

TRIUMF Quality Manual		
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TRIUMF

Quality Manual



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TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

History of Changes

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TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

Approval and Authorization of Most Recent Revision


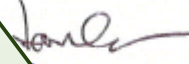
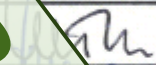



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TABLE OF CONTENTS

TABLE OF CONTENTS.....	4
PURPOSE AND SCOPE	6
Purpose	6
Scope	6
FOREWORD	7
CHAPTER 1: QUALITY POLICY AND OBJECTIVES.....	8
1.1 TRIUMF Mission.....	8
1.1.1 Performance Objectives.....	8
1.2 Quality Assurance Policy and Objectives.....	9
1.2.1 Management Expectations	9
1.2.2 Management Commitment.....	9
CHAPTER 2: ORGANIZATION, RESPONSIBILITIES & AUTHORITIES	10
2.1.1 TRIUMF Accelerators Inc.	10
2.1.2 The University of British Columbia (UBC) Lease	11
2.1.3 Board of Management	11
2.1.4 Director of TRIUMF	11
2.1.5 TRIUMF Divisions.....	11
2.1.6 Groups with Operational Responsibilities	13
2.1.7 Internal Communications	14
2.1.8 External Communication.....	15
2.1.9 Other Advisory Committees.....	17
CHAPTER 3: ELEMENTS OF THE PROGRAM.....	19
3.1 Overview.....	19
3.2 TRIUMF Standard Operating Procedures.....	20
3.2.1 Documents and Records Management	20
3.2.2 Nonconformity Reporting and Resolution	20
3.2.3 TRIUMF Training Program	21
3.2.4 Procurement	21
3.2.5 Engineering Design, Manufacture and Assembly.....	21
3.2.6 Approval of Experiments	21

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

3.2.7	Calibration and Inspection.....	22
3.2.8	Quality Program Assessment	22
3.2.9	Site Access	22
3.2.10	Operations Management	22
3.2.11	Configuration Management	22
3.2.12	Commissioning.....	22

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

Purpose and Scope

Purpose

This Manual defines the Quality Management System for TRIUMF, Canada's National Laboratory for Particle and Nuclear Physics.

Scope

The policies outlined in this manual apply to all activities governed by the TRIUMF Operating Licence.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

FOREWORD

The Quality Assurance (QA) program at TRIUMF ensures we complete projects on time and on budget as well as deliver on promises of service. As TRIUMF moves forward to fulfill its mission, QA will play an ever increasing role in the life of our laboratory. The laboratory is now in the midst of improving, better defining, upgrading documentation, and implementing our QA program. I view the implementation of a site wide QA policy and plan of the upmost importance. This process is steered by the [Quality Management System Implementation Panel](#). The panel is Chaired by the Head of the Engineering Division with strong guidance from the QA Manager. The committee members are all senior staff members with the broadest and deepest knowledge of TRIUMF activities. All the divisions at TRIUMF are represented. This panel is charged with ensuring the documentation is up-to-date and the staff are properly trained and following the TRIUMF Standard Operating Procedures (TSOPs) as outlined in this manual. The resources required for both the implementation and sustainability of the QA program are reviewed at the Quarterly Safety Management Meeting. As Director, I view QA as a vital component of daily activities at TRIUMF and critically important to our success.

November 2008

Nigel Lockyer

Director

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

Chapter 1: Quality Policy and Objectives

1.1 TRIUMF Mission

TRIUMF is Canada's national laboratory for particle and nuclear physics. It is owned and operated as a joint venture by a consortium of Canadian universities via a contribution through the National Research Council Canada with building capital funds provided by the Government of British Columbia.

Its mission is:

- To make discoveries that address the most compelling questions in particle physics, nuclear physics, nuclear medicine, and materials science;
- To act as Canada's steward for the advancement of particle accelerators and detection technologies; and
- To transfer knowledge, train highly skilled personnel, and commercialize research for the economic, social, environmental, and health benefit of all Canadians.

