71-0932

RAM Services, Inc.

19 April 2006

Mr. James Pearson
Spent Fuel Project Office
The U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852 – 2738

Dear Mr. Pearson,

Pursuant to our recent telephone conversation, we have tried to address the errors and oversights in Revision 1 of our proposed Part 71 Quality Assurance Program. To simplify matters, we request that Revision 1 be withdrawn from consideration and replaced with the enclosed Revision 2 of our document QAP-2-1, Quality Assurance Program.

We have highlighted significant changes and additions in boldface. Although tedious to read, it may make your review easier. We also made several minor corrections which, sadly, escaped the first proofreading.

We thank you and all the staff of the Spent Fuel Project Office for their courteous assistance and constructive criticism.

Sincerely,

Jerry Wiza

Jerry Wiza, President

enc.

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NMSS01*

Procedure	QA Program for 20WC Users
Revision	2
Date	April 2006
Approval	Jerry P. Wiza, President

RAM Services, Inc.

Specification 20WC Protective Wooden Jacket

Quality Assurance Program

1 Quality Assurance Organization [10 CFR 71.103]

This section describes the distribution of Quality Assurance Program duties and responsibilities among RAM Services personnel.

RAM Services currently employs three persons and does not envision major expansions in the immediate future. In order to achieve the objectives of 10 CFR 71.103, particularly the objective that "[c]onformance to established requirements is verified by individuals and groups that are not directly responsible for performing the work." [Regulatory Guide 7.10 Rev.2 at 5], the QA functions will be distributed between the President and the Health Physicist. The distribution of responsibilities is defined by RAM Services Quality Assurance Program Organization Chart, document QAP-1-1, which is reproduced below in its current form.

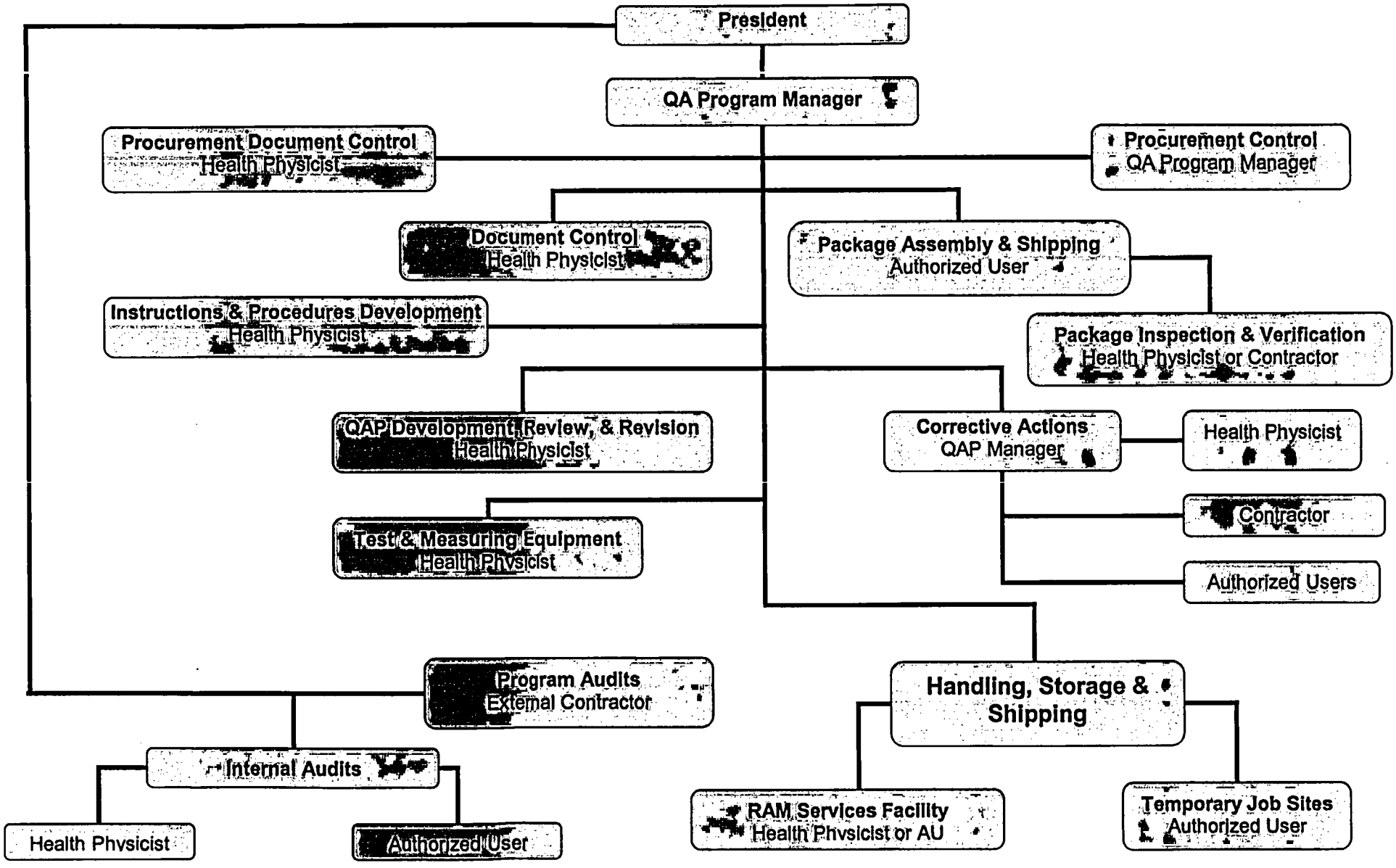

Figure 1. RAM Services QA Organization, Document QAP-1-1.

The President of RAM Services, Inc. [hereinafter, the President], will be the Quality Assurance Program Manager and will exercise overall control and oversight of the QA Program. The President **will** commit funds, personnel, and all other company resources as necessary to achieve all quality and safety objectives, and **will** terminate **unsafe** activities or reject packagings that may be unsafe. The President has endorsed a company policy, specified in document QAP-1-2, that declares safety and quality assurance as preeminent concerns when shipping radioactive materials.

