

Successfully Increasing DOE-STD-1027 Hazard Category 3 (HC-3) Threshold Quantities (TQs)

Mr. Stacey J. Strickland, CSP, CET (Sonalysts, Inc.)
Mr. Richard A. Norman (Los Alamos National Laboratory)

Abstract

The objective of the work being reported was a Supplemental Hazard Categorization request to NNSA, with justification, to increase hazard category (HC) -3 threshold quantities (TQs) for phosphorus 32 (P-32) and phosphorous 33 (P-33) radionuclides at two facilities. The current HC-3 TQs for P-32 and P-33 limit the production capacity for the Sr-82 isotope. The increase in TQs was needed in order for LANL to meet Department of Energy (DOE) production requirements for strontium 82 (Sr-82) used in the medical industry for heart treatment. Sr-82 is the parent isotope of Rb-82, a positron emitter used in Positron Emission Tomography (PET) studies of cardiac perfusion. The Department of Energy's Office of Nuclear Energy Science and Technology (DOE-NE) provides Sr-82 to GE Healthcare. LANL produces this isotope for DOE-NE.

Introduction

Mission-Related Issue Requiring Safety Analysis Support

This request for adjusting the HC-3 TQs for P-32 and P-33 was necessitated by the mission requirement to support Sr-82 production. Sr-82 is the parent isotope of Rb-82, a positron emitter used in Positron Emission Tomography (PET) studies of cardiac perfusion. More than 5,000 patients each month receive this potentially life saving diagnostic procedure. The Sr-82/Rb-82 CardioGen-82 biomedical generator is manufactured by GE Healthcare, Inc. under a contract with Bracco Diagnostics, Inc. that markets this product in the United States. The Department of Energy's Office of Nuclear Energy Science and Technology (DOE-NE) provides Sr-82 to GE Healthcare. LANL produces this isotope for DOE-NE. Current Sr-82 production involves the irradiation of RbCl targets, which leads to production of P-32 and P-33 as byproducts. The current HC-3 TQs for P-32 and P-33 limit the production capacity for the Sr-82 isotope. It also increases the number of irradiated targets and number of times irradiated targets are transported from the Isotope Production Facility (IPF) to RC-1.

The growth of PET as a nuclear medicine diagnostic tool is nearly exponential. There are currently more than 800 PET centers in the U.S., and over 1,200 worldwide. Therefore the CardioGen-82 generator is experiencing rapid growth as well. The quantity of Sr-82 required by GE Healthcare to support generator manufacture has grown from 1.5 Ci per month approximately 18 months ago to 4.5 Ci per month currently, and is projected to grow to 8-10 Ci

per month in the next 12 months. Also, GE Healthcare has increased the number of deliveries from 1 to 2 per month, and GE projects weekly deliveries within the next 12 months. DOE-NE has requested that LANL increase Sr-82 production to meet this need. Weekly deliveries of this isotope will make the production logistics at the 100MeV Isotope Production Facility (IPF) at Los Alamos Neutron Science Center (LANSCE) and the Radio Chemistry Facility (RC-1) hot cell facility very challenging. However, with the proper operational approach to target irradiation and processing, these challenges will be met safely and in compliance with DOE regulations.

Sr-82 production activities took place in the IPF and RC-1. RC-1 was unable to support the projected Sr-82 programmatic production levels of up to 10 Ci/month with the P-32 and P-33 HC-3 TQs from DOE-STD-1027, Table A.1. Due to RC-1's ongoing radioactive material inventory, RC-1 could only receive around 1.6 Ci of Sr-82 from IPF and still remain below 0.9 sum of fractions (SOF) (administrative limit). Based on this limitation, RC-1 processing staff involved with Sr-82 production would have to perform at least 7 full target processing cycles each month to obtain the required projected production level of 10 Ci/month of Sr-82. The RC-1 current processing staff and facility capabilities are limited to 2 processing cycles per month, which limits the production capability to less than 3.2 Ci/month of Sr-82. With the adjusted HC-3 TQs for P-32 and P-33, RC-1 could receive up to 5.4 Ci of Sr-82 from IPF in a single shipment/process cycle and still remain below 0.9 SOFs. With the current staff operational limit of 2 cycles per month, the production level at RC-1 would be 10.8 Ci/month Sr-82.