1.1.1 Performance Objectives

TRIUMF is a national research institution providing unique facilities and infrastructure for a large Canadian and international user community. The laboratory is based upon the exploitation of particle accelerators and subatomic techniques. The laboratory's output is increased knowledge as documented in refereed publications. TRIUMF strives to generate new knowledge in an accident-free environment, with as low as reasonably achievable (ALARA) radiation exposure to its personnel, users and the public and within the resources provided by the Federal government's annual budget contribution and other peer-reviewed funding from granting agencies. TRIUMF will spend more than 80% of its total expenditures in Canada. TRIUMF will meet the objectives outlined in Schedule "A" of the [NRC Contribution Agreement](#).

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

1.2 Quality Assurance Policy and Objectives

1.2.1 Management Expectations

TRIUMF management expects that all TRIUMF employees strive to achieve the highest quality in the work performed and to carry out this work in a safe and responsible manner and according to the policies and practices set out in this manual and the supporting Standard Operating Procedures.

The TRIUMF Quality Assurance Program describes the management processes in place to meet the following Quality Objectives.

- TRIUMF will comply with the Canadian Nuclear Safety and Control Act
- TRIUMF will comply with its Operating License conditions
- TRIUMF will meet the annual performance metrics set in the previous annual program assessment

1.2.2 Management Commitment

TRIUMF is committed to maintaining a working environment that safeguards the health and safety of all workers on the TRIUMF site. It is the responsibility of management to demonstrate by example TRIUMF's commitment to safety, and to support, develop, and require the leadership of supervisory staff in occupational health and safety matters. Management shall ensure that the workplace is effectively monitored so that all hazards are recognized and understood. They shall plan, organize and maintain all operations and equipment so as to minimize hazards, ensure that workers are trained in safe practices and encourage the participation of all workers in the identification and solution of safety problems in the workplace. TRIUMF management will strive to create an environment that promotes quality and continuous improvement in quality throughout the entire organization. Management will cultivate and sustain an environment that fosters and encourages creativity, intellectual stimulation, innovation and collaboration. Management will assure that all employees understand their respective roles and responsibilities in carrying out the quality policy.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

Chapter 2: Organization, Responsibilities & Authorities

TRIUMF is owned and operated by a consortium of Canadian universities and funded via a contribution from the government of Canada through the National Research Council Canada (NRC). Building funds are provided by the government of British Columbia.

TRIUMF is not incorporated; it operates as a joint venture and the [Joint Venture Agreement](#) is the governing document between the university owners of TRIUMF. The Agreement sets out the governance and operational requirements and responsibilities as identified and defined by the full member universities.

TRIUMF is funded by the Government of Canada in a series of five-year plans. The [NRC Contribution Agreement](#) describes the five-year funding arrangement between the Government of Canada and the universities that own TRIUMF including a “Statement of Work” that itemizes TRIUMF’s obligations to accomplish specific tasks and meet certain milestones during the funding period. The Federal Government has tasked NRC with ensuring TRIUMF is fully accountable for the federal funding provided to it in the Contribution Agreement. The agreement is signed by the President of NRC and the Presidents of the universities that own TRIUMF.

The overall organization of TRIUMF is described in the [Organization Chart](#) and the internal functions of TRIUMF are outlined in the [Function Chart](#).

2.1.1 TRIUMF Accelerators Inc.

The Nuclear Safety and Control Act requires that operating licenses for nuclear facilities be held by an incorporated entity. TRIUMF Accelerators Inc. (TAI) is a not-for-profit corporation, incorporated September 1, 2006 and established pursuant to Part II of the Canada Corporations Act. TAI was incorporated for the sole purpose of holding [TRIUMF’s Canadian Nuclear Safety Commission \(CNSC\) Class 1B particle Accelerator Operating licence](#). TAI has no assets or liabilities and incurs no expenses; all costs of the TRIUMF facility are the responsibility of the TRIUMF joint venture.

The sole purpose of TAI is to hold the CNSC operating license for TRIUMF and a [Management Agreement](#) has been put in place between TRIUMF the Joint Venture and TAI that recognized TAI’s responsibility to

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

operate TRIUMF in a manner consistent with the CNSC regulations governing nuclear facilities such as TRIUMF.

