NUCLEAR REGULATORY COMMISSION
DIVISION OF NUCLEAR MATERIALS SAFETY
REGION III

SAFETY EVALUATION REPORT
RELATED TO APPROVAL OF THE DECOMMISSIONING PLAN
LICENSE NO. 24-15595-01, DOCKET NO. 030-09415

APTUIT, LLC
KANSAS CITY, MISSOURI

August 27, 2013

1.0 Executive Summary

In a letter dated August 30, 2012, Aptuit, LLC (Aptuit) submitted the Aptuit Scientific Operations Decommissioning Plan (DP) (ADAMS Accession Number ML12248A095) and a request to amend NRC License No. 24-15595-01 to incorporate the DP into their license. The Aptuit facility is located at 10245 Hickman Mills Drive, Kansas City, Missouri, 64134. Aptuit occupies 7 of 13 primary buildings in an industrial complex at the location. The DP only addresses the decommissioning of sections of the B building and the Waste Storage Building as described in Section IV and listed in Appendix C of the DP. Since being initially licensed in 1973, the Aptuit facility has been primarily used for performing research and development in the synthesis of labeled pharmaceuticals. In 2008, Aptuit also began performing synthesis of radiolabeled compounds. Currently, Aptuit has ceased principal activities and the remaining radiological contamination in the areas covered by the DP consists of Tritium (H-3) and Carbon-14 (C-14).

Aptuit's objective is to clean the contamination at the facility and demonstrate to the NRC that the property is acceptable for release and unrestricted use in accordance with the requirements of the License Termination Rule in 10 CFR 20.1402, "Radiological criteria for unrestricted use." To meet the unrestricted use criteria, the licensee plans to use conservative Derived Concentration Guideline Levels (DCGLs) that are based on the screening values developed by the NRC which can be found in NUREG-1757, Volume 2, Appendix H, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria – Criteria for Conducting Screening Dose Modeling Evaluations". Once the Aptuit facility has been cleaned, the licensee plans to request license termination.

Section 1.0, "Executive Summary," of the DP provided a summary and overview of licensed activities, current site conditions, and sufficient details for the NRC and members of the public to understand Aptuit's goals and plans for decommissioning the facility. The licensee's decommissioning approach described in the DP will support the licensee's objective to meet the NRC unrestricted use criteria of 10 CFR 20.1402 in support of license termination. The timeframe proposed for decommissioning the facility, approximately eight months, is reasonable and in accordance with the requirements of 10 CFR 30.36(h)(1).

2.0 Facility Operating History

NRC staff reviewed the information in the "Facility Operating History" section of the Decommissioning Plan for Aptuit, license number 24-15595-01 (Docket No. 030–09415) located at 10245 Hickman Mills Drive, Kansas City, Missouri, according to the Consolidated Decommissioning Guidance, NUREG-1757, Volume 1, Section 16.2 (Facility Operating History). Based on this review, NRC staff determined that the licensee, Aptuit, provided sufficient information to aid NRC staff in evaluating the licensee's determination of the radiological status of the facility addressed in the DP and the licensee's planned decommissioning activities, to ensure that the decommissioning can be conducted in accordance with NRC requirements.

2.1 License Number/Status/Authorized Activities

The NRC staff compared the information submitted in section II.A of the DP to the previous (Amendment No. 34) and current (Amendment No. 35) Aptuit license amendments, and to previous NRC inspection reports for the facility. The information submitted was consistent with the authorized type of radioactive materials, chemical and/or physical forms of the material, and the maximum possession limits for these

materials. The areas covered by the DP include sections of the B building and the Waste Storage Building which are part of the licensee's authorized locations of use in the license. Consistent with the authorized activities listed in Amendment No. 34, the only radionuclides used in those areas, as described in Section V.A.1 of the DP, were H-3 and C-14. They were used for the synthesis of radiolabeled compounds and pharmaceutical research, development, and analysis.

2.2 License History

The DP provides a list of past license amendments in Table 1-1 that includes the type of radionuclides, maximum possession limits, chemical form of the radionuclides, and the general uses of the material for each amendment. The NRC staff compared the information provided in the DP to significant license amendments for the facility (Amendment Nos. 9, 10, 13, 17, 19, 20, 21, 22, 23, 24, 25, 27, 28, 31, 32, 33, and 34) and found the information to be consistent with the information in those amendments. The Aptuit license has had several ownership changes. The NRC originally issued License No. 24-15595-01 to Marion Laboratories, Incorporated in 1973. Since then, the licensee's name on the license has been changed five times to the following: (1) Marion Merrell Dow, Inc. via Amendment No. 13 in 1990, (2) Hoechst Marion Roussel via Amendment No. 19 in 1996, (3) Quintiles, Inc. via Amendment No. 21 in 1999, (4) Aptuit, Inc. via Amendment No. 24 in 2006, and (5) Aptuit, LLC via Amendment No. 33 in 2012.