Issue History

LANL had previously submitted two requests for increasing P-32 and P-33 HC-3 TQs for the RC-1 facility. Both requests were disapproved by NNSA due to inadequate supporting hazard analysis. Both of these requests cited the applicable methodology from NTSP 2002-2¹, recognized by NNSA as the appropriate methodology, but did not provide adequate supporting unmitigated hazard analysis per NTSP 2002-2. The two request submissions and NNSA response are listed in Table 1.:

Table 1. Background Correspondence.

LANL Request Correspondence	NNSA Response Correspondence
PS-DO:05-148, subj: Hazard Category 3 Thresholds for Phosphorous -32 and -33, dated 10/24/05	SABT/DL:05-015/STEELE:112305/JM:111705, subj: Disapproval of Proposed Airborne Release Fractions (ARF)/Respirable Fractions (RF) for 32P and 33P Pending Receipt of Additional Information from Los Alamos National Laboratory (LANL), dated 12/20/05
LANL C-INC:06-016, subj: Proposed Airborne Release Fractions (ARF)/Respirable Fraction (RF) for 32P and 33P for the Production of Medical Isotopes at the Isotope Production Facility at TA-53 and the Radiochemistry Hot Cells at TA-48, dated 3/6/06	SABT/5485.3/04182006, subj: Disapproval of Proposed Airborne Release Fractions (ARF)/Respirable Fractions (RF) for 32P and 33P for the Production of Medical Isotope Production Facility and the Radiochemistry Hot Cells at TA-48, dated 4/20/06

Sr-82 Production Process Overview

Figure 2 provides the production process steps performed for Sr-82 production in RC-1 and IPF.