This management agreement ensures that TAI has a suitable level of control and authority over the assets and operations of TRIUMF to be in compliance with the CNSC operating license while still complying with the obligations outlined in the Joint Venture Agreement by the full member universities, and NRC Contribution Agreement.

The Directors of TAI are the voting members of the TRIUMF Board of Management, appointed by the full member universities.

2.1.2 The University of British Columbia (UBC) Lease

TRIUMF has occupied the land on the south campus of UBC since 1968 without a lease. The incorporation of TAI, required by the Nuclear Safety and Control Act, necessitated a formal land use arrangement be put in place between TRIUMF and UBC. [A lease](#) was established between UBC, TRIUMF and TAI to ensure that TAI could operate the TRIUMF facility under the terms of the CNSC operating license, and under the authority of the TRIUMF joint venture members in compliance with UBC's campus rules and regulations.

2.1.3 Board of Management

The TRIUMF [Board of Management](#) is the formal Board responsible for the operation, supervision, and control of TRIUMF. It consists of two voting members from each full-member university plus two voting members from the private sector appointed by the board and one non-voting member from each associate-member university. The Board meets three to four times per year.

2.1.4 Director of TRIUMF

The Director has the overall responsibility for the operation and development of TRIUMF and its program of science at the national and international level. He/she must represent and promote TRIUMF at the highest international levels via international collaborative committees and forums and interact with member universities to maximize the scientific value of TRIUMF to the universities.

2.1.5 TRIUMF Divisions

2.1.5.1 Accelerator Division

The Accelerator Division has operational, maintenance and required upgrade responsibility for all of the 500 MeV Cyclotron, ISAC, and TR13

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

facilities. The Division also has responsibility for the design, construction, and commissioning of future accelerators on-site and it provides support for external accelerator projects.

2.1.5.2 Engineering Division

The Engineering Division has general responsibilities for the engineering, design and fabrication of mechanical, structural and electronic components. The Division also has responsibility for Electrical and Mechanical Services, and Site Maintenance.

2.1.5.3 Science Division

The Science Division is responsible for scheduling experiments approved by the Experiment Evaluation Committee (EEC). The Science Division is also responsible for the design, installation, operation and maintenance of components, systems, and subsystems for all experimental operations at the TRIUMF site. The Science Division is also responsible for coordination of infrastructure support for external programs.

2.1.5.4 Nuclear Medicine Division

The Nuclear Medicine Division is responsible for the support of projects approved by the Life Science Projects Evaluation Committee (LSPEC) and provides support for collaborations with the Pacific Parkinson's Research Centre (PPRC), BC Cancer Agency (BCCA), MDS Nordion and other university faculties relying on radio-tracers from TRIUMF for their research. This Division is also responsible for the design, installation, operation and maintenance of components, systems, and subsystems for the radioisotope production and processing facilities for tracers to be used in research projects both at TRIUMF and at other laboratories.

2.1.5.5 Director's Office

The Director's Office has responsibility for accounting, material control, human resources, general administration, security, quality assurance as well as environment, health and safety, and communications and outreach.

The Director's Office also oversees several important committees: the Experiment Evaluation Committees; the Policy and Planning Advisory Committee; and the Safety Management Committee.

The heads of each of TRIUMF's divisions report to the Director's Office.

In addition, the Director's Office has operational, maintenance and required upgrade responsibility for the radioisotope production cyclotron facilities (ATG) operated on behalf of MDS Nordion.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

The Director's Office also acts as TRIUMF's liaison with MDS Nordion and AAPS as they are located on the TRIUMF site.

2.1.6 Groups with Operational Responsibilities

2.1.6.1 500 MeV Operations

The 500 MeV Facility Operations Group (OPS) is responsible for safely delivering proton beams from the 520 MeV cyclotron to various experimental facilities at TRIUMF. OPS also has, because of its continuous presence, immediate responsibility for all operations carried out on the TRIUMF site. This responsibility is generally based on the advice and direction they receive, hence the OPS members rely to a large extent on the advice of staff who have direct responsibility for a particular operation or facility. The OPS Group is, therefore, explicitly authorized to communicate directly with any group, employee or visitor concerning any perceived safety matter.