RAM Services' Health Physicist will develop all procedures, forms, checklists, and instructions required to implement the QAP. The Health Physicist will submit these procedures and instructions to the President and, as required, the NRC for approval prior to implementation and will maintain the revision history of all program documents. The Document Control List, QAP-6-1 summarizes responsibilities for document production, approval, distribution, and retention requirements. The Health Physicist maintains and updates the Document control list.

The QA Program Manager will only designate fully qualified personnel as Authorized Users of the 20WC wooden jackets to package radioactive materials, whether at temporary job sites or at RAM Services facility.

The President will approve Authorized Users for the 20WC packagings only after they have demonstrated adequate understanding of the applicable regulatory requirements of 49 CFR Parts 100 – 185 and 10 CFR Part 71, have been indoctrinated in the 20WC QA Policy and have been instructed in the procedures of the 20WC QA Manual, **the applicable Certificate of Compliance**, and the structure of the QA Program.

The List of Authorized Users approved by the President will be maintained by the Health Physicist as document QAP-1-3. This document will summarize the review of a prospective Authorized User's qualifications and will include all supporting documentation, e.g. training certificates.

The President will approve suppliers of 20WC packagings for use by RAM Services when he has determined that they have an established Q/A program for the construction of the 20WC. The list of approved suppliers will be maintained by the Health Physicist as document QAP-7-1.

The President will perform an on-site inspection of all suppliers prior to approval in order to audit their records, verify compliance with their QAP, the quality of manufacture, and the safe storage and handling of completed packagings. His inspection findings will be documented on RAM Services' form QAP-7-2 and the

records will be transmitted to the Health Physicist for retention with all procurement documents.

A 20WC supplier's approval will be automatically suspended if an on-site inspection and audit has not been performed within the last year. The President will certify in writing that a 20WC supplier has been approved by RAM Services. All 20WC authorizations will terminate on 30 September 2008 (when the General License to use the 20WC packagings expires) and no inspections or audits will be performed after that date. Authorized Users will use 20WC containers only if they have been provided by RAM Services' certified suppliers and if that supplier has been inspected or audited within the last year.

Before offering any package employing a 20WC overpack, the Authorized User will complete an inspection checklist on form QAP-7-3 appropriate for the particular packaging; **i.e., the Inspection Checklists will be adapted to incorporate the provisions of the Certificate of Compliance and any special instructions.** The inspection will be conducted in accordance with the Quality Assurance Manual, document QAP-5-1, which are summarized on the checklist. The "tests" [actually visual inspections of various key components] required by 49 CFR 178.362-4 have been incorporated into the Manual, as well as any additional specific inspections imposed by RAM Services. The Authorized User will also complete a shipping checklist, form QAP-13-2 and document a radiation survey of the package on form QAP-13-4. **The Survey Form will include an operational check to ensure that the instrument is in calibration and is performing satisfactorily. The current calibration certificate will be attached to the Survey Form and made a part of the Plan records.**

The Authorized User shall submit the completed checklists, the radiation survey, and the shipping documents to the Health Physicist for review prior to offering the package for transport. The package shall not be transported until the Health Physicist has completed his review and communicated his approval **to the Authorized User to release the package for transport.** The Authorized User may submit the completed checklists for review by electronic means (e.g., facsimile or email) and the Health Physicist may respond electronically or verbally.

In reviewing the Inspection checklists, the Health Physicist shall ensure the packaging was obtained from an approved vendor that has been inspected by RAM Services within the last year and that all required package inspections have been documented. The Health Physicist will review the shipping checklist and the shipping papers to ensure that all DOT and NRC requirements have been complied with. The Health Physicist will maintain an archive of Inspection Checklists, QAP-7-3, and shall consult this historical record to determine if a package was previously reported as damaged, advising the Authorized User as necessary. Completed checklists, and all shipping documents shall be retained

by the Health Physicist for 3 years after the use of the packaging or as otherwise required by NRC and DOT regulations.

If either the Health Physicist or the Authorized User finds material defects affecting safety then the 20WC will be rejected and returned to the vendor for repair or replacement. The person noting the defects (the Health Physicist or Authorized User) shall describe the defects on the inspection checklist, form QAP-7-3, and shall complete a Non-conforming Package Report, form QAP-15-1 and submit it to the Health Physicist for review, retention, and copy distribution. The Health Physicist will also note the incident on the Approved Vendor List, form QAP-7-1. Copies of these forms will also be transmitted to the vendor's contact person and to the President of RAM Services for appropriate action. If the defects occurred while the packaging was in RAM Services possession, then the President will issue a Corrective Action Order, QAP-16-1, to effect the necessary remedies. Further use of the packaging will be suspended until the President certifies completion of the corrective actions in writing.

The President has established a corporate policy that all 20WC Authorized Users must understand and apply the quality and safety objectives described in 10 CFR Part 71, all applicable sections of 49 CFR Parts 100 – 185, and the elements of the Q/A Policy, Program, and manual. This policy affirms that safety and quality assurance takes precedence over all other matters in allocation of personnel and financial resources when using these packagings. Additionally, the Policy asserts that any Authorized User or QAP participant may reject any packaging or completed package if they find or suspect deficiencies that may compromise the safety of the package.

The President will ensure that RAM Services' QAP program is audited at least annually to assess the scope, status, implementation, and effectiveness of the program. A qualified external entity will perform the audit and report the findings to the President. A qualified auditor will be a person engaged in a Part 71 Quality Assurance Plan approved by the NRC (or Agreement State equivalent) or a Quality Assurance program certified by an independent agency (e.g., ISO-9000). The audit will review all program elements, especially container procurement, inspection checklists, package use, instances of defective or sub-standard containers, completeness of required documentation, and recordkeeping integrity.

