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and
When required for critical, sensitive, perishable, or high-value items, specific procedures	When required for critical, sensitive, perishable, or high-value items, specific procedures	When required for critical, sensitive, perishable, or high-value items, specific procedures for
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling.	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling.	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling.
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at	 When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at 	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with
When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at	 When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at 	When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used. 400 TOOLS AND EQUIPMENT Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or

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Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.	Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.	Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.
600 MARKING OR LABELING Marking or labeling shall be utilized as necessary to adequately maintain and preserve the	600 MARKING OR LABELING Marking or labeling shall be utilized as necessary to adequately maintain and preserve the	600 MARKING OR LABELING Marking or labeling shall be utilized as necessary to adequately maintain and preserve the
item, including indication of the presence of special environments or the need for special	item, including indication of the presence of special environments or the need for special	item, including indication of the presence of special environments or the need for special
controls. REQUIREMENT 14 Inspection, Test, and Operating Status 100 BASIC	controls. REQUIREMENT 14 Inspection, Test, and Operating Status 100 GENERAL	controls. REQUIREMENT 14 Inspection, Test, and Operating Status 100 GENERAL
The status of inspection and test activities shall be identified either on the items or in documents traceable	The status of inspection and test activities shall be identified either on the items or in documents traceable	The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it
to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the	to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the	is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not
required inspections and tests are not inadvertently installed, used, or operated.	required inspections and tests are not inadvertently installed, used, or operated.	inadvertently installed, used, or operated.
Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.	Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.	Status shall be maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.
The authority for application and removal of tags, markings, labels, and stamps shall be specified.	The authority for application and removal of tags, markings, labels, and stamps shall be specified.	The authority for application and removal of tags, markings, labels, and stamps shall be specified.
Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.	Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.	Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.
REQUIREMENT 15 Control of Nonconforming Items 100 BASIC	REQUIREMENT 15 Control of Nonconforming Items 100 GENERAL	REQUIREMENT 15 Control of Nonconforming Items 100 GENERAL
Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.	Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.	Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use.
Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of	Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of	Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.
nonconforming items, and for notification to affected organizations. 200 IDENTIFICATION	nonconforming items, and for notification to affected organizations. 200 IDENTIFICATION	200 IDENTIFICATION

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Nonconforming items shall be	Nonconforming items shall be	Nonconforming items shall be identified by
identified by legible marking, tagging,	identified by legible marking, tagging,	legible marking, tagging, or other methods
or other methods not detrimental to	or other methods not detrimental to	not detrimental to the item, on either the
the item, on either the item, the	the item, on either the item, the	item, the container, or the package
container, or the package containing	container, or the package containing	containing the item.
the item.	the item.	
300 SEGREGATION	300 SEGREGATION	300 SEGREGATION
(a) Nonconforming items shall be	(a) Nonconforming items shall be	(a) Nonconforming items shall be
segregated, when practical, by placing	segregated, when practical, by placing	segregated, when practical, by placing
them in a clearly identified and	them in a clearly identified and	them in a clearly identified and designated
designated hold area until properly	designated hold area until properly	hold area until properly dispositioned.
dispositioned.	dispositioned.	
(b) When segregation is impractical or	(b) When segregation is impractical or	(b) When segregation is impractical or
impossible due	impossible due	impossible due
to physical conditions such as size,	to physical conditions such as size,	to physical conditions such as size, weight,
weight, or access limitations, other	weight, or access limitations, other	or access limitations, other precautions
precautions shall be employed to	precautions shall be employed to	shall be employed to preclude inadvertent
preclude inadvertent use of a	preclude inadvertent use of a	use of a nonconforming item.
nonconforming item.	nonconforming item.	
400 DISPOSITION	400 DISPOSITION	400 DISPOSITION
401 Control	401 Control	401 Control
Nonconforming items shall be	Nonconforming items shall be	Nonconforming items shall be evaluated
evaluated and recommended	evaluated and recommended	and recommended dispositions shall be
dispositions shall be proposed.	dispositions shall be proposed.	proposed.
Further processing, delivery,	Further processing, delivery,	Further processing, delivery, installation, or
installation, or use of a	installation, or use of a	use of a nonconforming item shall be
nonconforming item shall be	nonconforming item shall be	controlled pending the evaluation and an
controlled pending the evaluation and	controlled pending the evaluation and	approved disposition by authorized
an approved disposition by	an approved disposition by	personnel.
authorized personnel.	authorized personnel.	