In the past, the licensee has been authorized for the use of Tritium (H-3), Carbon-14 (C-14), Sodium-22 (Na-22), Phosphorus-32 (P-32), Sulfur-35 (S-35), Potassium-42 (K-42), Calcium-45 (Ca-45), Chromium-51 (Cr-51), Nickel-63 (Ni-63), Technetium-99m (Tc-99m), Iodine-125 (I-125), Iodine-131 (I-131), Barium-133 (Ba-133), and Cesium-137 (Cs-137). The radionuclides, as supported by the authorized uses on the previous licenses, were mostly used for research and development in the synthesis of labeled pharmaceuticals for nonhuman experimentation and in vivo and/or in vitro animal studies. Sealed sources Ba-133 and Cs-137 were used as calibration sources and the Ni-63 sealed sources were used in detector cells for chromatographs.

The decommissioning activities in the DP focus on the cleanup of H-3 and C-14 because those are the only radionuclides that have been used in the areas addressed by the DP in recent years. This is consistent with the guidance in NUREG-1757 and NUREG-1575. The Ba-133 and Cs-137 calibration sources are sealed sources (not required to be leak tested) which would not contribute to any contamination at the facility. Through a review of past inspection reports and the NRC Nuclear Materials Event Database (NMED) there are no known instances where Ni-63 sealed sources, previously authorized in the license, were found to be leaking. This provides reasonable assurance that there is no Ni-63 contamination at the facility.

The DP does not specify cleanup criteria for P-32, S-35, K-42, Ca-45, Cr-51, Tc-99m, I-125, and I-131 because there is reasonable assurance that the radioactive materials have decayed to insignificant quantities due to their limited use, limited authorized possession limits, the significant length of time since their last use, and their relatively short half-lives. In addition, the DP does not specify cleanup criteria for Na-22 because there is also reasonable assurance that it is not a contaminant of concern due to the fact that the licensee has no record of its use at the facility, the authorized possession limit for it was relatively small (20 millicuries), it has a relatively short half-life (2.6 years), it has not been authorized on the license since about 1994, sufficient time (about 19

years) has passed for it to decay to an insignificant quantity if it had been used at the facility, and it has not been identified as a contaminant of concern in previous site investigations.

The DP provides a list in Appendix D and figures (Figures 2-1 through 2-8) of past locations of use and storage of radioactive material at the facility. In addition to the locations listed, a license application dated September 13, 1993, incorporated into Amendment No. 17 of the license, includes building D of the Hickman Mills Drive complex as a building where licensed activities could be performed. The NRC will evaluate the activities performed at that building, and any other buildings where licensed activities may have been performed in the past, to determine if the correct documentation exists demonstrating their suitability for unrestricted use when Aptuit submits a license termination request.

The information presented in section II.B of the DP is consistent with previous license amendments and sufficient to enable the staff to fully understand what licensed activities were performed by the licensee in the past in the portions of the facility addressed by the DP.

2.3 Previous Decommissioning Activities

Section II.C of the DP provides a summary of previous decommissioning activities performed at the Aptuit facility. In addition, a list is provided in Appendix D that summarizes the historical radioactive material use and storage areas, provides their status, and whether they have been released for unrestricted use. Previously decommissioned areas were used for research and development in the synthesis of labeled pharmaceuticals for nonhuman experimentation and in vivo and/or in vitro animal studies, in accordance with authorized activities in previous licenses. The radioactive materials used in these areas were the same as those mentioned in Section 2.2 of this Safety Evaluation Report (SER) with H-3 and C-14 also being the only contaminants of concern.

There are three previous submittals to the NRC that document major decommissioning efforts for the Aptuit Hickman Mills Drive facility that validate the information provided in the DP. The first documented decommissioning activity was completed in 2006 and provided to the NRC during an inspection of the facility in 2011. It is a final status survey for lab A3-367 (ML110620362).

The second is a final status survey report submitted to the NRC in 2007 (ML070080417, ML070090653, and ML071230265) for releasing the L Building and a large portion of the second floor of B Building (known as the Lab Animal Resources). The NRC reviewed and approved the release of the L Building for unrestricted use through the issuance of Amendment No. 25 of the Aptuit license (ML072040439 and ML071990570). The release of the L Building is also documented in a Federal Register Notice issuing an Environmental Assessment (EA) and a Finding of No Significant Impact (FONSI) (ML071840213 and FR Vol. 72 No. 134 Page No. 38629, July 13, 2007).

