Commenter	Location in Document (section, subsection, paragraph, sentence)	Comment	Response
GNF	In General	"The word 'should' is repeatedly used even when the activity is not optional. We thought this occurred because the document is a Guide. However, we noted there are places in the Guide, such as in section B Discussion, where the word 'must' is used. It may be useful to provide a short explanation on why certain words such as 'should', 'must', etc. are used in the Guide."	A word search for "should" and "must" has been done, and each instance has been modified as necessary.
NRC	B, REGULATORY FRAMEWORK..., 2, 3	Add: "or fissile material packages" after the words: "Type B package." "All three of the numbered statements in that paragraph also apply to fissile material in packages."	The comment has been implemented.
NRC	B, REGULATORY FRAMEWORK..., 3, 1	"The proposed use of QA program user is confusing. Insert clarifying text here to separate the use of 'QA program user' with a user of a transportation packaging. Suggest possible using 'QA program holder.' This terminology would then be used through the rest of the guide."	The comment has been implemented.
NRC	B, CHANGES TO APPROVED..., 1, 2	Should read: "Based on the NRC regulations determined to apply and the associated approved QA program, the QA program holder should develop and implement lower level (working level) procedures governing the conduct of QA activities that are important to safety." "This sentence as written indicates that the QA program holder will have to translate regulations, when in fact translation should be performed only by the agency responsible for the regulation. The QA program holder should read the regulation, determine if it has to meet the regulation and then apply the meaning of the regulation in the development of lower level documents clearly enough to meet the requirement. In addition this sentence does not address that the QA program holder should also implement those working level documents to provide appropriate control over their quality activities."	The comment has been implemented.
NRC	B, CHANGES TO APPROVED..., 2, 1	Delete: the entire first sentence. "This sentence has nothing to do with making changes to the QA program and only adds confusion to the paragraph."	The comment has been implemented.
TVA	B, CHANGES TO APPROVED..., 2, 2	"NRC did not use this opportunity in the regulations and regulatory guide to make changes that would have reduced regulatory burned and increased efficiency by providing a method similar to	"This has been and is still being considered for inclusion into a rulemaking to modify Part 71."

		the provisions of 10 CFR 50.54 (a) (3) and (4) for making changes to QA programs.“	
NRC	B, CHANGES TO APPROVED..., 2, 2	Delete: the word “plan” from the sentence. “The use of the word ‘plan’ is not consistent with the rest of this draft guide. ‘QA program’ and ‘QA program Description’ should be the only wording used to identify reference to a licensees/CoC holder’s/applicant’s QA program.”	The comment has been implemented.
NRC	C, 2, Last	Should read: “The approval expires on the last day of the month and year sated on the approval and may be renewed prior to the expiration at the QA program holder’s request.” “Specifying the number of years does not allow any flexibility in the guidance if the timeframe were to be reduced or expanded in the future.”	The comment has been implemented.
Trojan	C, 3, Last	Delete: “and are contained in quality assurance/quality control (QC) manuals.” “This additional phase is overly restrictive. This Regulatory Guide should not require the procedures, which apply to each of the specified activities to be in any specific procedure manual(s). Licensees have different procedure programs and the contents of their different procedure manuals should be left up to the licensees.”	The comment has been implemented.
NRC	C, 1.2, 1, Last	Delete: the word “plan” from the sentence and change the word “manuals” to “procedures.” “The use of the word ‘plan is not consistent with the rest of this draft guide. ‘QA program’ and ‘QA program Description’ should be the only wording used to identify reference to a licensees/CoC holder’s/applicant’s QA program. The changing of the word manuals to procedures is basis on the fact that almost all implementation of a QA program occurs through the use of procedures developed from a QA program.”	The comment has been implemented.
TVA	C, 1.2, 2, 1	“Company policy statements can accomplish the goal of designating authority by identifying functional and positional responsibilities versus “identifying,” as stated.”	The comment has been implemented.
TVA	C 2.1, 1, 3	“Identify the user vs. design and fabricator governing activities with the applicable RG section with a matrix. Such as: DG-7004 Quality Activity Regulation 1 QA Organization 71.103 2 QA Program 71.105 4 Procedural Document Control 71.109	“The whole regulatory guide provides suggested matrix items. However, each applicant must determine for themselves which criteria apply and a matrix may be too easily misused without proper consideration of all criteria that might apply to program development.”