402 Responsibility and Authority	402 Responsibility and Authority	402 Responsibility and Authority
The responsibility and authority for	The responsibility and authority for	The responsibility and authority for the
the evaluation and disposition of	the evaluation and disposition of	evaluation and disposition of
nonconforming items shall be	nonconforming items shall be	nonconforming items shall be defined.
defined.	defined.	
Responsibility for the control of	Responsibility for the control of	Responsibility for the control of further
further processing, delivery,	further processing, delivery,	processing, delivery, installation, or use of
installation, or use of nonconforming	installation, or use of nonconforming	nonconforming items shall be designated in
items shall be designated in writing.	items shall be designated in writing.	writing.
403 Personnel	403 Personnel	403 Personnel
Personnel performing evaluations to	Personnel performing evaluations to	Personnel performing evaluations to
determine a disposition shall have	determine a disposition shall have	determine a disposition shall have
(a) demonstrated competence in the	(a) demonstrated competence in the	(a) demonstrated competence in the
specific area they are evaluating	specific area they are evaluating	specific area they are evaluating
(b) an adequate understanding of the	(b) an adequate understanding of the	(b) an adequate understanding of the
requirements	requirements	requirements
(c) access to pertinent background information	(c) access to pertinent background information	(c) access to pertinent background information
404 Disposition	404 Disposition	404 Disposition
-	-	-
A disposition, such as use-as-is, reject,	A disposition, such as use-as-is, reject,	A disposition, such as use-as-is, reject,
repair, or rework of nonconforming items shall be made and documented.	repair, or rework of nonconforming items shall be made and documented.	repair, or rework of nonconforming items shall be made and documented.
Technical justification for the	Technical justification for the	Technical justification for the acceptability

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acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented.	acceptability of a nonconforming item dispositioned repair or use-as-is shall be documented.	of a nonconforming item dispositioned repair or use-as-is shall be documented.
Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.	Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.	Nonconformances to design requirements dispositioned use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design.
Required as-built records shall reflect the use-as-is or repair condition.	Required as-built records shall reflect the use-as-is or repair condition.	Required as-built records shall reflect the use-as-is or repair condition.
405 Reexamination Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.	405 Reexamination Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.	405 Reexamination Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.
Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.	Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.	Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.
REQUIREMENT 16 Corrective Action 100 BASIC	REQUIREMENT 16 Corrective Action 100 GENERAL	REQUIREMENT 16 Corrective Action 100 GENERAL
Conditions adverse to quality shall be identified promptly and corrected as soon as practicable.	Conditions adverse to quality shall be identified promptly and corrected as soon as practicable.	Conditions adverse to quality shall be identified promptly and corrected as soon as practicable.
In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.	In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.	In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.
The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.	The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.	The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.
Completion of corrective actions shall be verified.	Completion of corrective actions shall be verified.	Completion of corrective actions shall be verified.
REQUIREMENT 17 Quality Assurance Records 100 BASIC	REQUIREMENT 17 Quality Assurance Records 100 GENERAL	REQUIREMENT 17 Quality Assurance Records 100 GENERAL
The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities.	The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities.	The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities.
Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.	Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.	Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.
Quality assurance records shall be identified, generated, authenticated,	Quality assurance records shall be identified, generated, authenticated,	Quality assurance records shall be identified, generated, authenticated, and

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and maintained, and their final	and maintained, and their final	maintained, and their final disposition
disposition specified.	disposition specified.	specified.
Record control requirements and	Record control requirements and	Record control requirements and
responsibilities for these activities	responsibilities for these activities	responsibilities for these activities shall be
shall be documented.	shall be documented.	documented.
200 GENERATION OF RECORDS	200 GENERATION OF RECORDS	200 GENERATION OF RECORDS
(a) Records shall be legible.	(a) Records shall be legible.	(a) Records shall be legible.
