

HIGH ENERGY PHYSICS DIVISION QUALITY ASSURANCE PLAN

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QUALITY ASSURANCE PLAN HIGH ENERGY PHYSICS DIVISION

1. INTRODUCTION

The High Energy Physics Division carries out a program of research aimed at advancing the understanding of the structure of matter and energy at the most fundamental level. This includes particle physics experiments, theoretical research, and accelerator research and development.

The quality of basic scientific research work is continually monitored through the peer review process. This is a continuous process since most of the experimental projects in the HEP Division are collaborative efforts with several outside groups. It also is formalized through such actions as the publishing of research results in refereed journals and the periodic review of research and development projects by outside committees of peers appointed by DOE or the University of Chicago as well as by the host accelerator laboratories such as DESY and Fermilab.

This plan addresses the quality management practices considered suitable by the Division Director for that portion of the Division's work to which it is appropriate to apply formalized quality assurance, as well as overall policy guidance for HEPD QA practices. As described below, for each activity that the Division Director decides is of appropriate size and type, an individual QA plan is prepared by the project leader or his/her designate with assistance of the Division's Quality Assurance Representative (QAR). These individual plans, in turn, establish guidance and structure for the specific QA practices followed by that group. The individual plans also point to specific documentation and individuals in whom is vested the records and results of the QA program.

2. **DEFINITIONS OF TERMS AND NOTATION**

2.1 *Definitions of Terms*

Terms used in this document are defined as indicated below.

Activity: Any task or operation that may affect quality; sometimes referred to as a quality-affecting activity.

Applied Research: Research and development activities having specific goals and goal-related funding, involving expansion or application of knowledge known to science.

Assessment and Verification: The act of reviewing, inspecting, testing, checking, conducting surveillance, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. As an integral part of a work process, verification is conducted by or for the organization performing the work but not by the person who performed the work. Assessment is generally performed by or for management to periodically evaluate performance with regard to requirements and the achievement of goals and objectives for quality.

Authority: The sanctioned freedom and power that allow an individual or organization to make decisions and determine a particular course of action without direction of a superior influence.

Basic Program Requirements: The 10 QA criteria that constitute the foundation of a comprehensive QA program. For each of these criteria, this plan prescribes basic requirements. The applicability of the requirements must be determined by each organizational unit.

Basic Research: Research activities having the goal of producing knowledge new to science.

Certification: The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, or items in accordance with specified requirements.

Compliance-Based: A requirement defined in terms that describe the specific manner in which an action or process is performed to achieve a specific outcome. Compare with performance-based.

Control: A practice that regulates an action or directs an activity in order to facilitate a consistent and predictable outcome.

Criterion: One of the ten areas of management concern on which this manual is based.

Critical Material: Material that, if damaged, could cause significant programmatic delay, could jeopardize the operation or safety of a facility or experiment, and/or could allow significant release of chemicals or radioactivity or create other undesirable conditions.

Customer or User: In general, a customer or user is an individual or organizational unit that directly uses or requires items or services to be provided by other individuals or organizations formally defined as providers. The use of "customer" and "provider" in the context of this Program Plan is not intended to unnecessarily formalize working

relationships at ANL but to focus attention on the importance of the mutual understanding of the requirements and expectations and how their achievement will be measured.

Document: Issued material recorded on paper or machine-readable or other physical media that (1) describes, specifies, reports, certifies, provides results, or otherwise furnishes information or (2) defines policies, practices, procedures, or requirements.

Experiment: A test or investigation performed in a laboratory, operating facility, or field site for the purpose of meeting programmatic objectives.

Formality and Rigor: The degree to which a mechanism for assuring quality is implemented relative to (1) strictly adhering to required rules, procedures, standards, or conventions or (2) being highly detailed, accurate, precise, or comprehensive. Some illustrative comparisons are provided: oral vs. written instructions; guiding instructions and customary practices vs. task-specific, step-by-step procedures; uncontrolled vs. controlled documents; absence or presence of hold-points in written procedures; visual inspection of purchased items vs. prescribed acceptance testing; worker-selected vs. organization-prescribed practices for records management; and sampling vs. examination of each piece of product quality verification.

Goals: See mission, goals, and objectives.

Hazardous Material: Material that is known to cause biological or physical damage to the user or the environment (e.g., radioactive materials, fissile materials, and certain chemicals).

Inspection: The verification function of examining, measuring, or testing to obtain data to determine whether an item or process conforms with specified requirements.