The third is a final status survey report submitted to the NRC in 2012 for releasing impacted portions of the A Building, B Building, and E Building. This final status survey is currently under NRC review as part of a license amendment request for the Aptuit facility controlled under NRC Mail Control No. 577059.

Past decommissioning activities performed at Aptuit typically involved wiping contaminated surfaces with water and detergent mixtures and in some cases removal of items and materials that were disposed as radioactive waste. As stated above, the NRC has reviewed and approved the release of the L Building for unrestricted use. The licensee has performed other decommissioning activities to make portions of the facility suitable for unrestricted use and have released these from radiological controls. The NRC will evaluate the licensee's final status survey reports for those portions of the facility when Aptuit submits a license termination request.

The DP provides sufficient information to enable the staff to fully understand what decommissioning activities ~~that~~ were performed at Aptuit in the past, and whether these were sufficient to comply with current NRC criteria for license termination.

2.4 Spills

Section II.D of the DP and Appendix B of the DP describe incidents of spills (or uncontrolled releases) in areas to be decommissioned under the DP. Appendix B also lists other incident reports for areas outside of the scope of the DP where spills occurred. All of the spills involved either C-14 and/or H-3, consistent with the contaminants of concern at the facility. The information provided for the spills is sufficient to enable staff to evaluate the current radiological status of the facility.

3.0 Facility Description

3.1 Site Location and Description

The Aptuit facility is located at 10245 Hickman Mills Drive, Kansas City, Missouri, Jackson County, 64134. Aptuit occupies 7 of 13 primary buildings in an industrial complex that is approximately 45.5 acres. Figure 1-1 of the DP provides a diagram of the campus. The buildings occupy a total of approximately 38,740 square meters. The Aptuit property is approximately 940 feet above sea level and slopes to the West and South. There are no known wells within one mile of the property except for two mineral exploratory test holes drilled in 1946 that are assumed to be closed. However, the regional water supply for the Kansas City area comes from alluvial valleys of the Missouri River and its tributaries. The nearest residence to the Aptuit facility is approximately 0.25 miles away.

Through a review of past licenses, and Table 1-1 of the DP, NRC staff noted that there have been several different locations of use authorized on the license. License Amendment No. 1 authorized 10236 Bunker Ridge Road, Kansas City, Missouri, 64137, as the location of use. Due to a mailing address change, not a change in the physical location of the facility, Amendment No. 9 of the license changed the authorized location of use to Marion Park Drive, Kansas City, Missouri 64137 as requested in a letter dated July 16, 1985. On October 11, 1988, Amendment No. 10 of the license added a facility at 6633 Troost, Kansas City, Missouri, as a location of use to the license. The facility was used for research and development purposes by the licensee. A final survey report was submitted to the NRC by letter dated March 13, 1997, with additional information dated August 14, 1997, which supported the release of the facility for unrestricted use. The NRC reviewed the information provided and approved the release of the building for unrestricted use through the issuance of Amendment No. 20 of the license on August

25, 1997. On January 19, 1999, the address to the facility, not the actual physical location of the facility, again changed with the change in ownership from Hoechst Marion Roussel Inc. to Quintiles, Inc. The new address (same physical location of authorized use) was changed to the current address of the facility, 10245 Hickman Mills Drive, Kansas City, Missouri, 64134 through the issuance of Amendment No. 21 of the license as requested through a letter dated December 31, 1998.

Through a review of past licensing documents and inspection reports, the NRC staff determined that the DP provides sufficient information to generally understand the location and physical characteristics of the site. Based on the contamination levels and planned decommissioning activities, there are no anticipated impacts to the populations in the surrounding areas or to the environment.

3.2 Population Distribution

The Aptuit facility is located in Kansas City, Jackson County, Missouri. The Kansas City population, according to 2010 census data, was 459,787. NRC staff compared the population information provided in the DP to the United States Census Bureau information and found it to be consistent. The licensee's planned decommissioning activities are not anticipated to result in doses to offsite individuals. Therefore, the information provided in the DP is sufficient to enable staff to understand the population in the vicinity of the site.