(b) Records shall be traceable to	(b) Records shall be traceable to	(b) Records shall be traceable to associated
associated items and activities and	associated items and activities and	items and activities and accurately reflect
accurately reflect the work	accurately reflect the work	the work accomplished or information
accomplished or information	accomplished or information	required.
required.	required.	(c) Records to be generated, supplied, or
(c) Records to be generated, supplied,	(c) Records to be generated, supplied,	maintained
or maintained	or maintained	shall be specified in applicable documents,
shall be specified in applicable	shall be specified in applicable	such as design specifications, procurement
documents, such as design	documents, such as design	documents, test procedures, and
specifications, procurement	specifications, procurement	operational procedures.
documents, test procedures, and	documents, test procedures, and	
operational procedures.	operational procedures.	
300 AUTHENTICATION OF RECORDS	300 AUTHENTICATION OF RECORDS	300 AUTHENTICATION OF RECORDS
(a) Documents shall be considered	(a) Documents shall be considered	(a) Documents shall be considered valid
valid records only	valid records only	records only
if stamped, initialed, or signed and	if stamped, initialed, or signed and	if stamped, initialed, or signed and dated
dated by authorized personnel or	dated by authorized personnel or	by authorized personnel or otherwise
otherwise authenticated. Corrections	otherwise authenticated. Corrections	authenticated. Corrections to documents
to documents shall be reviewed and	to documents shall be reviewed and	shall be reviewed and approved by the
approved by the responsible	approved by the responsible	responsible individual from the originating
individual from the originating or	individual from the originating or	or authorized organization.
authorized organization.	authorized organization.	(b) Electronic documents shall be
(b) Electronic documents shall be	(b) Electronic documents shall be	authenticated with comparable
authenticated with comparable	authenticated with comparable	information as in para. 300(a), as
information as in para. 300(a), as	information as in para. 300(a), as	appropriate
appropriate	appropriate	(1) with identification on the media; or
(1) with identification on the media;	(1) with identification on the media;	(2) with authentication information
or	or	contained within or linked to the document
(2) with authentication information	(2) with authentication information	itself.
contained within or linked to the	contained within or linked to the	
document itself.	document itself.	
400 CLASSIFICATION	400 CLASSIFICATION	400 CLASSIFICATION
Records shall be classified as <i>lifetime</i>	Records shall be classified as lifetime	Records shall be classified as lifetime or
or nonpermanent and maintained by	or nonpermanent and maintained by	nonpermanent and maintained by the
the Owner, or authorized agent, in	the Owner, or authorized agent, in	Owner, or authorized agent, in accordance
accordance with the criteria given in	accordance with the criteria given in	with the criteria given in paras. 401 and
paras. 401 and 402 of this	paras. 401 and 402 of this	402 of this Requirement and consistent
Requirement and consistent with	Requirement and consistent with	with applicable regulatory requirements.
applicable regulatory requirements.	applicable regulatory requirements.	
401 Lifetime Records	401 Lifetime Records	401 Lifetime Records
401.1 Lifetime records are those that	401.1 Lifetime records are those that	401.1 Lifetime records are those that meet
meet one or more of the following	meet one or more of the following	one or more of the following criteria:
criteria:	criteria:	(a) those that would be of significant value
(a) those that would be of significant	(a) those that would be of significant	in demonstrating capability for safe

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value in demonstrating capability for	value in demonstrating capability for	operation
safe operation	safe operation	(b) those that would be of significant value
(b) those that would be of significant	(b) those that would be of significant	in maintaining,
value in maintaining,	value in maintaining,	reworking, repairing, replacing, or
reworking, repairing, replacing, or	reworking, repairing, replacing, or	modifying an item
modifying an item	modifying an item	(c) those that would be of significant value
(c) those that would be of significant	(c) those that would be of significant	in determining the cause of an accident or
value in determining the cause of an	value in determining the cause of an	malfunction of an item
accident or malfunction of an item	accident or malfunction of an item	(d) those that provide required baseline
(d) those that provide required	(d) those that provide required	data for inservice
baseline data for inservice	baseline data for inservice	inspections
inspections	inspections	
401.2 Lifetime records are required to	401.2 Lifetime records are required to	401.2 Lifetime records are required to be
be maintained by or for the Owner for	be maintained by or for the Owner for	maintained for the life of the particular
the life of the particular item while it	the life of the particular item while it	item while it is installed in the plant or
is installed in the plant or stored for	is installed in the plant or stored for	stored for future use.
future use.	future use.	