Item: In the context of the Laboratory's Quality Assurance Program, "item" is an all-inclusive term used in place of any of the following: documented concepts or data, sample, material, component, assembly, subassembly, module, equipment, part, system, subsystem, unit, structure, facility, or appurtenance.

Line Management: The chain of authority and responsibility in any branch of the Laboratory organizational structure, originating with the Laboratory Director and extending unambiguously to individual employees. The term should not be confused with the categorization of "line" and "support" organizations at the Laboratory, which conduct research programs or provide support functions, respectively.

Manager: The head of an organization or a person with technical management responsibility.

Mission, Goals and Objectives: In the context of this Quality Assurance Plan, the series mission → goals → objectives represent a continuum of diminishing scope and increasing specificity and time dependence. These three programmatic elements, along with externally and internally defined expectations and specifications, are achieved by meeting performance requirements.

Nonconformance: A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity indeterminate or unacceptable.

Objective: See mission, goals, and objectives.

Organizational Unit: A division, program, office, department, section, project, or other organized entity that functions as a unit and has common mission, goals, and similar risks and operational characteristics.

Peer: An individual with widely recognized expertise and judgment in a particular field. Generally, such a person has an education in an appropriate technical discipline, a level of academic education equivalent to those performing the work, an established record of technical achievement, and an awareness of current progress in the research field under evaluation.

Peer Review: A documented process whereby the quality and validity of technical work are evaluated by technical peers who did not directly participate in the work being evaluated. Peer reviews may be used during all phases of the scientific/engineering process.

Performance-based: Any type of requirement expressed in terms that define the desired outcome without defining a specific mechanism, practice, or procedure whereby the desired outcome is achieved. Compare with compliance-based.

Performance indicator: A suitable and attainable milestone that, when accomplished, demonstrates a particular degree of effectiveness in the completion of a objective. Performance indicators can also include fewer objective measures of attainment of performance requirements.

Performance requirements: Expectations and requirements derived from an organization's mission as well as internally and externally defined goals, objectives, and specifications for the characteristics of items, processes, and activities, including ES&H requirements.

Price-Anderson Amendment Act: Enacted by Congress in 1998 to require DOE to take enforcement actions against contractors who violate nuclear safety requirements and make indemnification mandatory. It also gave DOE authority to issue notices of violation when noncompliance with nuclear safety requirements are identified.

Procedure: A prescribed set of instructions, usually written and implemented in a prescribed sequence.

Process: A series of actions that achieve an end or result.

Product: A tangible outcome of work, including research. Some examples of the broad spectrum of ANL products are programmatic and administrative plans, hardware for experimental apparatus, information conveyed through various media, ideas, and theories, and various operational services.

Quality: The degree to which an item, research activity, or process meets or exceeds the internal or external user's requirements and expectations.

Quality Affecting: Personnel, activities, or items that can affect the ability to meet a requirement.

Quality Assurance: Those actions that, when carried out, provide confidence that quality is achieved.

Quality Assurance Program: (a) The overall Laboratory program established to implement the requirements of DOE Order 5700.6C. (2) An organization-specific quality assurance program that implements the requirements of this Quality Assurance Plan.

Readiness review: A systematic and documented review to determine and inform management of the state of preparedness to advance from one activity or phase of an activity to another.

Records: Papers, books, notebooks, reports, drawings, specifications, machine-readable materials, or other documentary materials that, regardless of physical form, preserve evidence of policies, decisions, procedures, results, operations, organizations, functions, conformance, or activities.

Responsibility: An assumed obligation with granted authority that requires an individual or group to be accountable for the outcome of an event.

Risk: A qualitative or quantitative expression of possible loss that considers both the consequences of an undesired event and the probability that the event will occur. Risk applies to (1) the organizational mission, goals, objectives, and performance requirements and (2) environmental protection, health, and safety. The degree of risk helps determine the level of formality and rigor with which appropriate quality assurance actions are implemented.

Sensitive Item: Items such as computer equipment, software packages, and other expensive, confidential, or proprietary articles that can be stolen or destroyed.

Service: The performance of work for persons and/or organizations that do not have direct control over the conduct of the work but depend on the reliability and quality of the work product. Establishment of a service organization or process creates special requirements for reliability, communication of customer and user requirements, definition of capabilities, and assessment of quality.

Software: Computer programs, procedures, rules, and associated documentation and data pertaining to the operation of a computer system.

Test: The verification function or the determination of the capability of an item or process to meet specified requirements by subjecting it to physical, chemical, environmental, or operating conditions.

Validation: An activity that demonstrates that an item or process will perform under conditions of actual use and satisfy the requirements of the end user.

Verification: See assessment and verification.