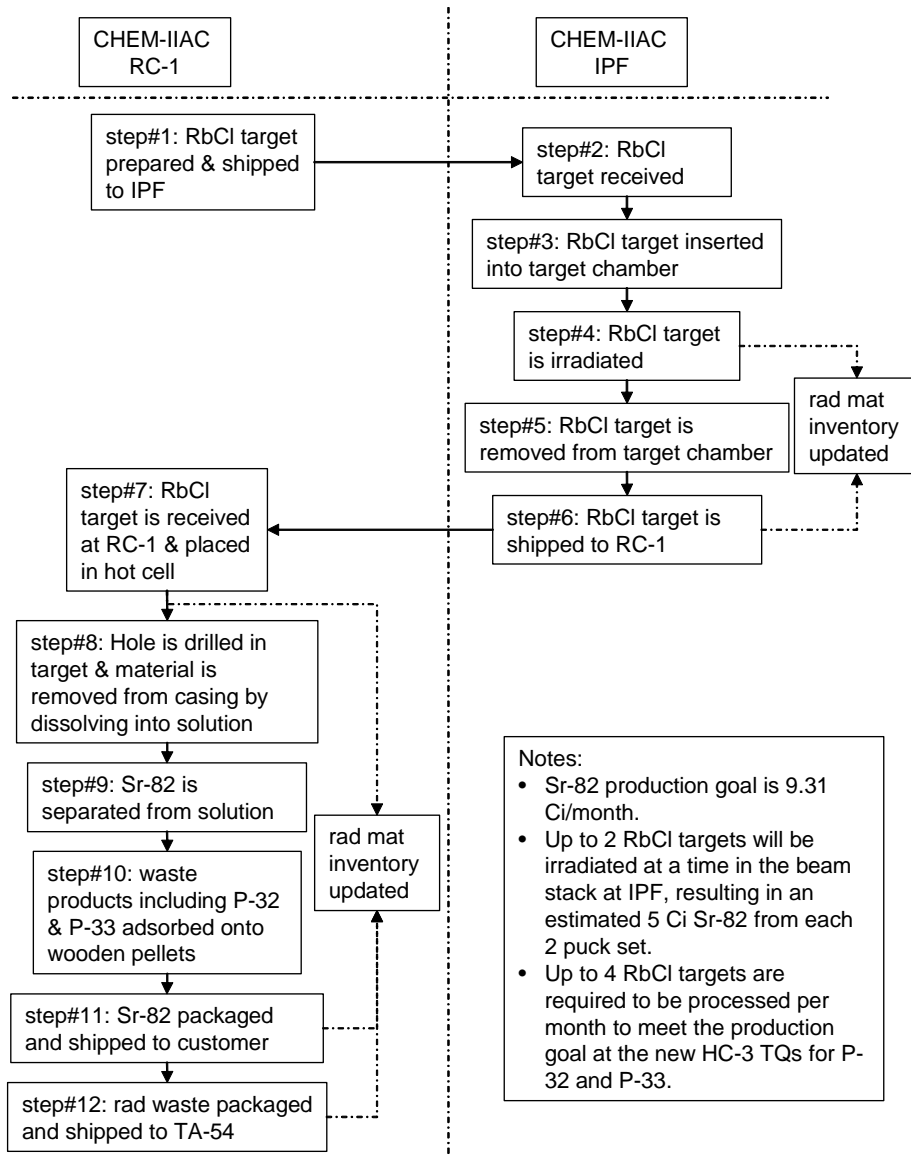


Figure 1. Sr-82 Production Process Flowchart.

Safety Analysis Solution

The focus of this safety analysis project was to prepare a request submission that demonstrably executes the NTSP 2002-2 methodology for increasing HC-3 TQs, including preparation of the required supporting unmitigated hazard analysis, and address the inadequacies of the previous submissions requesting approval to increase HC-3 TQs for P-32 and P-33 for the IPF and RC-1. The safety analysis solution deliverable was in the form of a supplemental final hazard analysis following LANL facility hazard analysis and categorization process requirements and guidance from the LANL Safety Analysis Handbook² and Laboratory Implementing Requirement (LIR) Facility Hazard Categorization³.

Overview of NTSP 2002-2 Methodology for Increasing HC-3 TQs

NTSP 2002-2 was developed in order to provide the DOE/NNSA complex with a process for increasing DOE-STD-1027 HC-3 TQs. Although DOE-STD-1027 provides a process for increasing HC-2 TQs, prior to the issuance of NTSP 2002-2, there was no published or DOE/NNSA recognized process for increasing HC-3 TQs. Figure 2 shows the decision flowchart from NTSP 2002-2 for increasing HC-3 TQs. Note that EPA Technical Background Document (EPA TBD) refers to “Technical Background Document to Support Final Rulemaking Pursuant to Section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act: Radionuclides: A Report to the Emergency Response Division, Office of Emergency and Remedial Response, U. S. Environmental Protection Agency,” February 1989⁴.