402 Nonpermanent Records	402 Nonpermanent Records	402 Nonpermanent Records
Nonpermanent records are those	Nonpermanent records are those	Nonpermanent records are those required
required to show evidence that an	required to show evidence that an	to show evidence that an activity was
activity was performed in accordance	activity was performed in accordance	performed in accordance with the
with the applicable requirements but	with the applicable requirements but	applicable requirements but need not be
need not be	need not be	retained for the life of the item because
retained for the life of the item	retained for the life of the item	they do not meet the criteria for lifetime
because they do not meet the criteria	because they do not meet the criteria	records.
for lifetime records.	for lifetime records.	
Nonpermanent records shall be	Nonpermanent records shall be	Nonpermanent records shall be maintained
maintained for the identified	maintained for the identified	for the identified retention period.
retention period.	retention period.	
500 RECEIPT CONTROL OF RECORDS	500 RECEIPT CONTROL OF RECORDS	500 RECEIPT CONTROL OF RECORDS
Each organization responsible for the	Each organization responsible for the	Each organization responsible for the
receipt of records shall designate a	receipt of records shall designate a	receipt of records shall designate a person
person or organization responsible for	person or organization responsible for	or organization responsible for receiving
receiving the records.	receiving the records.	the records.
The designee shall be responsible for	The designee shall be responsible for	The designee shall be responsible for
organizing and implementing receipt	organizing and implementing receipt	organizing and implementing receipt
controls for permanent and	controls for permanent and	controls for permanent and temporary
temporary storage.	temporary storage.	storage.
Receipt controls shall provide a	Receipt controls shall provide a	Receipt controls shall provide a method for
method for identifying the records received, receipt and inspection of	method for identifying the records received, receipt and inspection of	identifying the records received, receipt and inspection of incoming records, and
· · ·		
incoming records, and submittal of	incoming records, and submittal of records to storage.	submittal of records to storage.
records to storage. 600 STORAGE	600 STORAGE	600 STORAGE
601 General	601 General	601 General
(a) Records shall be stored at a	(a) Records shall be stored at a	(a) Records shall be stored at a
predetermined location(s) in facilities,	predetermined location(s) in facilities,	predetermined location(s) in facilities,
containers, or a combination thereof,	containers, or a combination thereof,	containers, or a combination thereof,
constructed and maintained in a	constructed and maintained in a	constructed and maintained in a manner
manner that minimizes the risk of	manner that minimizes the risk of	that minimizes the risk of loss, damage, or
loss, damage, or destruction from	loss, damage, or destruction from	destruction from
(1) natural disasters such as winds,	(1) natural disasters such as winds,	(1) natural disasters such as winds, floods,
$1 \pm j$ matural analytic 3 such as Willus,	$ (\pm)$ natural algasters such as willus,	$ 1^{\pm}\rangle$ matural ansasters such as withus, hours,

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(2) environmental conditions such as high and low	(2) environmental conditions such as high and low	(2) environmental conditions such as high and low
temperatures and humidity	temperatures and humidity	temperatures and humidity
(3) infestation of insects, mold, or	(3) infestation of insects, mold, or	(3) infestation of insects, mold, or rodents
rodents	rodents	(4) dust or airborne particles
(4) dust or airborne particles	(4) dust or airborne particles	(b) Activities detrimental to the records
(b) Activities deterimental to the records shall be prohibited in the storage area.	(b) Activities deterimental to the records shall be prohibited in the storage area.	shall be prohibited in the storage area. (c) Access to the processing, storage, and retrieval of records shall be limited to
(c) Access to the processing, storage,	(c) Access to the processing, storage,	authorized personnel.
and retrieval of records shall be	and retrieval of records shall be	(d) Provisions shall be made to prevent
limited to authorized personnel.	limited to authorized personnel.	damage from harmful conditions (such as
(d) Provisions shall be made to	(d) Provisions shall be made to	excessive light, stacking,
prevent damage from harmful conditions (such as excessive light,	prevent damage from harmful conditions (such as excessive light,	electromagnetic fields, temperature, and humidity), as
stacking,	stacking,	applicable to the specific media utilized for
electromagnetic fields, temperature, and humidity), as	electromagnetic fields, temperature, and humidity), as	record storage.