		13	Handling, Storage, and Shipping Controls	71.127	
		16	Corrective Action	71.133	
		17	QA Records	71.135	
		18	Audits	71.137	
NRC	C, 2.1, 3, 2	Should read: "The approval expires on the last day of the month and year stated on the approval and may be renewed according to the requirements of 71.38, not less than 30 days prior to expiration by the request of the QA program holder." "Specifying the number of years does not allow any flexibility in the guidance if the timeframe were to be reduced or expanded in the future."			The comment has been implemented.
Doyle	C 2.2, 3rd Bullet	"In the Revision 1 (June 1986) version of 7.10, there is a subsection 1.2.2 Personnel, which discusses the requirements for training and qualification of personnel. In the draft DG-7004, the only reference to training is found in Section 2.2, third bullet. Has the amplification of the training and qualification requirements noted in Revision 1 been deleted from DG-7004?"			"The amplification has been reduced some by the reduction of volume of text and level of detail provided in the beginning of the newer guidance. The newer guidance was attempting to make reference to the need for trained and qualified throughout the revised text thus spreading the amplification out over the whole document. The newer guidance includes least sixteen places where reference is made to training and qualification. In addition Appendix A, Section 3, still makes specific reference to nondestructive examination personnel under the sixth bullet. Also, this same appendix makes reference to information regarding inspection personnel under the eleventh bullet. This draft guide was revised with the intent of sharing the quality assurance and inspection experience gained by NRC personnel over the last four to five years. Most quality assurance program description submittals have provided adequate, or better, direction for training and qualification of personnel. Inspection

			results have not indicated that training and qualification has been a significant factor in inspection findings. With this experience as a basis, additional effort was expended in the discussion to describe information which might be helpful for program development and submittal."
Trojan	C 2.4, Last, 1	Delete: "and is contained in QA/QC manuals." "This additional phase is overly restrictive. This Regulatory Guide should not require the procedures, which apply to each of the applicable Part 71 activities to be specified in any specific procedure manual(s). Licensees have different procedure programs and the contents of their different procedure manuals should be left up to the licensees."	The comment has been implemented.
NRC	C, 2.5, Title	Should read: "2.5, Controlled Conditions and Assignments of Responsibilities." "The responsibility for all quality activities should be clear and the position responsible should be identified."	The comment has been implemented.
NRC	C, 5.1, 3rd bullet	Should read: "All word activities are coordinated with QA personnel to ensure that appropriate inspection and hold points are incorporated into work controlling documents to verify that initial work, planned work, effective repairs or rework have been performed satisfactorily." "Necessary verification of work to determine acceptance cannot be accomplished if the responsible quality assurance position does not have knowledge that the work will be performed and an opportunity to identify hold/witness points in the work document to perform the verifications."	The comment has been implemented.
NRC	C, 5.1.1 - 5.1.5	"Steps could be bulleted instead of numbered. This would be consistent with the use of bullets in other portions of this draft guide."	The comment has been implemented.
NRC	C, 6.2, 1, Last	Add the following words at the end of the sentence: "by title or position." "Identifying responsibilities for quality activities allows application of corrective action processes where corrective action is required. In addition, individual persons who fill the various positions may change so identity of titles of positions will allow more flexibility within the organization as people move from position to position."	The comment has been implemented.