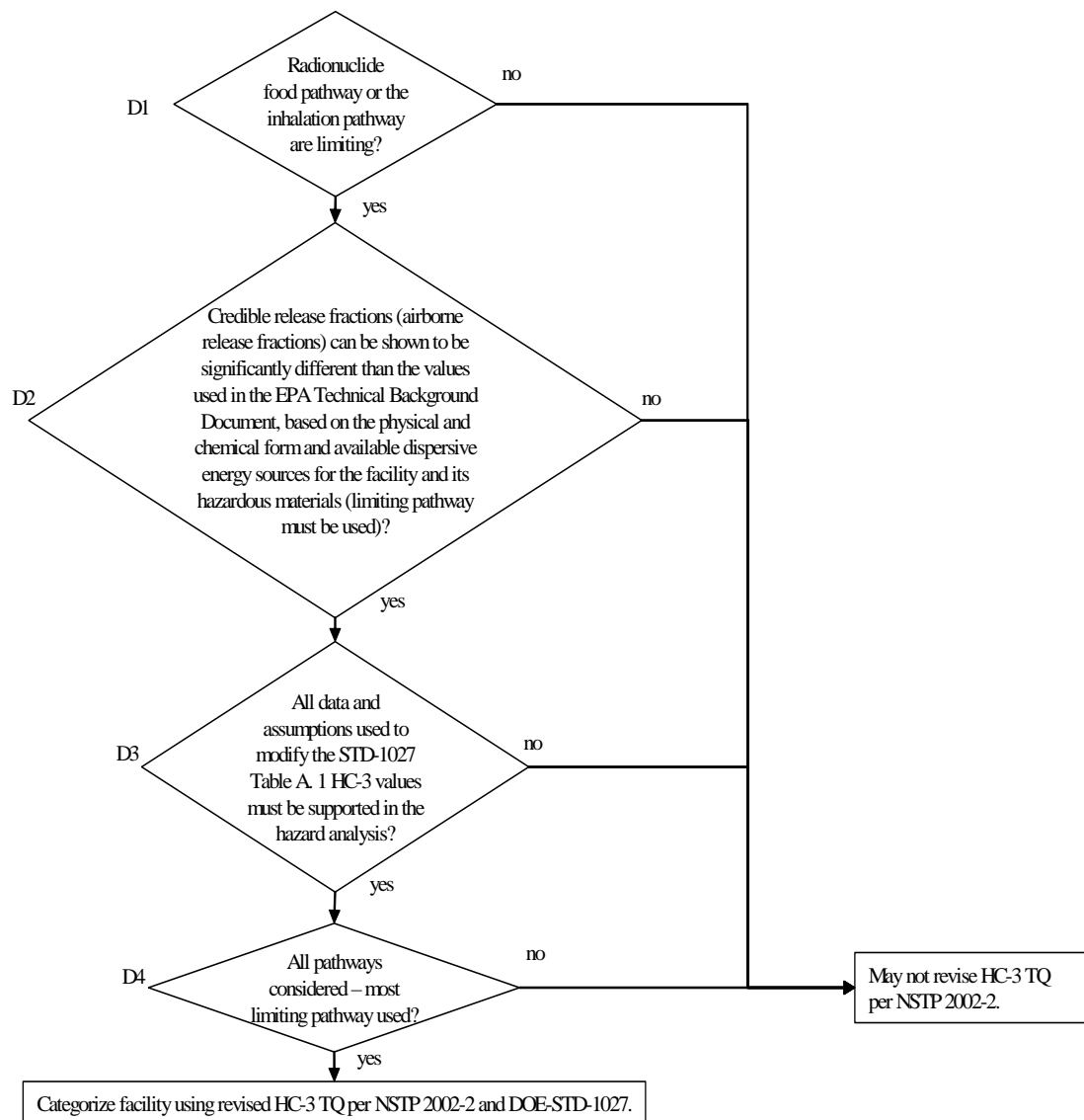


Figure 2. HC-3 TQ Revision Decision Flowchart.

Application of NTSP 2002-2 Methodology for Increasing HC-3 TQs

This project focused on clearly and comprehensively demonstrating that the NTSP 2002-2 methodology. The safety analysis demonstrated that a “yes” answer to each decision condition from NTSP 2002-2 was adequately supported by unmitigated hazard analysis.

Developing Assumptions

In order to apply NTSP-2002-2, data and assumptions used to modify HC-3 TQs must be established and supported by unmitigated hazard analysis. Table 2 presents the assumptions used modifying HC-3 TQs.

Table 2. Assumptions for Modifying DOE-STD-1027 HC-3 TQs.