applicable to the specific media utilized for record storage.	applicable to the specific media utilized for record storage.	602.2 Dual facilities, containers, or a
		combination thereof shall be at locations
		sufficiently remote from each other to
602.2 Dual facilities, containers, or a	602.2 Dual facilities, containers, or a	eliminate the chance exposure to a
combination thereof shall be at	combination thereof shall be at	simultaneous hazard. Facilities used for
locations sufficiently remote from	locations sufficiently remote from	dual storage are not required to satisfy the
each other to eliminate the chance	each other to eliminate the chance	requirements of para. 602.1, but shall meet
exposure to a simultaneous hazard.	exposure to a simultaneous hazard.	the requirements of para. 601.
Facilities used for dual storage are not	Facilities used for dual storage are not	
required to satisfy the requirements	required to satisfy the requirements	
of para. 602.1, but shall meet the	of para. 602.1, but shall meet the	
requirements of para. 601.	requirements of para. 601.	
602 Facility Types	602 Facility Types	602 Facility Types
There are two equally satisfactory methods of providing storage, single	There are two equally satisfactory methods of providing storage, single	There are two equally satisfactory methods of providing storage, single or dual.
or dual.	or dual.	or providing storage, single or dual.
602.1 Single storage consists of a	602.1 Single storage consists of a	602.1 Single storage consists of a storage
storage facility, vault, room, or	storage facility, vault, room, or	facility, vault, room, or container(s) with a
container(s) with a minimum two-	container(s) with a minimum two-	minimum two-hour fire rating. The design
hour fire rating. The design and	hour fire rating. The design and	and construction of a single storage facility,
construction of a single storage	construction of a single storage	vault room, or container shall be reviewed
facility, vault room, or container shall	facility, vault room, or container shall	for adequacy by a person competent in fire
be reviewed	be reviewed	protection
for adequacy by a person competent	for adequacy by a person competent	or contain a certification or rating from an
in fire protection	in fire protection	accredited organization.
or contain a certification or rating	or contain a certification or rating	
from an accredited organization.	from an accredited organization.	
603 Temporary Storage	603 Temporary Storage	603 Temporary Storage
When temporary storage of records	When temporary storage of records	When temporary storage of records (such
(such as for processing, review, or	(such as for processing, review, or	as for processing, review, or use) is
use) is required, the storage facility or	use) is required, the storage facility or	required, the storage facility or container
container shall provide a one-hour	container shall provide a one-hour	shall provide a one-hour fire rating, unless
fire rating, unless dual storage	fire rating, unless dual storage	dual storage requirements of para. 602.2
requirements of para. 602.2 are met.	requirements of para. 602.2 are met.	are met.

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700 RETENTION	700 RETENTION	700 RETENTION
(a) Record retention periods shall be	(a) Record retention periods shall be	(a) Record retention periods shall be
documented.	documented.	documented.
(b) Records shall be maintained for	(b) Records shall be maintained for	(b) Records shall be maintained for their
their retention periods.	their retention periods.	retention periods.
800 MAINTENANCE OF RECORDS	800 MAINTENANCE OF RECORDS	800 MAINTENANCE OF RECORDS
(a) Records shall be protected from	(a) Records shall be protected from	(a) Records shall be protected from
damage or loss.	damage or loss.	damage or loss.
(b) Record controls shall provide for	(b) Record controls shall provide for	(b) Record controls shall provide for
retrievability	retrievability	retrievability
within planned retrieval times based	within planned retrieval times based	within planned retrieval times based upon
upon the record type or content.	upon the record type or content.	the record type or content.
(c) The methods for record changes shall be documented.	(c) The methods for record changes shall be documented.	(c) The methods for record changes shall be documented.
(d) Provisions shall be established to	(d) Provisions shall be established to	(d) Provisions shall be established to ensure
ensure that no	ensure that no	that no
unacceptable degradation of the electronic record media	unacceptable degradation of the electronic record media	unacceptable degradation of the electronic record media
occurs during the established	occurs during the established	occurs during the established retention
retention period.	retention period.	period.