2 Quality Assurance Program [10 CFR 71.105]

2.1 Scope of the Program

This QA Program applies to the procurement and use of the Specification 20WC Wooden Protective Jacket by RAM Services **to package byproduct and NARM radioactive materials for transportation.** Ram Services will only use

Specification 20WC-1, 20WC-3, 20WC-4, 20WC-5, and 20WC-6 wooden jackets; the 20WC-2 will not be used.

RAM Services will not construct 20WC wooden jackets but will only use those constructed and supplied by others to ship materials under the General License granted at 10 CFR 71.20. Consequently, we believe that only the Q/A program elements pertaining to procurement, shipment and handling are relevant.[1]

RAM Services will not ship radioactive materials in 20WC packages after the General License granted at 10 CFR 71.20 expires on 01 October 2008, or as otherwise determined by the Commission.

RAM Services will restrict its use of these packagings to byproduct material, naturally occurring and accelerator-produced radioactive materials and will not make shipments of fissile material with them.

The activities most relevant to safely using the 20WC are inspection of the packaging before use to identify defects and weaknesses, properly closing the completed package, and inspecting the completed package to ensure that all fasteners have been properly installed and that the package has not been damaged in the process.

These functions are described in detail in RAM Services Part 71 QA Manual, QAP-5-1, which also incorporates the specific safety instructions of 49 CFR 178.362.

All persons participating in the QA will be indoctrinated in the requirements of:

- 10 CFR Part 71
- 49 CFR 178.362
- **the Certificate of Compliance for the packaging**
- RAM Services QA Policy
- RAM Services QA Program
- RAM Services QA Manual

Additionally, Authorized Users must receive function-specific hazmat shipping and security training as required by 49 CFR Part 172 Subpart H.

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[1] "For example, an individual or organization using a general license solely for transportation of radioactive material in packages purchased or leased for that purpose would be expected to address regulations governing activities such as procurement, shipment, and handling." [Reg. Guide 7.10 Rev. 2, March 2005, at Page 6].

Copies, printed or electronic, of all QA Program instructional materials (i.e., those listed immediately above) will be provided to all QA Program participants. Documentation that a QAP Authorized User or participant has received the appropriate instructions will be maintained by the President as part of each employee's general training records for as long as required by the NRC, DOT, or for 3 years after the termination of the program, whichever is longest.

2.2 Package Design Control. [10 CFR 71.107]

This does not apply because RAM Services will not design packagings, but will only use approved designs constructed by others. In particular, the designs of the various 20WC packagings are specified by DOT regulation.

2.3 Procurement Document Control. [10 CFR 71.109]

Suppliers of 20WC packagings will be required to conform to the requirements and specifications described in document QAP-4-1. In particular, suppliers must provide access for RAM Services' personnel to inspect all facilities, goods and records, pertinent to the packaging. Suppliers must also provide copies of their manuals for using the packaging, special instructions, certificates, packaging inspections, and repair history.

The President will approve the vendors authorized to provide 20WC packagings based on an initial audit of their quality assurance program and construction records, and an inspection of their facilities, completed packagings, and storage conditions. The results of this inspection will be documented on form QAP-7-2 and these records will be maintained by the Health Physicist. Subsequent audits of a vendor may be performed by an Authorized User other than the President.

The Health Physicist will also maintain the list of approved (and rejected or expired) vendors on form QAP-7-1, which will reflect the current status of all vendors.

RAM Services personnel will only replace ordinary closure hardware such as threaded rods, nuts, washers, lock-nuts or lock washers, and weatherproof tape as needed. Since Specification 20WC imposes no special requirements on these items we do not believe that commonly available replacements will materially affect the packaging quality and critical safety performance. [I.e., these parts would be classed as Class C components in the graded approach described in Reg. Guide 7.10] Consequently, we do not believe that replacement of these parts by RAM Services needs to be documented to ensure maintenance of packaging quality, although the Authorized User may note the replacements on the Inspection Checklist, form QAP-7-3.

The Health Physicist will keep copies of all packaging inspection checklists in order to compile a history for each container.

Repair or replacement of critical components will be made only by the vendor, who will document these repairs, or other disposition, on form QAP-7-3 (or the vendor's equivalent) and provide copies of repair records to RAM Services prior to the next use of the container.

The Health Physicist will keep copies of all these inspection checklists in order to compile a history for each container.

2.4 Instructions, Procedures, and Drawings. [10 CFR 71.111]

Instructions and procedures for using the 20WC overpack are contained in the QAP Manual, QAP-5-1. This manual incorporates and expands on the basic instructions provided at 49 CFR 178.362 and also provides instructions for maintaining compliance with this Quality Assurance Program, the Certificate of Compliance, and 10 CFR Part 71.

The procedures for using the 20WC provide that the Authorized User must complete an inspection checklist, form QAP-7-3, a shipping checklist, form QAP-13-2, and a radiation survey of the package, QAP-13-4, and submit these, along with all shipping documents, to the Health Physicist for review and approval before releasing a completed package for transport.

The construction and use specifications at 49 CFR contain fairly crude quantitative specifications, e.g., 6 mm tie rods for the 20WC-1 versus 9.5 mm tie rods for the 20WC-3. Moreover, the exact dimensions of these components do not seem critical to the safe performance of the packaging. Consequently, we believe that the visual inspections, described in QAP-5-1 and QAP-7-3, without the use of specialized measuring apparatus will be adequate to ensure safety. These documents also incorporate and amplify the qualitative inspections required by 49 CFR 178.362-4.

The Certificate of Compliance usually limits the activity and the thermal output of the contents. To remain within the activity limits we intend to rely primarily on documentary evidence of the original activity of the material. When necessary, prudent, practical, and within the limits of maintaining exposures ALARA, we will perform appropriate radiation measurements to estimate **and confirm** the actual activity to be transported. RAM Services already possesses a wide assortment of survey instrumentation, which we will augment as necessary in order to achieve these goals.