3.3 Current/Future Land Use

The Aptuit facility is located in an area that is used primarily for industrial purposes. There is currently commercial land development to the North, South, and West, and a residential area to the East. The land use in and around the site is not expected to change. As the licensee has contained all radioactive material within a confined space and has developed procedures to limit the potential for contamination to enter the environment, the licensee's planned decommissioning activities are not anticipated to result in doses to offsite individuals. Therefore, the information provided in the DP is sufficient to enable the staff to understand the current and future land use in and around the Aptuit facility.

3.4 Meteorology and Climatology

As the licensee has contained all radioactive material within a confined space and has developed procedures to limit the potential for contamination to enter the environment, the licensee's planned decommissioning activities are not anticipated to impact onsite or offsite individuals from airborne radioactive materials. Therefore, the DP does not provide any meteorology and climatology data because it is not needed by the NRC staff to evaluate the licensee's estimation of doses to onsite and offsite individuals during and at the completion of decommissioning operations.

3.5 Geology and Seismology

The lithology at the site is mainly silty clays and silty clay loams overlying a sequence of shale and limestone of the Kansas City Group. The depth to bedrock is typically less than five feet below the ground surface. The licensee's planned decommissioning activities, which are limited to a confined internal space, are not anticipated to impact

onsite or offsite individuals during or after the completion of decommissioning operations. Therefore, the information provided in the DP is sufficient to enable the staff to understand the geology of the site.

3.6 Surface Water Hydrology

The drainage classes of the soils at the Aptuit site range from somewhat poorly drained to well drained. As the licensee has contained all radioactive material within a confined space and has developed procedures to limit the potential for contamination to enter the environment, the licensee's planned decommissioning activities are not anticipated to impact onsite or offsite individuals during or after the completion of decommissioning operations. Therefore, the information provided in the DP is sufficient to enable the staff to understand the surface water hydrology at the site.

3.7 Ground Water Hydrology

The groundwater at the site is expected to flow south-southwest, based on topography, and was not encountered at depths of 15 feet below the ground surface with the exception of perched groundwater in fill material on top of bedrock. There are no known wells within one mile of the property except for two mineral exploratory test holes drilled in 1946 which are assumed to be closed. As the licensee has contained all radioactive material within a confined space and has developed procedures to limit the potential for contamination to enter the environment, the licensee's planned decommissioning activities are not anticipated to impact onsite or offsite individuals during or after the completion of decommissioning operations. Therefore, the information provided in the DP is sufficient to enable the staff to understand the ground water hydrology at the site.

3.8 Natural Resources

The licensee's planned decommissioning activities are not anticipated to impact onsite or offsite individuals during or after the completion of decommissioning operations. In addition, the licensee plans to terminate their license and release the property for unrestricted use in the future. Therefore, the DP does not provide any information on natural resources because it is not needed by the NRC staff to evaluate the impacts of the decommissioning alternative chosen by the licensee or their dose estimates for the site.

4.0 Radiological Status of Facility

The NRC staff reviewed the information in the "Facility Radiological Status" section of the Decommissioning Plan for Aptuit. Based on this review, NRC staff has determined that the information provided by the licensee has described the types and activity of radioactive material contamination at the Aptuit facility was sufficient to allow the NRC staff to evaluate the radiological status of the facility. The NRC staff evaluated the potential safety issues associated with remediating the facility, whether the remediation activities and radiation control measures proposed by the licensee are appropriate for the type of radioactive material present at the facility, whether the licensee's waste management practices are appropriate, and whether the licensee's cost estimates are plausible, given the amount of contaminated material that will need to be removed or remediated. There are no impacts of site radiological operations to the surface and subsurface soil.

5.0 Dose Analysis

The NRC staff reviewed Aptuit's clean-up criteria to determine compliance with the NRC's decommissioning criteria. Aptuit's objective is to clean the contamination at the facility and demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402, "Radiological criteria for unrestricted use," by correctly using conservative Derived Concentration Guideline Levels (DCGLs) for H-3 and C-14 that are based on radionuclide-specific screening values for building surface contamination developed by the NRC, found in NUREG-1757, Volume 2, Appendix H.

6.0 Environmental Exposure Information

The NRC staff reviewed the environmental exposure information in the Decommissioning Plan for the Aptuit, LLC (licensee), license number 030–09415 located in Kansas City, Missouri according to the Consolidated Decommissioning Guidance, Volume 1, Section 17.4 (Environmental Monitoring and Control Program). Based on this review, to which specific references are made within this SER, the NRC staff has determined that the licensee has provided sufficient information for the staff to conclude that the licensee's program will comply with 10 CFR Part 20.