<i>(e)</i> Provisions shall be made to ensure	(e) Provisions shall be made to ensure	(e) Provisions shall be made to ensure that
that the records	that the records	the records
remain retrievable after hardware,	remain retrievable after hardware,	remain retrievable after hardware,
software, or technology changes.	software, or technology changes.	software, or technology changes.
(f) Provisions shall be established to	(f) Provisions shall be established to	(f) Provisions shall be established to ensure
ensure the following	ensure the following	the following
when records are duplicated or	when records are duplicated or	when records are duplicated or transferred
transferred to	transferred to	to
the same media or to a different	the same media or to a different	the same media or to a different media for
media for the purposes	media for the purposes	the purposes
of maintenance or storage:	of maintenance or storage:	of maintenance or storage:
(1) duplication or transfer is	(1) duplication or transfer is	(1) duplication or transfer is appropriately
appropriately authorized	appropriately authorized	authorized
(2) record content, legibility, and	(2) record content, legibility, and	(2) record content, legibility, and
retrievability are	retrievability are	retrievability are
maintained	maintained	maintained
REQUIREMENT 18	REQUIREMENT 18	REQUIREMENT 18
Audits	Audits	Audits
100 BASIC	100 GENERAL	100 GENERAL
Audits shall be performed to verify	Audits shall be performed to verify	Audits shall be performed to verify
compliance to quality assurance	compliance to quality assurance	compliance to quality assurance program
program requirements, to verify that	program requirements, to verify that	requirements, to verify that performance
performance criteria are met, and to	performance criteria are met, and to	criteria are met, and to determine the
determine the effectiveness of the	determine the effectiveness of the	effectiveness of the program.
program.	program.	
These audits shall be performed in	These audits shall be performed in	These audits shall be performed in
accordance with written procedures	accordance with written procedures	accordance with written procedures or
or checklists by personnel who do not	or checklists by personnel who do not	checklists by personnel who do not have
have direct responsibility for	have direct responsibility for	direct responsibility for performing the
performing the activities being	performing the activities being	activities being audited.
audited.	audited.	
Audit results shall be documented	Audit results shall be documented	Audit results shall be documented and

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and reported to and reviewed by responsible management.	and reported to and reviewed by responsible management.	reported to and reviewed by responsible management.
Follow-up action shall be taken where indicated.	Follow-up action shall be taken where indicated.	Follow-up action shall be taken where indicated.
200 SCHEDULING Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity.	200 SCHEDULING Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity.	200 SCHEDULING Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity.
Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.	Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.	Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.
		A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance.
		When the grace period is used, the next scheduled date for the activity shall be based on the activity schedule date and not on the date the activity was actually performed.
		If the activity is performed early, the next schedule date shall be based on the date the activity was actually performed.
		201 Internal Audits Except where specific regulatory guidance exists or Code restrictions apply, organizations shall audit internal activities at the following intervals.
		201.1 Nuclear Facilities Prior to Placing the Facility Into Operation. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter.
		201.2 Nuclear Facilities After Placing the Facility Into Operation. All applicable quality assurance program elements for each functional area1 shall be audited within a period of 2 yr.
		For well-established activities, the period may be extended 1 yr at a time beyond the 2-yr interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished.
		However, the internal audit interval shall not exceed a maximum of 4 yr.201.3 Suppliers and Other Nuclear Support
		Organizations. All applicable quality assurance program elements shall be audited at least once

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		each year or at least once during the life of
		the activity, whichever is shorter.
		This interval may be extended up to 2 yr
		based on the results of an annual
		evaluation and objective evidence that the
		activities are being satisfactorily
		accomplished in accordance with the
		applicable quality assurance program elements.
		202 External Audits
		External audits (e.g., Supplier audits) shall
		be performed on a triennial basis and
		supplemented by annual evaluations of the
		Supplier's performance to determine if the
		regular schedule audit frequency shall be
		maintained or decreased or if other
		corrective action is required.
		A continuous or ongoing evaluation of the
		Supplier's performance may be conducted in lieu of the annual evaluations, provided
		that the results are reviewed in order to
		determine if corrective action is required.
300 PREPARATION	300 PREPARATION	300 PREPARATION
301 Audit Plan	301 Audit Plan	301 Audit Plan
The auditing organization shall	The auditing organization shall	The auditing organization shall develop an
develop an audit plan for each audit.	develop an audit plan for each audit.	audit plan for each audit.