The Health Physicist will calculate **the actual activity, if measurements are required**, and the thermal output using conservative assumptions and will advise

the Authorized User if the limits may be approached or exceeded. Evaluations of activity and thermal output will obviously be done prospectively when planning a shipment but they will be re-evaluated by the Health Physicist when reviewing the shipment checklists and documents prior to releasing the package for transport.

[The copy of the expired certificate USA/5800/B that we currently have in our possession is incomplete in that it lacks Appendixes A – F, so we cannot discuss our methods of complying with the requirements expressed therein. However, we will obtain a complete copy of the certificate, or its valid successor, and will revise or augment our existing checklists to include its requirements.]

RAM Services will observe all the requirements of the Certificate of Compliance for any packaging that we may use, incorporating specific requirements as necessary into the Inspection Checklists, form QAP-7-3 and the shipping checklists, QAP-13-2; variants of these forms developed for different packagings will be differentiated by the incorporating the packaging name or the CoC in the designation.

The QAP manual contains instructions on recordkeeping requirements and for the preservation of electronic documents.

2.5 Document Control. [10 CFR 71.113]

Changes and revisions to any and all QA Program documents [except the Document Control List, QAP-6-1] require the approval of the QAP Manager, the President of RAM Services.

The Health Physicist maintains the Document Control List, QAP-6-1, which summarized the current revision status of all QAP documents, as well as certain other essential items such as retention periods, distribution, etc.

The Health Physicist maintains electronic versions of all QAP document templates and manuals on the company's principal computer and can easily provide current copies of any QAP document to any Authorized User electronically, as is currently routinely done with many other company documents.

The security of the company's main computer is maintained by a variety of physical and procedural methods, such as limited network access and a hardware firewall. Electronic document integrity is maintained by a regular schedule of tape backups. RAM Services undertakes these security measures for a variety of company purposes, which ensures that security and integrity of program documents will be maintained as well

2.6 *Control of Purchased Material, Equipment, and Services [10 CFR 71.115]*

RAM Services will only procure fully assembled 20WC overpacks and, possibly, replacement closure hardware, which are not critical to packaging safety.

Vendors of completed 20WC overpacks will be approved only if they agree to the conditions of the Procurement Specifications, QAP-4-1 and have been approved by the President after an inspection of their facility, documented on form QAP-7-2. Among the elements of this inspection and audit is consideration of the adequacy of the vendor's quality assurance program to meet the requirements of Subpart H of 10 CFR Part 71, his adherence to its requirements, the quality of construction and in-process materials, and the proper storage and handling of completed packagings. Repeat inspections may be performed by an Authorized User other than the President.

We currently anticipate using 20WC overpacks provided by a single supplier so we do not anticipate inviting bids for any packagings or components.

We plan to continually measure a supplier's performance by evaluating the inspection checklists, form QAP-7-3, that will be returned to the Health Physicist prior to every shipment. These checklists will eventually provide a historical perspective of each supplier which, in addition to any Non-conforming Package Reports, form QAP-15-1, will identify any consistently failing supplier in a timely manner.

Since the General License to use the DOT specification packagings expires on 01 October 2008, we do not expect that many more 20WC packagings will be constructed, or that seriously damaged containers will be repaired; at this time any replacements can be provided from the supplier's current inventory. If, however, RAM Services orders construction of a new 20WC packaging, an Authorized User will visit the vendor's facility to inspect at least part of the construction process and audit the vendor's adherence to the construction requirements and his quality Assurance Plan. This inspection will be documented on the Audit Form, QAP-18-1

RAM Services intends to control non-conforming packagings with the inspection checklist, form QAP-7-3, and the Nonconforming Package Report, form QAP-15-1, which are intended to identify and document, and track seriously defective packagings. The historical record of these forms will allow us to identify suppliers of consistently defective 20WC packagings. Such vendors will be removed from the list of Approved Vendors, form QAP-7-1, by the President.

RAM Services Procurement Specification, form QAP-4-1 requires that suppliers of completed packagings provide all necessary documentation needed to use the container safely. These requirements include, among others, certification that the

packaging has been constructed and maintained according to Specification 20WC, reports of non-conformance by any user, and instructions for use of the container.

2.7 Identification and Control of Materials, Parts, and Components. [10 CFR 71.117]

Since RAM Services will only obtain fully completed 20 WC packagings, we believe that this section is not applicable to our program.

The closure hardware that RAM Services' personnel would be authorized to replace, such as threaded rods, nuts, lock nuts and washers, etc. are not individually critical to the safety of the packaging (I.e., Class C components) so **commonly** available replacements are adequate and require no special control or identification.

While auditing and inspecting vendor's records and facilities the Authorized User will evaluate the vendor's control over components, parts and materials and document this on the Audit Form.

2.8 Control of Special Processes. [10 CFR 71.119]

We do not believe that this is applicable since none are involved in the proper use of the 20WC.

2.9 Internal Inspection. [10 CFR 71.121]

RAM Services QA Manual, document QAP-5-1, describes a number of inspections that are to be made on 20WC packagings and completed packages. These inspections incorporate and expand upon those described in 49 CFR 178.362-4, and are to be documented on form QAP-7-3. The manual describes the quantitative and qualitative standards that must be met in order to ensure safety and the checklist documents that these.

While planning a prospective shipment the Authorized User and the Health Physicist will jointly evaluate the materials to be shipped for compliance with the limitations of the Certificate of Compliance, the regulatory requirements of 49 CFR Parts 100-185 , and with 10 CFR Part 71. Additionally, when arranging for the transportation of Quantities of Concern, we will comply with the provisions of our Security Plan (currently in preparation for submission to the State of Wisconsin), which we incorporate into our Quality Assurance Plan by Reference.