The 500 MeV Operations Shift Supervisor is in charge during any emergency. He has the authority at any time to take immediate action or suspend any activity until the responsible supervisor can be consulted.

2.1.6.2 Applied Technology Group

The Applied Technology Group (ATG) is responsible for the two TR30 and the CP42 cyclotron facilities and subsystems. The ATG is responsible for safely delivering proton beams to the various cyclotron target stations and, by liaising with MDS Nordion, for ensuring the safe transfer of radioisotope production targets to the appropriate processing facility.

2.1.6.3 ISAC Operations Group

The ISAC Operations Group is responsible for the safe operation of the ISAC facility from the production target through to the interface to the experimental stations.

2.1.6.4 TR13 Operations, Positron Emission Tomography (PET) Group

The TR13 Operations (PET) Group is responsible for safely operating the TR13 cyclotron primarily for the production of PET isotopes. They are also responsible for the safe delivery of these agents to processing facility. From time to time they also carry out special irradiations in support of the science program at TRIUMF.

2.1.6.5 Office of Environment, Health & Safety

The Office of Environment, Health and Safety (EH&S) has responsibility for monitoring the safety and general environmental conditions from all

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

operations on the TRIUMF site. It is also responsible for auditing the monitoring and control procedures that other groups at TRIUMF use to maintain good radiological and general occupational hygiene conditions. The monitoring and auditing ensures that TRIUMF operates safely and within all regulatory requirements. EH&S must effectively communicate the result of its programs to the work force and management of TRIUMF. EH&S also makes training and certain resources and supplies available to the TRIUMF workforce and ensures that the risks and appropriate mitigation techniques are communicated to all staff and visitors. The manager of EH&S reports to the Director of TRIUMF and serves as a link to the director on all safety matters.

2.1.6.6 Quality Assurance

The QA Manager administers the QA program and chairs the QA Assessment Team. The QA Manager reports to the TRIUMF director. He reports on the status of the program to the Safety Management Committee at their regular meetings.

2.1.7 Internal Communications

2.1.7.1 Safety Management Committee

The [Safety Management Committee](#) meets in each quarter-year to review reports from all groups and committees with explicit personnel safety responsibilities to make recommended and/or indicated adjustments in the policies, responsibilities and resource assignments to maintain safe conditions for everyone on the TRIUMF site and contiguous public areas. MDS Nordion has observer status on this committee.

2.1.7.2 Safety and QA Oversight Panel

The Safety and QA Oversight Panel meets regularly and reviews safety and QA issues to ensure compliance with the TRIUMF Operating Licence. The composition and scheduling of meetings is defined in the [terms of reference](#).

2.1.7.3 Technology Transfer Panel

The Technology Transfer Panel is responsible for reviewing technology transfer opportunities for TRIUMF. It is chaired by the Director and includes engineering and administrative support. Engineering support on this panel coordinates the activities related to TRIUMF's responsibilities for the operation of the Proton Therapy Facility and Proton and Neutron irradiation facilities.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

2.1.7.4 Safety Committees

TRIUMF has divisional safety committees that review the safety issues that lie within the area of responsibility of that division. The committees are chaired by the respective Division Head. A Technology Transfer Safety Committee is chaired by the head of the Applied Technology Group. The composition and schedule of meetings are at the discretion of the chair of the committee.

2.1.7.5 TRIUMF Accident Prevention Committee (TAPC)

The TRIUMF Accident Prevention Committee is the Joint Health & Safety Committee required as per the WorkSafe BC Occupational Health & Safety Regulations (Part 3). The composition and scheduling of meetings is defined in the [terms of reference](#).

2.1.7.6 Quality Management System Implementation Panel

The Quality Management System Implementation Panel consists of selected managers and group leaders. It assists the QA Manager in the implementation, internal auditing and continuing improvement of the TRIUMF Quality Management System.