This plan shall identify the audit	This plan shall identify the audit	This plan shall identify the audit scope,
scope, requirements, audit personnel,	scope, requirements, audit personnel,	requirements, audit personnel, activities to
activities to be audited, organizations	activities to be audited, organizations	be audited, organizations to be notified,
to be notified, applicable documents,	to be notified, applicable documents,	applicable documents, schedule, and
schedule, and written procedures or	schedule, and written procedures or	written procedures or checklists.
checklists.	checklists.	
302 Personnel	302 Personnel	302 Personnel
Audit personnel shall have sufficient	Audit personnel shall have sufficient	Audit personnel shall have sufficient
authority and organizational freedom to make the audit process meaningful	authority and organizational freedom to make the audit process meaningful	authority and organizational freedom to make the audit process meaningful and
and effective.	and effective.	effective.
303 Selection of Audit Team	303 Selection of Audit Team	303 Selection of Audit Team
An audit team shall be identified prior	An audit team shall be identified prior	An audit team shall be identified prior to
to the beginning of each audit.	to the beginning of each audit.	the beginning of each audit.
This team shall contain one or more	This team shall contain one or more	This team shall contain one or more
Auditors, one being designated Lead	Auditors, one being designated Lead	Auditors, one being designated Lead
Auditor who organizes and directs the	Auditor who organizes and directs the	Auditor who organizes and directs the
audit.	audit.	audit.
The audit team shall have experience	The audit team shall have experience	The audit team shall have experience or
or training commensurate with the	or training commensurate with the	training commensurate with the scope,
scope, complexity, or special nature	scope, complexity, or special nature	complexity, or special nature of the
of the activities to be audited.	of the activities to be audited.	activities to be audited.
400 PERFORMANCE	400 PERFORMANCE	400 PERFORMANCE
Elements selected for audit shall be	Elements selected for audit shall be	Elements selected for audit shall be
evaluated against specified	evaluated against specified	evaluated against specified requirements.
requirements.	requirements.	
Objective evidence shall be	Objective evidence shall be	Objective evidence shall be

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examined to the depth necessary to	examined to the depth necessary to	examined to the depth necessary to
determine if these elements are being implemented effectively.	determine if these elements are being implemented effectively.	determine if these elements are being implemented effectively.
Conditions requiring prompt	Conditions requiring prompt	Conditions requiring prompt corrective
corrective action shall be reported	corrective action shall be reported	action shall be reported immediately to
immediately to management of the	immediately to management of the	management of the audited organization.
audited organization.	audited organization.	
500 REPORTING	500 REPORTING	500 REPORTING
The audit report shall be signed or	The audit report shall be signed or	The audit report shall be signed or
otherwise endorsed by the Lead	otherwise endorsed by the Lead	otherwise endorsed by the Lead Auditor
Auditor and issued to the audited	Auditor and issued to the audited	and issued to the audited organization.
organization. The contents of the report shall	organization. The contents of the report shall	The contents of the report shall
(a) describe the audit scope	(a) describe the audit scope	(a) describe the audit scope
(b) identify Auditors and persons	(b) identify Auditors and persons	(b) identify Auditors and persons contacted
contacted	contacted	(c) summarize audit results, including a
(c) summarize audit results, including	(c) summarize audit results, including	statement on the effectiveness of the
a statement on the effectiveness of	a statement on the effectiveness of	elements audited
the elements audited	the elements audited	(d) describe each audit finding
(d) describe each reported adverse	(d) describe each reported adverse	
audit finding	audit finding	
600 RESPONSE	600 RESPONSE	600 RESPONSE
Management of the audited	Management of the audited	Management of the audited organization
0		
organization or activity shall	-	or activity shall investigate audit findings,
organization or activity shall investigate adverse audit findings,	organization or activity shall investigate adverse audit findings,	or activity shall investigate audit findings, schedule corrective action, including
	organization or activity shall	
investigate adverse audit findings, schedule corrective	organization or activity shall investigate adverse audit findings,	schedule corrective action, including
investigate adverse audit findings,	organization or activity shall investigate adverse audit findings, schedule corrective	schedule corrective action, including measures to prevent recurrence of
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