Assumption	Method of Protecting Assumption
<p>P-32 and P-33 inventory for which the adjusted HC-3 TQ applies, will be in one of the following physical or chemical forms:</p> <ul style="list-style-type: none"> • P-32 and P-33 are bound in a solid RbCl crystalline matrix (puck) inside a stainless steel containment (RC-1 and IPF) • P-32 and P-33 will be in the form of phosphates in a chloride solution in dilute concentrations. • P-32 and P-33 will be in the form of phosphate anions (PO_4^{3-}) during Sr-82 separation. • P-32 and P-33 will be converted to hydrogen-phosphate adsorbed on hardwood pellets. 	<p>The radioactive material inventory control procedure (PRO-C-DO-007 for RC-1 and IPF Operations Manual, Chapter 6, Section 2 for IPF), ensures that the adjusted HC-3 TQs for P-32 and P-33 will only be applied to the P-32/-33 radionuclide inventory associated with the Sr-82 production process described in the HC document.</p> <p>The Sr-82 production process will be controlled to the process described in this HC document, per MCO change control process and the IWM process.</p>
<p>There are no explosive or flammable material sources present in significant quantities that would significantly influence the adjusted HC-3 TQs for P-32 and P-33.</p>	<p>The hazard identification process is performed per OST300-00-06, Section 1, LANL Hazard Analysis Technical Methodology Handbook to ensure that no explosive or flammable material sources are present in the vicinity of the Hot Cell Facility.</p> <p>Facility operating limit that prohibits explosive material in the Hot Cell Facility (new).</p> <p>Introduction of hazards and hazardous material into RC-1 are controlled per MCO change control process and the IWM process.</p>
<p>An oxygen-rich environment does not exist in the vicinity of the materials or solutions containing P-32/-33 radionuclides.</p>	<p>Compressed oxygen gases and welding rigs are not present as a hazard or initiator in the hot cell facility while P-32 or P-33 radionuclides are present.</p>

Hazard Analysis

This project developed hazard analyses to determine if the assumptions are valid in unmitigated conditions. Figure 3 illustrates the unmitigated hazard analysis development and evaluation.