The manual instructs the Authorized User to perform a preliminary inspection of the packaging to identify non-conforming containers before they have been loaded with radioactive materials; the manual also recommends a "dry run" to ensure that the filled container can be securely closed. These measures are intended to minimize potential radiation exposures, but nevertheless constitute non-mandatory witness points

The QA Manual requires a mandatory hold-point when the completed package has been prepared and inspected. Copies of the inspection checklist, form QAP-7-3, the shipping checklist, QAP-13-2, the radiation survey QAP-13-4, the shipping papers, and any required security plan checklists and notifications, must be transmitted to RAM Services' Health Physicist for review, approval, and archiving before the package may be offered for shipment.

The inspection checklists, QAP-7-3, do not cover DOT requirements since these are covered by other checklists that RAM Services has developed. Specifically an Authorized User will also complete the appropriate portions of the radioactive shipment checklist, form QAP-13-2. This form is currently specifically designed for air shipments, but is readily adaptable for ground transport as well.

The Authorized User will also perform, or personally supervise, a radiation survey of the completed package and ensure that radiation and contamination levels are documented on form QAP-13-4. The surveyor will use instruments that have currently valid calibration certificates and whose proper operation has been verified with a check source. The operational check will be documented on the Survey Form, QAP-13-4, to which a copy of the instrument's calibration certificate will be attached.

RAM Services will not ordinarily maintain the 20WC packagings (except for superficial components) but will return them to the supplier for storage, maintenance, refurbishment, or repair. Consequently, RAM Services will not perform routine maintenance inspections.

However, there are conceivable circumstances where RAM Services itself may be the recipient of the 20WC, with or without radioactive contents. In such cases, a RAM Services Authorized User or Health Physicist will complete an inspection checklist before releasing the packaging for use at another job site. Maintenance while a packaging is in RAM Services' possession will be limited to ordinary cleaning, replacing closure hardware, removal of superficial rust, and touching up the paint or markings.

All inspections will be performed by Authorized Users or the Health Physicist, so their qualifications to make the required inspections will have been established.

The Health Physicist will maintain an archive of all checklists, forms QAP-7-3 and QAP-13-2 , prepared by the Authorized Users as well as any Non-conforming Package Reports, form QAP-15-1.

2.10 Test Control. [10 CFR 71.123]

We do not believe that this section is applicable to our proposed program for use of the 20WC overpack. The "Tests" described at 49 CFR 178.362-4 are straightforward and simple inspections and have been incorporated into the QA Manual, QAP-5-1, the inspection checklists, QAP-7-3, and the Non-conforming Package Report, QAP-15-1. The inspections require no special equipment or expertise.

2.11 Control of Measuring and Test Equipment. [10 CFR 71.125]

The only measuring equipment that we believe is relevant to our proposed operations under this Plan is survey instrumentation used to measure radiation and contamination levels.

As described in our Wisconsin license application, we possess an array of portable instrumentation capable of measuring dose rates from microrem per hour to 10's of rads per hour produced by X-ray, gamma, and neutron radiation. We also possess portable instrumentation capable of measuring, and distinguishing, alpha and beta surface contamination. Wipe samples collected at temporary job sites can be counted with portable instrumentation (i.e., an alpha/beta scaler) or in a liquid scintillation counter at RAM Services' Wisconsin facility.

Portable survey instruments for measuring X-ray or gamma radiation are usually calibrated by RAM Services under the terms of its Wisconsin license. Dose rate calibrations are performed according to RAM Services' procedure RAMSOP-300-300, which conforms to the requirements of ANSI N323A-1997.

The activity contained in RAM Services' calibration source was recertified by the manufacturer on 03 February 2004 and the radiation field from the source has been measured periodically *in situ* using a transfer standard ion chamber whose calibration is traceable to NIST. Records of these measurements are maintained as part of our instrument calibration program.

Dose rate and other limitations occasionally compel RAM Services to have instruments calibrated by other vendors. If these instruments will be employed in this program, then RAM Services will only use vendors whose procedures conform to ANSI N323A-1997, or who have been accredited by

NVLAP, the Health Physics Society, the American Association of Physicists in Medicine. If necessary, we may also send instruments directly to NIST.

Instruments to measure surface contamination or neutron radiation will be calibrated by external vendors that meet one or more of the certification standards for dose rate measurements and who employ reference standards traceable to NIST.

RAM Services, and any external vendor meeting the certification criteria described above, always attaches a sticker to each survey instrument indicating the next required calibration date, as well as correction factors if the indicated dose is not within 10% of the true dose. RAM Services also attaches a sticker to each instrument capable of measuring dose rates or surface contamination indicating its response to one or more of RAM Services' check sources.

RAM Services ordinarily performs an operational check of all instruments in service on a quarterly basis. Instruments that are broken or out of calibration are deemed out of service until repaired and/or calibrated. We have observed this practice because the scale and pace of our current operations does not justify maintaining all instruments in calibration all the time. In particular, instruments to measure surface contamination are frequently not calibrated until shortly before the anticipated use, and then usually for the specific isotopes expected. Records of these operational checks are maintained as part of our license commitments.

Before each package survey is performed under this Plan, the instrument used will be checked for proper operation by comparing the reading from one of the check sources with the Conventionally True Value [CTV]for that source, which is usually recorded shortly after calibration. Instruments that fail to read within ± 10% of the CTV will be rejected. This operational check will be recorded on the Package Survey Form, QAP-13-4.

The check sources that RAM Services employs will not be NIST traceable since the actual activity does not need to be well known, it just needs to be stable.

Quality Assurance records for instruments used to measure wipe test samples are maintained as part of our licensed leak testing services. Proper operation of the these instruments is verified on each day-of-use, which is usually every business day for the liquid scintillation counter, by counting reference standards and evaluating the results statistically.

2.12 Handling, Storage, and Shipping Control. [10 CFR 71.127]

The QA Manual, QAP-5-1, has been revised to include instructions on the proper storage, maintenance, and handling of the packaging and the completed package. These instructions address the concerns of Reg. Guide 7.10 in Section 13 [at 19] and are also summarized in the Instructions for Storage, Maintenance and Handling, document QAP-13-1, which is briefly discussed below.