7.0 ALARA Analysis

The NRC staff reviewed the "as low as is reasonably achievable" (ALARA) information in the Decommissioning Plan for the Aptuit, LLC (licensee), license number 030–09415 located in Kansas City, Missouri according to the Consolidated Decommissioning Guidance, Volume 1, Section 17.4.1 (Environmental ALARA Evaluation Program). Based on this review, to which specific references are made within this SER, the NRC staff has determined that the licensee has provided sufficient information for the staff to conclude that the licensee's program will comply with 10 CFR Part 20.

8.0 Planned Decommissioning Activities

The NRC staff reviewed the decommissioning activities described in the DP for the Aptuit facility and determined that the licensee had provided sufficient information to allow the NRC staff to evaluate their planned decommissioning activities and verify that the decommissioning could be conducted in accordance with NRC requirements.

9.0 Project Management and Organization

Using the guidance in NUREG 1757, Vol. 1, Rev. 2, Section 17.2, the NRC staff reviewed the description of the decommissioning project management organization; which included position descriptions, management and safety position qualification requirements and the manner in which Aptuit will use contractors during the decommissioning of its facility. Based on this review, the NRC staff determined that Aptuit's descriptions of the proposed decommissioning management and organization are adequate to serve as the basis for concluding that the licensee's management program will exercise the appropriate control during decommissioning operations.

9.1 Decommissioning Management Organization

In Section XI, Project Management and Organization, of the DP, Aptuit indicates that implementation of the DP will be managed by a team comprised of management, radiation safety, occupational safety personnel, a Radiation Oversight Committee and a Quality Assurance Audit team from Aptuit, a decommissioning contractor and waste disposal sub-contractor. Aptuit will retain overall responsibility for management and execution of the DP. Aptuit will contract with a well established decommissioning contractor to execute the DP. The decommissioning contractor will provide the equipment, materials, and a trained and experienced labor force to perform the decommissioning activities. The waste disposal sub-contractor will provide the knowledge, experience and transportation resources to dispose of licensed material to an authorized facility. Responsibilities of key individuals are described in the DP. The NRC noted that the decommissioning contractor and the waste disposal sub-contractor had experience in handling radioactive material for the purposes of decommissioning and disposal.

9.2 Decommissioning Task Management

Section IX of the Aptuit DP discusses work control practices and the use of Radiation Work Permits. Radiation Work Permits provide administrative control of activities within and around areas that may have radiological hazards. Radiation Work Permits will address radiation safety precautions, including external dosimetry, contamination control, protective clothing, access controls, air sampling and respiratory protection requirements. Aptuit's Radiation Safety Officer or designee will review and approve Radiation Work Permits prior to implementation. The Radiation Safety Officer will ensure that ambient radiation, surface radioactivity, and airborne radioactivity surveys are performed as required to define and document the radiological conditions for each job. Aptuit will use Radiation Work Permits to describe tasks to be performed, outline tasks with elevated dose potentials and significant radiological hazards, define protective clothing and equipment to be used, and identify personnel monitoring requirements. Information in Radiation Work Permits will specify any special instructions or precautions pertinent to radiation hazards in the area.

9.3 Decommissioning Management Positions and Qualifications

Responsibilities of key individuals are summarized in Section IX.A of the DP. Key positions provided by Aptuit include the Decommissioning Project Manager, Radiation Oversight Committee and the Radiation Safety Officer. Aptuit will use contractors to perform decommissioning activities on site. The contractor will provide qualified trained field technicians to conduct the decommissioning activities under the Aptuit DP. In the DP, Aptuit indicates that the contractor's technical staff will be experienced professionals possessing the expertise and technical competence to perform decommissioning activities. Additional staff, along with applicable subcontractors, may be utilized as appropriate.

9.3.1 Aptuit Decommissioning Project Manager

Aptuit's Decommissioning Project Manager is responsible for coordinating all high level aspects of the decommissioning activities as well as the completion of the decommissioning project. The Aptuit Decommissioning Project Manager may be asked to provide input on any aspect of the decommissioning process including internal audit program and Radiation Work Permits.

9.3.2 Aptuit Radiation Oversight Committee (ROC)

Members of the ROC consist of Aptuit Laboratory staff and management and serve, with the Radiation Safety Officer, to oversee the decommissioning project. The ROC has the authority to review radioactive material activities, procedures, current issues, etc.

9.3.3 Aptuit Radiation Safety Officer

Aptuit's Radiation Safety Officer was listed on the NRC license and is responsible for the overall management of the radiation protection program, including the responsibility to ensure that all decommissioning activities are conducted in strict conformance to the License and DP and implementation of ALARA principles.