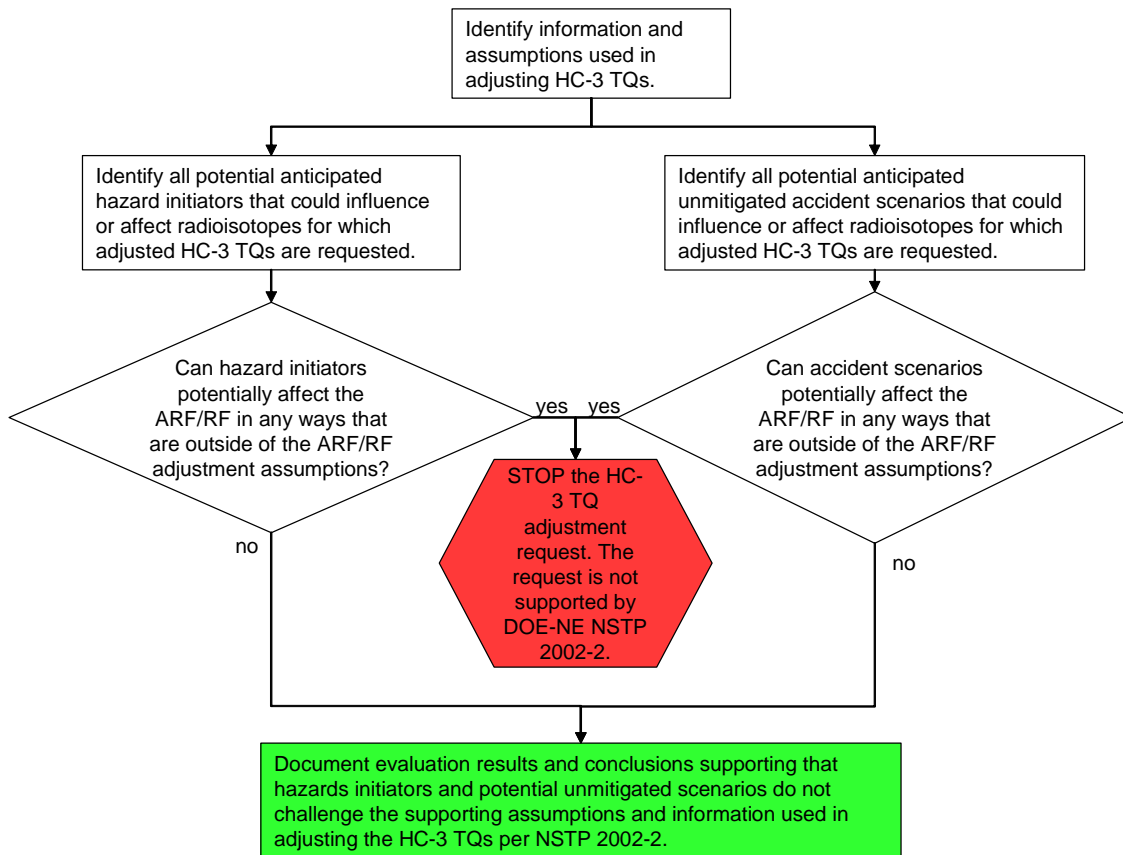


Figure 3. Development of Assumptions and Supporting Unmitigated Hazard Analysis.

Supporting unmitigated hazard analyses were performed for each facility (IPF and RC-1) per the guidelines from the LANL Safety Analysis Handbook. The HA development approach involved:

- performing or validating hazard identification
- developing bounding hazard scenarios relative to the categorization assumptions
- selecting appropriate ARF/RF values from DOE-HDBK-3010⁵
- adjusting the HC-3 TQs using the bounding selected ARF/RF for the bounding scenarios.

For the IPF, the hazard identification information from the approved and up-to-date safety basis was used. For RC-1, hazard information from a developed, but unimplemented, HC-3 DSA (BIO) was updated by facility hazard identification walkdowns and used. Also, specific hazard identification from the Fire Hazard Analysis was used.

Two bounding unmitigated hazard scenarios were developed and evaluated for each facility, which were a fire and mechanical impact. ARF/RF values were selected from DOE-HDBK-3010 based on unmitigated scenario assumptions, which are summarized in Table 3.

Table 3. Bounding ARF/RF from Unmitigated Hazard Analysis.

	IPF	RC-1
Fire Scenario	2.5E-05	1.0E-02 (DOE-HDBK-3010, vol. I, section 5.2.1.2)
Impact Scenario	6E-04	6E-04 (DOE-HDBK-3010, vol. I, section 4.4.3.1.2 – spilled powder)

An alternative defensible ARF/RF for impact selection from 4.3.3 of DOE-HDBK-3010, not used in the request would be:

$$\text{ARF} \times \text{RF} = (A)(P)(g)(h)$$

Where:

- A = empirical correlation, 2E-11 cm³ per g-cm²/s²
- P = specimen density, g/cm³
- g = gravitational acceleration, 980cm/s²
- h = fall height, cm

Using the following representative assumptions:

- 1000 grams (weight of object impacting target)
- 200 cm drop
- 100 cm³ target volume

The resulting ARF/RF product would be:

$$(2\text{E-}11 \text{ cm}^3 / \text{g-cm}^2/\text{s}^2)(1000 \text{ g}/100 \text{ cm}^3)(980 \text{ cm}/\text{s}^2)(200 \text{ cm}) = 3.9\text{E-}05$$

The ARF/RF for spilled powder is more conservative than the ARF/RF product using the estimation formula from DOE-HDBK-3010, section 4.3.3.

The overall bounding ARF/RF product for both types of bounding scenarios in either facility is the value of 1E-02 for (DOE-HDBK-3010, vol. I, section 5.2.1.2)

Per NSTP 2002-2, in adjusting the ARF/RF values, “...All pathways must be considered...” The following tables demonstrate the effect of changing the ARF/RF values on all pathways. This evaluation generally applies to both IPF and RC-1.

The EPA Release Values (Curies) for the four pathways (with the minimum value in bold) are:

Table 4. EPA Release Values.