The instructions in the Manual and QAP-13-1 require that the 20WC packaging be stored away from extremes of temperature and humidity which could cause failure of the plywood jacket or swelling that prevents secure closure. Additionally, we will comply with the storage and handling requirements specified in the Certificate of Compliance.

The instructions prohibit handling of the 20WC by its chimes, threaded rods, or other possible attachment points. Smaller packages may be carried by hand or placed on a dolly or cart. The larger packages shall always be handled on a pallet with a pallet jack, forklift, or crane attached to the pallet, unless circumstances or safety require an alternative method. Extraordinary lifting, loading, and unloading procedures will only be undertaken by an experienced rigger operating under the direct supervision of an Authorized User.

Maintenance by RAM Services shall be limited to minor cleaning with mild detergent solutions, touch-up of required markings, removal of superficial rust, and application of light oil to threaded components. These procedures are described in both the manual and in the Instructions of Storage, Maintenance, and Handling, document QAP-13-1.

These procedures also now require that a packaging be inspected and an inspection checklist, form QAP-7-3, be completed prior to use or shipment to a client facility if a container has been in storage longer than overnight.

Proper completion of all DOT and NRC requirements will be verified by the Authorized User by completing a shipping checklist, form QAP-13-2, prior to offering the package for transport. Copies of the inspection checklists, shipping checklists, radiation surveys, and shipping papers will be sent by the Authorized User to RAM Services' Health Physicist for review and approval before shipment.

Copies of the inspection checklists and the Storage, Handling and Maintenance Instructions, as well as any special instructions, will either accompany each shipment (among all other required documentation) or, usually, will be sent to the consignee in advance electronically.

2.13 Inspection, Test, and Operating Status. [10 CFR 71.129]

The Procurement Specifications, QAP-4-1, require that a vendor make an inspection of the packaging prior to shipment to RAM Services' or a clients facility and document this inspection on form QAP-7-3, or the vendor's equivalent.

Additionally, copies of the inspection checklist for the completed package, QAP-7-3, the standard Storage, Handling and Maintenance Instructions, QAP-13-1, and any special instructions will either accompany the shipment or be transmitted to the consignee in advance.

If a packaging is stored at RAM Services then an inspection checklist, QAP-7-3, will be completed by an Authorized User or the Health Physicist prior to shipment for use at a client facility. A copy of this inspection will either accompany the packaging or be sent to the Authorized User on-site in advance.

The most significant hold-point currently established in our program is a review by the Health Physicist of the checklists and shipping documents prior to releasing the package for shipment. This requirement is established in the QA Manual, QAP-5-1, and re-affirmed on the checklists.

The other significant hold would occur only if significant damage occurs to a packaging while it is in RAM Services' possession. In such a case the President will suspend the use of the affected packaging until corrective actions have been completed and certified.

2.14 Nonconforming Materials, Parts, or Components. [10 CFR 71.131]

A Non-conforming Package Report, form QAP-15-1, shall be prepared by an Authorized User (or the Health Physicist if the package has been removed from storage at RAM Services' facility) if any substantial defects affecting safety are found or suspected in a packaging. The defects shall also be noted on the inspection checklist, QAP-7-3. Copies of these documents will be transmitted to the vendor's contact person, as required by the Procurement Specifications, QAP-4-1.

The Procurement Specifications require that the vendor reclaim the damaged packaging and provide a sound replacement. RAM Services will not repair packagings with major defects, but may make minor repairs or provide replacement hardware, as described in the QA Manual, QAP-5-1, for non-critical items.

The Procurement Specifications also require that vendors provide RAM Services with reports of non-conformances that may have been made by other users of a specific packaging if they offer it for use by RAM Services and records of any repairs made to that packaging.

Additionally, the Health Physicist will maintain an archive of the completed inspection Checklists, form QAP-7-3, for each packaging used by RAM Services. These checklists, along with any Non-conforming Package Reports, QAP-15-1, will permit RAM Services Health Physicist or QA Manager, i.e., the President of RAM Services, to identify a vendor that consistently provides sub-standard packagings. In such a case the President may order that a vendor be removed from the List of Approved Suppliers, form QAP-7-1.

2.15 Corrective Actions. [10 CFR 71.133]

The Non-conforming Package Report, QAP-15-1, requests that the Authorized User (or the Health Physicist for packagings taken from storage at RAM Services) identify, if possible, the cause of the damage. Copies of this report and the Inspection checklist must be sent to the required vendor contact for reporting non-conforming packages.

The vendor is required by the Procurement Specifications, QAP-4-1, to report to RAM Services any repairs made to a damaged packaging before offering it for use. It is clearly in the interests of all that the vendor also provide RAM Services an explanation of the cause of the damage, if known, and corrective actions to prevent repeat occurrences.

In view of the limited time left before the General License for use of 20WC packagings expires, we believe that the only corrective action RAM Services needs to take for a consistently sub-standard vendor is to remove them from the Approved List, QAP-7-1, and seek an alternative.

The Non-conforming Package Report requests that the cause of the damage be identified, if possible, and that corrective actions be recommended. Upon review of this report the President will issue a Corrective Action Order, form QAP-16-1, that suspends use of the packaging until specified remedies have been successfully completed.

Inspectors performing the annual review of RAM Services' QA Program will report any deficiencies on the Annual Audit form, QAP-18-1, or equivalent provided by the audit team. These deficiencies will be reported to the QAP Program Manager, the President of RAM Services, who will be responsible for managing and documenting corrective actions. The corrective action documentation will be attached to the original Audit Report.

The President will ensure that the corrective actions are completed in a timely manner. Actions critical to safety will be corrected before the next use of a 20WC packaging and a follow-up inspection of deficient program elements will be completed before the next use of the 20WC Deficiencies in documentation may not be corrected until the packaging is next used, since they may not be produced until that time. E.g., we cannot verify proper completion of an inspection checklist until the next use. This interim audit may be conducted by RAM Services personnel not directly responsible for that program element to ensure a prompt response.