2.1.8 External Communication

2.1.8.1 Agency Committee on TRIUMF

The role of the Agency Committee on TRIUMF (ACT) is to oversee the Government of Canada's investment in TRIUMF and the economic benefits derived from that investment, with a particular focus on financial and commercialization matters. The Committee provides advice to the Minister of Industry, in conjunction with the reports of the NRC Advisory Committee on TRIUMF on scientific matters. The Agency Committee on TRIUMF usually meets twice a year. The Committee is chaired by the President of the NRC and includes representatives from Industry Canada and NSERC.

2.1.8.2 Advisory Committee on TRIUMF

The Advisory Committee on TRIUMF (ACOT) was formed to advise the National Research Council on specific matters relating to TRIUMF's program, and to provide scientific program advice to TRIUMF's Director. The Committee meets at TRIUMF twice yearly, and thereafter reports to the National Research Council on its findings and recommendations, with particular reference to the arrangement entered into by the National Research Council and TRIUMF under which contribution payments are made. It is the responsibility of the Committee to ensure that TRIUMF

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

utilises its program in support of its defined role as a national facility, and that TRIUMF works with all constituencies of the Canadian sub-atomic physics community to sustain a national program in the field of research, within the context of the funds available.

2.1.8.3 Interaction with Regulators

The interactions with each of the external agencies that exercise regulatory authority over TRIUMF are carried out via a designated single point of contact. In each instance the Director of TRIUMF appoints the individual with the responsibility for communicating with a particular regulatory agency and all communications with that agency are channeled through that individual. The single point of contact will inform TRIUMF management of any changes in the regulatory environment that impact the activities at TRIUMF and of all results of inspections or audits performed by the regulatory agency.

2.1.8.4 Interaction with MDS Nordion

TRIUMF operates several accelerator facilities that supply MDS Nordion with irradiated radioisotope production targets. These facilities include the two TR30 cyclotrons, the CP42 cyclotron, the 500 MeV Irradiation Facility and the Solid Target Facility on beam line 2C4. TRIUMF's responsibility for all irradiated targets ends at a Nordion Active Area hand-off point. The TRIUMF Safety Note on [TRIUMF-MDS Nordion Safety Responsibilities](#), defines specific safety-related responsibilities of both TRIUMF and MDS Nordion. The main purpose of the document is to clarify responsibilities that may potentially overlap, allowing the two organizations to demonstrate compliance to the terms of their respective CNSC licences. MDS Nordion at TRIUMF conforms to all TRIUMF policies and limits regarding dose rates and exposures. MDS Nordion is also responsible for minimizing and controlling all liquid and gaseous releases so as to conform to TRIUMF's Derived Release Limits. The TRIUMF Office of Environment Health and Safety has authority to audit MDS Nordion's operations for conformance to these policies and limits.

2.1.8.5 Interaction with Advanced Applied Physics Solutions

Advanced Applied Physics Solutions Inc. (AAPS) is a not-for-profit company funded through the Centres of Excellence for Commercialization and Research (CECR) program of the Networks of Centres of Excellence.

The mandate of AAPS is to research, develop and commercialize innovative platform and disruptive technologies with strong potential for social and/or economic benefit. AAPS will provide a core facility with an advanced level of expertise in sub-atomic physics and related disciplines. The technologies may be brought in from anywhere, but will initially have TRIUMF as a local prime technology generator.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

AAPS is located on the TRIUMF site and falls under the umbrella of TRIUMF's CNSC operating licence and UBC lease.

2.1.8.6 Interaction with Public and Media

All interactions with the public and the media are managed through the office of the Director of TRIUMF. It disseminates information about the activities at TRIUMF to the public and local community. It also encourages the interactions with the local community by offering public tours and encouraging visits by students from various educational institutions.

2.1.9 Other Advisory Committees

2.1.9.1 Policy and Planning Advisory Committee

The TRIUMF Policy and Planning Advisory Committee (PPAC) advises the Director on scientific policy and facilitates two-way communication with the research communities at the member universities.

The Policy and Planning Advisory Committee includes one member from each of the full member universities. The members are selected by the Director from a list provided by the relevant research community in each member university.