Radionuclide	Food ingestion	Water ingestion	Inhalation	Direct Radiation
EPA Release Values				
P-32	6.0E-1	7.2E+1	4.1E+0	--
P-33	4.7E+0	5.8E+2	3.1E+1	--
EPA RVs Adjusted HC-3 Threshold Quantities (Curies) (20 times the EPA RVs)				
P-32	1.20E+1	1.44E+2	8.20E+1	N/A
P-33	9.40E+1	1.16E+4	6.20E+2	N/A
Resulting RVs from Adjusting the HC-3 TQ				
P-32	6.00E+2	1.44E+2	4.10E+3	N/A
P-33	4.70E+3	1.16E+4	3.10E+4	N/A

No gamma rays are emitted or the gamma rays which are emitted have gamma ray energies of less than 0.07 MeV and are strongly attenuated in air. No release value for the direct exposure pathway was calculated.

The HC-3 Threshold Quantities (Curies) are 20 times the EPA RVs. The values for the four pathways (with the minimum value in bold) are shown in Table 4.

The food ingestion and inhalation Release Values depend on the airborne release fractions (ARFs). Changing the ARF from 0.5 to 0.01 increases the food ingestion and inhalation TQs by a factor of 50. The water ingestion TQs are not dependent on ARF and are not changed.

With the reduced ARF/RF and increased TQ, the most limiting pathway for P-32 exposure becomes water ingestion. The most limiting pathway for P-33 remains food ingestion. The HC-3 TQ for P-33 becomes 4,700 Curies, increasing TQ by a factor of 50.

Based on the resulting data in Table 4, water ingestion is considered for further evaluation.

The scenario is developed for evaluating the significance and relevance of ground water ingestion resulting from a release accident from RC-1 or IPF. The worst case scenario involves a release of the entire radioactive material inventory from the facility that migrates into the ground water. A fire could cause this release in the facility that consumes the inventory. The wet-pipe sprinkler system actuates. The resulting suppression water runoff from the facility entrains and releases the inventory, carrying the inventory to the ground water. The following site condition and radionuclide information exists:

- The depth of the aquifer is approximately 1000 ft. (reference: “Environmental Surveillance at Los Alamos during 2002”, January 2004).
- The half-life of P-32 is 14 days.
- The half-life of P-33 is 25 days.

LANL publication LA-UR-01-2547, Hydrologic Behavior of Unsaturated, Fractured Tuff: Interpretation and Modeling of a Wellbore Injection Test and Implications of Contaminant Transport⁶, includes interpretation of modeling and empirical data directly relevant to this scenario description and evaluation. LA-UR-01-2547 provides data results and interpretation of hydrology migration testing performed at TA-50, which were originally presented in the Purtyum Report (1989). Both measured and modeled vertical migration rates were closely correlated. From LA-UR-01-2547, measured vertical migration rates through Bandelier Tuff, which is the predominant soil type at the LANL site, including TA-53 and TA-48, ranged from 1.2 meters/day to on day 7 to 0.006 meters/day on day 327. Additionally, this study indicates that the measured vertical distance traveled by the contaminant (5% contaminant content front) in 327 days was 155 feet (depth of 5% contaminant front of 220 ft minus the test injection depth of 65 ft). Given the migration rate at the 327 day point of 0.029 meters/day (more conservative modeled rate), it would take another 8198 days [(780ft) x (0.3048 meters/ft) x (1day/0.029 meters)]. Given the relatively short half-lives of P-32 and P-33 (14 and 25 days respectively), P-32 and P-33 activity would not reach the aquifer.

Based on the time required for released P-32 or P-33 to reach the aquifer and the relatively short half-lives of P-32 and P-33 (14 and 25 days respectively), no discernable P-32 and P-33 activity will be introduced into the aquifer.

Hazard Analysis Conclusion

The limiting or bounding ARF/RF for RC-1 determined from this analysis is a value of 1E-02, which is associated with the following condition: “burning of surface-contaminated, combustible material” (burning of the wooden pellets contaminated with P-32 and P-33). The limiting or bounding ARF/RF for IPF determined from this analysis is a value of 6E-04, which is associated with the following the assumption that the P-32 and P-33 radioisotopes are not in the “highly volatile/combustible” form, but are in the “solid/powder/liquid” form. The limiting pathway for exposure for consideration, resulting from increasing the HC-3 TQs for P-32 and P-33 by 50 times, becomes groundwater ingestion. This pathway was evaluated and determined to not be of any consequence due to a very long transport time (years) compared with the relatively short half lives of P-32 and P-33 (14 and 25 days respectively).