9.3.4 Quality Assurance Manager

The Project Quality Assurance manager was assigned duties and responsibilities at the project level for enforcing quality plans and procedures, or specific duties and responsibilities for implementing elements of the corporate quality management program. The Project Quality Assurance manager shall have a Bachelor of Science in environmental sciences or business related field plus 10 years experience as a quality professional and 5 years of experience as a manager for quality related tasks at a program level.

9.4 Training

The training requirements for all decommissioning project staff, including specifically named positions, were described in Section IX of the DP. All decommissioning and decontamination (D&D) project staff shall have training and qualifications commensurate with their assigned duties. Minimal training for workers performing D&D activities include, but are not limited to, review of Radiation Worker Training, project and site-specific radiation awareness training to include daily "jobside" or "tailgate" training.

9.5 Contractor Support

The contractor will be responsible for performing D&D radiological activities including, but not limited to, decontamination of material, removal of contaminated material from the facility and disposal of radioactive material to an authorized facility. The contractor positions were listed in Figure 9-1 of the DP. In summary, the positions consist of a D&D subcontractor, Project CHP, Site Supervisor, RCT/Survey Technicians, demolition subcontractor and waste disposal subcontractor.

Aptuit's oversight of the D&D contractors was listed in Figure 9-1 of the DP. In summary, the Aptuit oversight consists of the Decommissioning Project Manager, QA manager, EH&S manager, Radiation Safety Officer and Radiation Oversight Committee. Aptuit maintains control of the radiation safety program and will ensure all NRC regulations and license conditions, including the DP, will be strictly implemented as stated.

10.0 Radiation Safety and Health Program

10.1 Radiation Safety Controls and Monitoring for Workers

10.1.1 Workplace Air Sampling Program

The NRC staff reviewed the workplace air sampling program in the licensee's DP and determined that the licensee has developed procedures, which include training of radiation workers and equipment, to significantly reduce indoor air borne radiological concentrations to below NRC regulatory limits and keep exposures to workers as low as reasonably achievable. Therefore, the NRC believes the licensee's air sampling program will comply with 10 CFR 20.1204, 10 CFR 20.1501, and 10 CFR 20.1502.

10.1.2 Respiratory Protection Program

Based on the review of planned decommissioning activities and contamination control stated in the licensee's DP, the NRC staff concluded that no respiratory protection will be required because the licensee plans to control airborne radioactive materials through the use of process and engineering controls such as use of a high efficiency particulate air vacuum to remove dust, and use of foam or fixatives to prevent removable contamination from becoming airborne.

10.1.3 Internal Exposure Determination

The NRC staff reviewed the internal exposure program in the licensee's DP and determined that the licensee has developed procedures, which includes training of radiation workers and equipment~~,~~ that will reduce radiological air borne to below NRC regulatory limits for the purposes of dose to a radiation worker or member of the public. Therefore, the NRC staff believes that the licensee's internal exposure determination will comply with 10 CFR 20.1101(b), 10 CFR 20.1201, 10 CFR 20.1204 and 10 CFR 20.1502.

10.1.4 External Exposure Determination

Based upon the radiological concentrations of C-14 and H-3, as described by the licensee, within the licensee's facility, the NRC does not believe that an external exposure will result in a radiological dose that will require monitoring in accordance with 10 CFR 20.1101, 10 CFR 20.1501 and 10 CFR 20.1502.

10.1.5 Summation of Internal and External Exposures

~~As t~~The licensee has determined, and the NRC concurs, that an external exposure does not require monitoring ~~in accordance with~~under 10 CFR 20.1202, as the NRC believes that the summation of internal and external exposure will not be required.

10.2 Contamination Control Program

The NRC staff reviewed the contamination control program in the Aptuit DP and determined that the licensee's procedures for the control of radiological contamination

was adequate to significantly reduce the probability of air borne radiological hazards and minimize the probably of a significant internal exposure either absorption or ingestion pathways. Specifically, the licensee's training program and radiological survey program are sufficient to keep contamination and radiological exposures as low as reasonably achievable. Therefore, the NRC believes the licensee's contamination control program will comply with 10 CFR 20.1501, 10 CFR 20.1701, and 10 CFR 20.1702.