2.16 Quality Assurance Records. [10 CFR 71.135]

The guidance provided in Section 17.1 of Reg. Guide 7.10 requires documentary evidence that elements of the Plan have been properly executed. Below we summarize the documentary evidence produced by RAM Services QA Plan.

- *design, procurement, manufacturing, and installation records*
  - QAP-4-1, Procurement Specifications
  - QAP-7-3, Inspection Checklists
- *supplier evaluations*
  - QAP-7-2, Supplier Site Visit and Inspection Audit
- *nonconformance reports*
  - QAP-7-1, List of Approved Suppliers
  - QAP-7-2, Supplier Site Visit Inspection & Audit Form
  - QAP-7-3, Inspection Checklists
  - QAP-15-1, Non-conforming Package Report
- *results of inspections and tests*
  - QAP-7-3, Inspection Checklists
  - **QAP-13-2, Shipping Checklists**
  - **QAP-13-4, Package Radiation Survey**
  - **Instrument calibration certificates**
- *failure analyses*
  - Not Applicable
- *as-built drawings and specifications*
  - 49 CFR 178.362
- *qualification of personnel, procedures, and equipment*
  - QAP-1-3, List of Authorized Users with supporting documentation
  - QAP-5-1, QA Manual
- *calibration procedures*
  - **RAM Services Series 300 Procedures (e.g., RAMSOP-300-300, Dose Rate Calibration Procedure)**
  - **ANSI N323A-1997**
  - **Beckman LS-6500 Operating Manual (for liquid scintillation samples)**

- *training and retraining records*
    - QAP-1-3, List of Authorized Users with supporting documentation
- *corrective action reports*
    - QAP-7-1, Approved Vendor List
    - QAP-7-3, Inspection Checklists or equivalent returned from vendor
    - **QAP-16-1, Corrective Action Order**
- *records demonstrating evidence of operational capability*
    - QAP-7-3, Inspection Checklists
- *records verifying repair, rework, and replacement*
    - QAP-7-3, Inspection Checklists
- *audit plans, audit reports, and corrective actions*
    - QAP-7-2, Supplier Site Visit and Inspection Audit
- records that are used as a baseline for maintenance
    - **archive of Inspection Checklists, form QAP-7-3** archive

RAM Services routinely maintains complete shipping records of incoming and outgoing shipments of radioactive materials as part of its inventory control program and for the security of Quantities of Concern while in transport. These practices will naturally continue.

The QA Manual, QAP-5-1, Inspection checklists, QAP-7-3, and the Non-conforming Package Reports, QAP-15-1 all specify the packaging elements that are crucial to safety and require that the Authorized User or Health Physicist making the inspection document that each element has been inspected. The QA Manual will also incorporate any inspection requirements contained in the Certificate of Compliance.

RAM Services will maintain paper copies all shipment document employing the 20WC wooden jackets in a binder or single file location, as necessary. Electronic copies of most, if not all, records will also be maintained in order to expedite retrieval.

The Document Control List, QAP-6-1, specifies the retention requirement for each Plan record. This is re-iterated on each individual document to prevent pre-mature destruction.

The Document Control List also specifies who generates the various plan documents and the distribution list and if any response is necessary. These instructions are repeated on each document as appropriate. The lines of communication involved in our plan are simple and direct and so a record receipt system seems unnecessarily cumbersome at this time.

Copies of all Plan records, paper and electronic, will be maintained at RAM Services Wisconsin facility. Electronic records will be generated and maintained with widely used software, so obsolescence over the lifetime of the program is highly unlikely. In the event that new hardware or software is installed, the QA Plan Manager will ensure that existing documents are converted and usable.

Section 17.5 of Reg. Guide 7.10 stipulates that the plan fulfills certain requirements. Below we summarize these requirements and RAM Services methods for compliance, if applicable.

- *Facilities used to store records should be constructed to minimize the risk from damage or destruction by severe natural conditions, such as wind, flood, fire, temperature humidity, mold, or infestation by insects or rodents.*
    - RAM Services occupies a robust structure made of brick-faced poured concrete. All Plan records will be stored in this facility and never in temporary external facilities, such as a Sea Land container, until at least 3 years after the termination of the Plan.
    - The facility is located near the top of the local terrain, so flooding is not a realistic problem. The building is constructed of fire resistant materials with ample separation from nearby woods.
    - RAM Services facility is occupied nearly every business day by employees and often on weekends as well. Consequently, there is ample opportunity to detect and correct conditions adverse to records preservation.
- *Records should be firmly attached in binders or placed in folders or envelopes or storage in steel file cabinets.*
    - This is normal operating procedure for all records at RAM Services
- *Electronic records should be maintained in facilities that minimize or eliminate the potential for destruction of information as a result of demagnetization.*
    - The electronic storage devices and media are located in a room separate from the operational areas of the facility.
    - RAM Services current and envisioned operations do not employ equipment or methods that would remotely demagnetize media.
    - All computers at RAM Services, except for portable versions, have their magnetic media configured as a RAID -1 array, providing some additional protection against media failure.
- *Electronic records should be backed up daily to eliminate the potential for loss of information as a result of equipment failure or human error.*
    - The scale and pace of RAM Services current operations do not warrant daily backups.
    - RAM Services regularly backs up important electronic information (i.e., the entire contents of the server) to magnetic tape. This is normally done by the Health Physicist weekly but intervals can occasionally be longer (10 - 14 days) if the Health Physicist is out of the office.
    - An archive of recent backups stretching back several months is ordinarily maintained to further guard against loss.

- Additionally, a permanent archival backup tape is created at the end of each year to guard against loss of important but rarely used files.
- RAM Services' computers connect to the Internet only through a hardware firewall, which cannot be hacked because there is no alterable software.
- In addition to the usual security measures of limiting access and the available ports, the connection to the Internet is normally physically disconnected at night and on weekends.
- Only RAM Services' database programmer ever accesses the main server remotely.