2.1.9.2 Experiment Evaluation Committees

Three Experiments Evaluation Committees (EECs) are in place at TRIUMF: the 'Subatomic Physics EEC' and the 'Molecular & Materials Science EEC' meet biannually at TRIUMF, and the 'Life Sciences Projects EEC' meets once a year. The purpose of these committees is to review new research proposals which are presented at the biannual and annual meetings and advise TRIUMF's management on the feasibility of such research proposals and the allocation of beam time in appropriate priority sequence. They also review the progress of ongoing experiments. The committee members are selected based on their expertise in areas such as nuclear and particle physics, nuclear astrophysics, nuclear medicine, radioisotope production, chemistry and application of muon spin rotation to condensed matter physics, chemistry and life sciences. The committees are comprised of eight or nine members from both national and international scientific communities and each member serves for a period of three years.

2.1.9.3 TRIUMF Users Group

The TRIUMF Users' Group is an organization of scientists and engineers with special interest in the use of the TRIUMF facility. Its purpose is to provide a formal means for exchange of information relating to the

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

development and use of the facility, to advise members of the entire TRIUMF organization of projects and facilities available and provide an entity responsive to the representations of its members for offering advice and counsel to the TRIUMF management on operating policy and facilities.

The business and affairs of the TRIUMF Users' Group are managed by an executive committee (TUEC) consisting of seven elected members: a chairman, a chairman elect, a past chairman, and four representatives.

2.1.9.4 International Peer Review Committee

An evaluation of the TRIUMF program is carried out every five years. This is done in accordance with the National Research Council's approved evaluation plan and the policies of the Government of Canada's Treasury Board Secretariat (TBS). The evaluation takes the form of a peer review and will focus primarily on issues related to relevance, success, level of scientific excellence and future opportunities for TRIUMF. Committee members are chosen and nominated by NRC.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

Chapter 3: Elements of the Program

3.1 Overview

Documents required by the quality management system consist of controlled documents and records. Controlled documents fall into a hierarchical scheme that is illustrated in Figure 2.

The TRIUMF Quality Manual represents level 1 of the document hierarchy.

Level 2 consists of the TRIUMF Standard Operating Procedures (TSOPs). These are policies which define the flow of various work processes, associated responsibilities and the control points that will ensure the process will meet its objectives for quality, safety or environmental impact. TSOPs are generalized policies that are applied facility-wide. Implementation details are relegated to the next level.

Level 3 consists of Technical Operating Procedures and Group Manuals. These are procedures and policies which describe the implementation of the generic TSOP processes at the level of a specific technical or operational activity.

Level 4 consists of those documents that provide the basis for generating evidence that work processes and practices are in compliance with the program as defined in the higher levels. The documents at this level consist of detailed working documents such as specific work instructions, checklists and forms.

This hierarchy of documents and the responsibilities for approval are shown in Figure 1.