Project Management

Project Milestones and Events

Table 5 lists the key milestones and events related to this project.

Table 5. Milestones and Events.

Date	Milestone/Event
4/24/06	SR-OPS (facility management organization) tasked with preparing the final submittal within a short timeline so that increased production could take place for the medical radioisotopes.
5/14/06	60% draft of final HC document released.
6/1/06	LANL management transition occurred.
6/15/07	90% cross-table review meeting held with involved LANL parties.
7/3/06	Final HC request submitted to NNSA for modifying HC-3 TQs.
8/15/06	NNSA approval of HC request received.
9/15/06	Implementation of related safety basis revisions implemented in IPF and RC-1.

Management Team and Approach

The project team included Operations Management, Safety Basis, and program points-of-contact. This project team was responsible for interfacing with NNSA and two facilities doing inter-related but separate program operations. Initial work began by reviewing the previous documentation, interviewing personnel, and coming to an understanding of the issues. An approach was developed and initial concurrence obtained from the stakeholders (PS-Div, Program Divisions, Facility Managers, Program Managers, and NNSA). Then the project was laid out for 60% and 90% review meetings and a final submittal. Weekly meetings were set up so that issues could be discussed and resolved.

Key Factors for Success of the Project

The following factors contributed directly to the success of this project:

Demonstrated Full Compliance with Approved Methodology: Earlier requests rejected by NNSA for adjusting HC-3 TQ did not fully comply with NTSP 2002-2 in that adequate unmitigated hazard analyses supporting the assumptions were not performed or submitted to NNSA. Existing hazard analyses for the IPF and RC-1 focused on worker safety and not necessarily on protecting the assumptions used for adjusting the HC-3 TQs per NSTP 2002-2. Additionally, request to NNSA focused on explicitly and overtly demonstrating how the request follows the NTSP 2002-2 requirements and methodology to assist and facilitate the NNSA reviewer to come to the conclusion that approval is justified.

Buy-in and Participation from Involved Parties: Programmatic and facility operations individuals and organizations from the Sr-82 Production Manager, to associated division and group leaders to hot cell and chemical process engineers and technicians, were actively engaged in pulling together information supporting the request to modify HC-3 TQs. Like most cases, the safety analysts are dependent on management and subject matter expertise in order to generate a safety analysis solution.

Clearly Established and Defined Scope: Several strategies regarding the scope and approach for developing this project were discussed with the project team. These varied from just answering the last rejection letter, to a complete Hazards Analysis and justification. The project team was constantly vigilant excluding agendas and issues that had nothing to do with the request, potentially giving NNSA a reason to disapprove this third request.

References:

¹ DOE Office of Nuclear and Facility Safety Policy Nuclear Safety Technical Position NSTP 2002-2, Methodology for Final Hazard Categorization for Nuclear Facilities from Category 3 to Radiological.

² LANL OST 300-00-06, Safety Basis Handbook, Section 1: LANL Hazard Analysis Technical Methodology Handbook.

³ LIR300-00-05.5, Facility Hazard Categorization.

⁴ EPA Technical Background Document to Support Final Rulemaking Pursuant to Section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act: Radionuclides: A Report to the Emergency Response Division, Office of Emergency and Remedial Response, U. S. Environmental Protection Agency," February 1989.

⁵ DOE-HDBK-3010-94, with change notice 1, Airborne Release Fractions/Rates and Respirable Fractions for Nonreactor Nuclear Facilities Handbook.

⁶ LA-UR-01-2547, Hydrologic Behavior of Unsaturated, Fractured Tuff: Interpretation and Modeling of a Wellbore Injection Test and Implications of Contaminant Transport.