- *If dual storage facilities are used to ensure the record integrity, the storage facilities should be sufficiently remote from each other to preclude a single event (such as a fire or flood) from damaging both facilities.*
  - Dual facilities are not currently practical for RAM Services.
  - The tape backup archive, however, is stored in a rated fire-resistant cabinet and the physical location renders flooding an extremely remote possibility.
- *The QA program user should take measures to protect special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature.*
  - Not applicable at this time.
- *The QA program user should take measures to prevent unauthorized personnel from entering record storage areas.*
  - RAM Services facility is situated in a sparsely inhabited rural location and there is very little pedestrian traffic near the building. Visitors, except for express couriers, are rare.
  - Vehicular approach is generally detectable or observable from the offices.
  - Most facility entrances are kept locked unless in use.
  - RAM Services will be implementing a security plan for Quantities of Concern so QA Plan documents will also be protected.
- *Electronic information storage systems should be accessible only through security measures such as passwords, and the number of personnel who have authorized access should be limited. In addition, personnel who have authorized access should have identified privileges, such as "read only" or "read and add only."*
  - Access is automatically limited by RAM Services small size.
  - Passwords for electronic records would be pointless since everybody in the company would know them anyway.

- The electronic version we plan to use for most documents, Adobe PDF format, is impossible or difficult to edit even if unprotected, and changes are usually detectable.
- Archival documents, which are never intended to be altered, could be protected by essentially random passwords but the current security situation at the company does not seem to warrant this measure,
- The Document Control List, QAP-6-1, and each document on it, specifies who generates a given record, who retains it, and who gets copies.

- *The QA program user should establish measures to ensure prompt replacement of a record that is lost or damaged.*
  - The electronic versions of most documents along with their tape backups will permit prompt restoration of lost or damaged paper records.
  - The paper versions of documents will be used to restore lost or damaged electronic versions.

2.17 Audits. [10 CFR 71.137]

In the QA Policy on Quality Assurance, QAP-1-2, the President has committed to having an independent person or organization perform a comprehensive annual review of RAM Services' Quality Assurance program and its use of these packagings. Company policy requires that the audit team have complete and unrestricted access to RAM Services' facilities, personnel, and records necessary to evaluate the program. Additionally, RAM Services will ensure that the audit team is free from financial pressures to insure that a comprehensive review of the program is completed. These policies are re-iterated in the QA Program Audit Form, QAP-18-1.

The President will schedule the audit so that qualified RAM Services personnel will be available for consultation with the auditors. The President will also ensure that RAM Services personnel will be sufficiently free from other duties to respond to the auditors needs and questions.

Since the audit scheduling involves parties beyond RAM Services' control, it seems possible that the audit period may exceed one year. If this were to occur, then the President will suspend use of the packaging until the audit has been performed and any deficiencies found have been corrected.

The Company QA Policy, QAP-1-2, and the Audit Form, QAP-18-1 require that auditors report their findings to the President orally and in a written report, transmitted to him in a timely manner, that highlights any deficiencies. The President will initial the written report to indicate his review and will oversee any corrective actions to ensure that they are completed in a timely manner.

The President will establish a schedule for completion of any corrective actions and will ensure that they are completed on time. When the corrective actions are completed, the President will document the actions taken and attach or append this response to the Audit Report. A follow-up inspection of deficient program elements will occur within six months after completion of the corrective actions. This inspection may be made by RAM Services personnel not directly responsible for the deficient program element.

We believe that annual reviews of the entire program will be adequate in view of the expected scale and frequency of our activities. The President may institute more frequent reviews of portions of the program if necessitated by a significant increase in Program activities, or by persistent deficiencies. These interim audits may be conducted by qualified RAM Services personnel who are not directly responsible for the particular program element.

An Authorized User will also periodically review the performance of 20WC vendors to ensure their compliance with their quality assurance program. These reviews may occur at intervals exceeding one year, if the pace of activities is slow, but the vendors approval will be suspended if one year has passed since the last audit. No packagings will be accepted from this vendor until a satisfactory audit has been completed, Audits of vendors will be documented on form QAP-7-2 and the vendor's status (Approved, Suspended, or Disapproved) will be maintained by the Health Physicist on the Approved Vendor List, Form QAP-7-1.

RAM Services' size and the scope of its activities suggest that routine internal audits of RAM Services entire QA Program by RAM Services management will be impractical and, possibly, ineffective since management would often be auditing itself. Internal management audits of the record keeping and preservation, program elements that are the main responsibility of the Health Physicist, will be useful and will be made annually.

We have also provided for internal audits of program elements by RAM Services personnel not directly responsible for performance of that element if deficiencies are found by an external auditor. E.g., if the Health Physicist has failed to maintain adequate electronic records, then the QA Program Manager will inspect these records frequently to ensure that the deficiency is corrected.

The Annual Audit Form, QAP-18-1, will define the qualifications required of the external auditors. Generally, we will consider persons qualified if they participate in an approved Part 71 Quality Assurance Program, or equivalent, **or have previous Part 71 audit experience in the applicable areas of our Program. The audit team leader shall have prior experience auditing the areas or our program.**

A pre-audit conference between RAM Services' management and the proposed auditor will naturally occur to arrange ordinary logistical and business matters. Naturally the scale and scope of the proposed audit must be discussed in the course of the conference to resolve these issues. RAM Services' size and the scope of its activities preclude any difficulties in defining the persons responsible for program elements and the lines of communication between RAM Services' personnel and the auditors.

The auditors will present their findings verbally to the President of RAM Services upon completion of their review, usually at an exit interview but possibly by conference call. A complete written report of the Audit findings and any recommendations will be required within 30 days of completion.

The President will establish, schedule, and manage the corrective actions required to address any deficiencies and document their completion in an appendix or attachment to the audit report. The President will also require that a follow-up inspection of deficient program elements be made, possibly by RAM Services personnel before the next use of a 20WC packaging, if the program element is critical to safety, at upon the next use of the packaging if the deficiency involves records production.

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