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

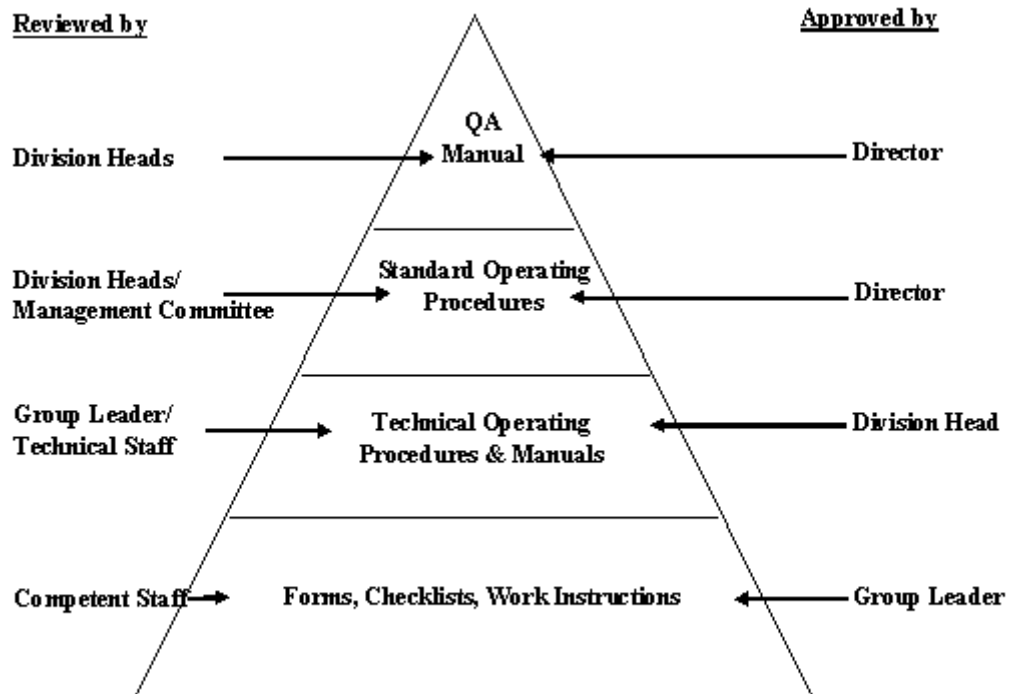


Figure 1: Documentation hierarchy

3.2 TRIUMF Standard Operating Procedures

3.2.1 Documents and Records Management

Document and record types required by the QA program are listed in the [Document Type Index](#). These documents and records are managed using the procedures outlined in [TSOP-01](#). The controlled documents workflow and more details supporting TSOP-01 are outlined in the [Document Manual](#).

3.2.2 Nonconformity Reporting and Resolution

Nonconformities are classified as either Type A or Type B.

Type A nonconformities consist of:

- a finding of an internal or external quality assurance or safety audit
- non-compliance with a safety requirement

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

- non-compliance with the TRIUMF QA program that compromises safety or facility operation
- recurrent malfunction of equipment and machinery outside normal expectations
- The procedures for reporting and resolving Type A nonconformities are defined in [TSOP-02](#).

Type B nonconformities consist of:

- nonconformities in manufacturing or assembly, which are in the scope of TSOP-06
- nonconformities involving equipment faults, which are in the scope of TSOP-12
- nonconformities in commissioning, which are in the scope of TSOP-13
- nonconformities in procurement, which in the scope of TSOP-05

3.2.3 TRIUMF Training Program

The TRIUMF Training Program is described in [TSOP-04](#). The procedures in TSOP-04 ensure that all new training programs follow the Systematic Approach to Training, that all personnel have their individual training requirements identified and that the appropriate training records are kept.

3.2.4 Procurement

Procurement of goods and services follow the procedures outlined in [TSOP-05](#) and the TRIUMF Purchasing Policy Manual and the TRIUMF Purchasing Procedures Manual.

3.2.5 Engineering Design, Manufacture and Assembly

Engineering Design, Manufacturing and Assembly work follows the procedures outlined in [TSOP-06](#). See the following link for [a complete list of design, manufacture and assembly authorities.](#)

3.2.6 Approval of Experiments

The Review and Approval Process for all experiments using the TRIUMF beam delivery facilities follows the procedures outlined in [TSOP-07](#).

TRIUMF Quality Manual		
Document-611	Release No. 2	Release Date.: 2008-12-05

3.2.7 Calibration and Inspection

The calibration and inspections performed at TRIUMF are listed in the Calibration and Inspection Index. Calibrations and inspections follow the processes described in [TSOP-08](#). The calibration schedule should be determined using manufacturer's recommendations and/or recognized industry standards.

3.2.8 Quality Program Assessment

The processes by which TRIUMF sets QA objectives and assesses the effectiveness of the QA program in meeting these objectives are outlined in [TSOP-09](#).

3.2.9 Site Access

Access to the TRIUMF site is controlled through the procedures outlined in [TSOP-10](#).

3.2.10 Operations Management

Processes for the management of beam delivery, the planning and management of maintenance periods are described in [TSOP-11](#).

3.2.11 Configuration Management

Configuration management processes for scheduled maintenance work, changes to commissioned systems, fault reporting and fault resolution are described in [TSOP-12](#).

3.2.12 Commissioning

Commissioning of new or modified systems follows the process described in [TSOP-13](#).