GNF	C, 7.7, 2, 1	"Change 'Iinstructions' to 'Instructions.'"	The comment has been implemented.
GNF	C, 7.7, Last, Last	Should read: "Documentation is to be retained at the facility or site of material or equipment use." Or: "Certificate of Compliance from the licensee or manufacturer, stating all appropriate requirements are met, is to be retained at..." "This could imply that all records are held wherever the container goes."	The comment has been implemented.
NRC	C, 10.1.1-10.1.6	"Steps could be bulleted instead of numbered. This would be consistent with the use of bullets in other portions of this draft guide."	The comment has been implemented.
GNF	C, 10.1, 5th bullet	Change "Approval of data by the supervisor to ensure..." to "Review and approval of data by appropriate personnel to ensure..." "We do not believe it necessary to specifically identify 'supervisors' as having this responsibility."	The comment has been implemented.
TVA	C, 10.2.3, 2, 7th bullet	"1. Is the requirement of 71.121 Internal Inspections applicable to general licenses that use the package for transport of radioactive material? 2. The user designates a qualification for performing activity by position (Radwaste shipper) rather than by individual."	"1. Yes, one example of internal inspection use would be to determine maintenance needs of the packaging. 2. The comment has been implemented."
NRC	C, 16.2, 1, Last	Add the following words at the end of the sentence: "by title or position." "Identifying responsibilities for quality activities allows application of corrective action processes where corrective action is required. In addition, individual persons who fill the various positions may change so identity of titles of positions will allow more flexibility within the organization as people move from position to position."	The comment has been implemented.
GNF	C, 17.3, 2	Change "period of 3 years after shipment" to "period of 2 years after shipment."	"The current regulatory guide is in error (typo)"
TVA	C, 17.4, 1, 1	"Identification of responsible individual or group is adequate."	The comment has been implemented.
Trojan	C, 18.1, 2, 1	"The phrase 'however, each [important to safety] activity should be audited at least once each year' is overly restrictive. 10 CFR 71.137, Audits, states: 'The licensee shall carry out a comprehensive system of planned and periodic audits, to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program.' Requiring a	"Not ALL users are experienced 10 CFR 50 licensees. The guide is to fit all users."

		licensee to audit ‘each [important to safety] activity’ is more restrictive than auditing ‘all aspects of the quality assurance program,’ because one aspect of the QA program can involve numerous activities.” “Additionally, the guideline to audit each important to safety activity "at least once each year" is considered overly restrictive and changing it to say "within a period of two years" is recommended. The NRC has provided guidance to Nuclear Power Plant licensees for auditing 10 CFR 50 safety -related activities in Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation), Revision 2." Section C.4 of this Regulatory G	
TVA	C, 18.1, 2, 2	“This guidance contradicts itself, in that if an item is not important to safety there is no reason to audit once each year. The frequency needs to be determined by the importance to safety, as stated, which would mean that the requirement to audit ‘each year ‘ is not needed.”	“The activities important to safety should be audited. They should be audited annually. The frequency should be based on the importance if the activity to safety. (Audits could be more frequent if it is determined to be necessary by program indicators.) If annually is too frequent, then audits should be performed based on program indicators.”
GNF	18.2, 2, 1	“Sentence reads ‘Management audits should be conducted at least once every 12 months.’ We are not familiar with the term ‘management audit’, and suggest it be defined. We recommend changing to: ‘Evaluations of supplier quality should be conducted at least once every 12 months, considering all supplier performance issues occurring in the evaluated time period and their affect on quality.’ We use ‘should’ in the same sense as used throughout the document, including this section, see generic comment above. Normally, we would say ‘must’ to both the triennial audit, and annual evaluation in this section.”	“The Reg Guide cannot define all of the various types of assessments which could be performed in regard to quality assurance programs. The wording has been modified to indicate ‘audits performed by management.’ This wording should allow for the implementation of various types of assessment tools.”
Trojan	C, 18.2, Last	“The guidelines stating ‘Internal audits of the applicable elements of the QA program should be audited at least annually or at least once within the life of the activity, whichever is shorter’ and ‘Management audits should be conducted at least every 12 months’ are overly restrictive. It is recommended that these audit frequencies be changed to say ‘within a period of two years.’”	“Not ALL users are experienced 10 CFR 50 licensees. The guide is to fit all users.”

TVA	C, 18.2, 2+3	"Scheduling of audits should be based on the activities importance to safety, i.e., at least once during the license cycle or five year period for internal and management audits."	"Since I do not have a basis for your comment, I will provide our basis for the wording. Not all users/fabricators are experienced Part 50 program holders. Some entities struggle to maintain quality due to size and/or resources. This guide is recommending annual audits however justification for audit frequency is the responsibility of each QA program approval holder. The guide is intended to help all users."
GNF	Appendix A, 3, 8, 1	Should read: "A representative of the buyer should be present at a supplier's facility, depending on the supplier's past history, and the rigor of their quality program, unless the product being procured can be adequately tested or inspected upon receipt, to approve...and authorize shipment." - General Idea	"The items listed in Appendix A are provided as examples. This guide is recommending guidance that should be helpful to all users. However justification for performing items/activities differently can be justified acceptably through the use of program indicators and other means and is the responsibility of each QA program user."