10.3 Instrumentation Program

The NRC staff reviewed the instrumentation program in the Aptuit DP and determined that the licensee will possess a sufficient type and quantity of radiological detection equipment and training to the users of that equipment to ensure the public health and safety. Specifically, the licensee's radiological detection equipment will have the capability of detecting radiological conditions that would harm workers in addition to assuring the capability to detect radiation at sufficiently low levels so the facility can be released in accordance with 10 CFR Part 20.1401 and 10 CFR 20.1402. Therefore, the NRC staff believes the licensee's instrumentation program will comply with 10 CFR 20.1501

10.4 Health Physics Audits and Recordkeeping Program

The NRC staff reviewed the description provided in the DP for the licensee's audit and recordkeeping program which they will utilize during the decommissioning of the Aptuit facility according to the Consolidated Decommissioning Guidance, NUREG-1757, Volume 1, Section 17.3.3 (Health Physics Audits, Inspections, and Recordkeeping Program). Based on this review, the NRC staff determined that the licensee provided sufficient information to allow the NRC staff to evaluate the licensee's executive management and RSO audit and recordkeeping program to determine if the decommissioning can be conducted safely and in accordance with NRC requirements.

11.0 Environmental Monitoring and Control Program

Based on the review of planned decommissioning activities and contamination control stated in in the Decommissioning Plan, the NRC staff concluded the radiological contamination releases to the environment are insignificant or not likely.

12.0 Radioactive Waste Management Program

The NRC staff reviewed Aptuit's descriptions of the radioactive waste management program according to the Consolidated Decommissioning Guidance, NUREG-1757, Volume 1, Section 17.5 (Radioactive Waste Management Program). Based on this review, the NRC staff determined that Aptuit's programs for the management of radioactive waste generated during decommissioning operations ensure that the waste will be managed in accordance with NRC requirements and in a manner that protects public health and safety.

12.1 Solid Radioactive Waste

In the DP, Aptuit estimated that approximately 68,000 pounds of Class A radioactive waste may be generated during decommissioning. The estimated total activity of H-3 and C-14 is 1 Curie and 2 Curies, respectively. Solid waste will be staged in

appropriately sealed containers prior to disposal by a waste disposal contractor. The licensee does not anticipate radiological volumetric material or soil to be generated.

12.2 Liquid Radioactive Waste

In the DP, Aptuit estimated that approximately 100 gallons of radioactive liquid waste would be generated through decommissioning activities. Most of the liquid waste would be in form of LSC cocktail and aqueous waste from sink traps and decontamination efforts. Liquid waste will be staged in appropriately sealed containers prior to disposal by a waste disposal contractor.

12.3 Mixed Radioactive Waste

Under the DP, Aptuit estimated less than 500 pounds of mixed waste would be generated through decommissioning activities. As other regulatory agencies have jurisdiction over mixed waste generated during decommissioning, Aptuit had filed a "Notification of Regulated Waste Activity" with the Missouri Department of Natural Resource to comply with Section 260.380 of the Missouri Hazardous Waste Management Law and Section 3010 of the Resource Conservation and Recovery Act. The EPA ID Number is MOR000542761. Mixed waste will be staged in appropriately sealed containers prior to disposal by a waste disposal contractor.

13.0 Quality Assurance Program

The overall Quality Assurance objective is to develop and implement procedures for obtaining and evaluating data to support decommissioning efforts under the DP. Radiological survey data will be generated for demonstrating that the remedial effort has achieved the DCGLs. Quality Assurance procedures are established to ensure, in part, that field measurements, sampling methods and analytical data provide information that is representative of actual field conditions and that the data generated are technically defensible.

Using the guidance in NUREG-1757, Vol. 1, Rev. 2, Section 17.6, the staff reviewed the Quality Assurance program associated with the DP for Aptuit and determined that the program, if effectively implemented as described, provides reasonable assurance that accurate, high-quality information will be developed to support the decommissioning of the facility. Areas reviewed are discussed in the following subsection and include: organization, a general program description, document control, control of measurement and testing equipment, corrective actions, Quality Assurance records, and audits and surveillances.

13.1 Organization

The Quality Assurance organization is shown in Figure 9-1 of the DP and consists of a QA Manager, Project QA Manager and Site QA/QC Manager. The QA Manager reports to the Decommissioning Project Manager. Persons responsible for ensuring that the Quality Assurance Program has sufficient authority, access to work areas, and organizational freedom to accomplish:

- Identify quality concerns;
- Ensure that further decommissioning activities are controlled until proper resolution of a non-conformance or deficiency has occurred;
- Initiate, recommend, or provide solutions to quality problems through designated channels;

- Verify implementation of solutions; and
- Daily safety meeting will provide additional training to ensure personnel are given clear direction and proper tools for performing respective tasks.

13.2 General Program Description

Activities associated with the DP will be performed in accordance with written procedures in order to ensure consistent and repeatable results. Topics covered in project procedures may include proper use of instrumentation, quality control requirements, equipment limitations, etc. Implementation of quality assurance measures for the DP is described in the sections below.

13.3 Document Control

The project QA documents will consist of:

- The DP (which includes the Quality Assurance Plan)
- Project Health and Safety Plan
- Radiation Protection Plan
- Site specific procedures

A formal system of controlling document distribution shall be used and shall be posted in a non-editable format (e.g., Adobe Acrobat pdf).

13.4 Control of Measurement and Testing Equipment

Personnel shall ensure that measuring and test equipment (M&TE) are of the accuracy and type suitable for the intended use and shall be controlled by Working Instruction (WI) - 002, work plans and supplemented by manufacturer's equipment operation manuals. If the M&TE is lost, damaged, or found to be out of calibration, an analysis will be performed to determine the validity of the information.

M&TE usage and operational checks shall be performed to verify continued accuracy and operational function. Documentation for each instrument, including calibration logs, shall be maintained for each instrument.

13.5 Corrective Actions

The project manager and the project QA manager shall focus on continuous improvement of the products and services provided during the decommissioning activities, including the implementation of procedures. Items and processes that do not meet established criteria shall be identified, controlled, and corrected. Personnel at all levels shall be responsible for identifying problems and process improvement opportunities.

Aptuit shall develop and document corrective actions for all non-conformances and assessment findings which will be maintained in the project files as a project quality record. All corrective actions shall be tracked from inception to completion on a Corrective Action Log.

13.6 Quality Assurance Records

The project manager is responsible for ensuring that project QA records are managed in a manner that precludes loss or damage and shall include, but is not limited to: results of reviews, inspections, tests, audits, material analyses, monitoring of work performed, records on qualifications of project personnel, procedures, and equipment.

All records generated shall receive a thorough review by the site QC manager or designee prior to submittal for inclusion into the project Records Management system. The QA manager shall conduct periodic assessments to ensure that records are being managed in a manner prescribed in the Aptuit Records Management procedures.

13.7 Audits and Surveillances

Independent audits, surveillance, and inspection will be scheduled for all project activities. Assessments will be based on established frequencies and other requirements, documents, trend data of activity, complexity of activity, history of compliance, and importance to safety and associated consequences to the public, environment and workers. Audits will be assigned to personnel based on their independence and technical expertise in the intended audit or surveillance area.

Management shall investigate audit findings, determine the root cause of the condition identified in the finding, and schedule corrective action for the finding, including measures to prevent recurrence, evaluation of the impact of the finding on completed work, and notify QA in a written report of action taken or planned. The QA manager will perform trend analysis on nonconforming conditions, deficiencies and audit findings to identify any possible negative trends.

14.0 Facility Radiation Surveys

14.1 Release Criteria

The NRC staff reviewed the release criteria described in the for the Aptuit facility and determined that the licensee adequately described the DCGLs to be used in the surveys for demonstrating compliance with the radiological criteria for license termination.

14.2 Characterization Surveys

The NRC staff reviewed the description of the characterization surveys proposed in the Aptuit DP and determined that the surveys proposed would be adequate to perform the radiological characterization of the site. The proposed surveys would permit planning for a remediation that will be effective and will not endanger the remediation workers, would demonstrate that it is unlikely that significant quantities of residual radioactivity will not go undetected, and would provide information that will be used to design the final status survey.

14.3 Remedial Action Support Surveys

Radiological support surveys will be performed during decommissioning activities to assist and guide remediation activities.

14.4 Final Status Survey Design

The NRC staff reviewed the final status survey design described in the Aptuit DP and determined that the final status survey design is adequate to demonstrate compliance with radiological criteria for license termination.

14.5 Final Status Survey Report

The licensee's Final Status Survey Report will provide a summary of the survey results and the overall conclusions that demonstrate that the site meets the radiological criteria for release for unrestricted use. The staff will review the Final Status Survey Report prior to making a final determination that the site meets the radiological criteria for release for unrestricted use.

15.0 Financial Assurance

Section XV of the DP provided a cost estimate of the decommissioning project, with a 25 percent contingency, of $2,011,375. The NRC staff reviewed the cost estimate for the Aptuit facility according to the Consolidated NMSS Decommissioning Guidance, Volume 3, Section 4.1 (Cost Estimate). The licensee had also submitted a Decommissioning Funding Plan with a financial instrument for $2,011,375. Based on the cost estimate as compared to the amount set aside for project completion, the staff determined that the requirements of 10 CFR 30.36(g)(4)(v) have been met.