Work, Work Process: Work processes in the Division are diverse in type and scope. They include, but are not limited to, research and development; data collection and analysis; software development and use; technical analysis; design, maintenance, and repair of equipment; safeguards; and administration.

2.2 *Notation*

The following notation is used throughout the text. In addition, "Laboratory" signifies Argonne National Laboratory, and "Division" signifies the High Energy Physics Division.

ALD	Associate Laboratory Director
ANL	Argonne National Laboratory
DD	Division Director
DOE	Department of Energy
EQO	Environment, Safety, Health/Quality Assurance Oversight
ES&H	Environment, Safety, and Health
FWP	Field Work Proposal
HEPD	High Energy Physics Division
IDR	Inspection/Disposition Report
M&TE	Measuring and Testing Equipment
MSDS	Material Safety Data Sheet
PAAA	Price-Anderson Amendment Act
PD	Position Description
PI	Principal Investigator
QA Plan	Quality Assurance Plan (High Energy Physics Division)
QA	Quality Assurance
QAPP	Quality Assurance Program Plan (Argonne)
QAR	Quality Assurance Representative
TMS	Training Management System

3. **POLICY**

The policy of the High Energy Physics Division is that all activities undertaken by Division personnel must be in compliance with all Laboratory policies and procedures, including the Argonne National Laboratory Quality Assurance Program Plan (QAPP) dated June 10, 2002 which implements the requirements of both DOE Order 5700.6C and 10 CFR 830.120. 10 CFR 830.120 deals specifically with QA requirements for nuclear material and is enforced by the Price-Anderson Amendment Act (PAAA). These activities must incorporate all reasonable measures to ensure that the Laboratory standards for quality are achieved. This policy applies to all Division activities, whether they are conducted on site at the Laboratory, at a contractor's facility, or at a remote field site. Quality assurance is a line responsibility, and such responsibility is automatically delegated when responsibility for performance of an activity is delegated. This policy requires that

- All research, development, and operational activities employ measures to achieve the required degree of quality while they simultaneously achieve effective safety and environmental protection for employees and the public;
- Testing services, calibrations, and computer-related activities (including computer software development) are performed in a manner that assures high technical quality; and
- Procurement and fabrication activities include a level of QA consistent with the requirements specified for each activity.

This policy recognizes that the basic QA requirements may not apply uniformly to each item, process, or activity and that they may vary depending on the associated risk. Therefore, a graded approach to QA is recognized, as defined in the Laboratory's QAPP.

This policy further recognizes that peer review is an additional QA instrument for the basic and applied research functions of the Division. Quality continues to be ensured by formal reviews by the University of Chicago, the Department of Energy, and other funding agencies and by external and internal peer review of manuscripts and proposals written by members of the Division.

4. **QUALITY ASSURANCE CRITERIA**

4.1 *Management Criteria*

4.1.1 **Criterion 1 - Program**

This QA Plan defines the quality management system that will facilitate the Division's efforts to address its mission successfully.

4.1.1.1 Organizational Structure

The Division's organizational chart (Appendix A) shows the structure that has been developed to provide the resources and support necessary to conduct the diverse research programs undertaken by the Division.

4.1.1.2 Responsibilities

The responsibility matrix for QA criteria (Appendix B) identifies the individuals responsible for preparation, review, and approval of quality-assuring criteria. The various administrative persons within the Division are responsible for assisting those with primary responsibility. Individuals responsible for and executing activities under this QA Plan may delegate tasks to others, but they retain the responsibility for assuring the effectiveness of QA. Persons not directly responsible for performing a specific task may be called upon to verify that quality goals are achieved. The functional responsibilities of the individuals with primary responsibility for QA are specified below.

Division Director

The Division Director (DD) is responsible for the quality of all work conducted by the Division. In particular, the DD is responsible for the establishment of the organizational structure, functional responsibilities, levels of authority, interfaces, and lines of communication for all activities in the Division; for the establishment of the Division's QA policy; and for the preparation and effective implementation of the Division's QA Plan.

Quality Assurance Representative

The Division QAR will (1) assist Division personnel in the development and implementation of task-specific QA Plan amendments, procedures, and training activities as needed; (2) review and assess quality-affecting activities; (3) assist in the identification of areas for quality improvement; (4) act as the Division's liaison with the EQO Division concerning QA matters; (5) represent the Division in QA matters as directed by the DD; (6) perform such other activities in the area of QA as directed by the ALD.

Principal Investigator

The principal investigator (PI) or, in large projects, the program manager, will establish detailed QA requirements and procedures for all activities affecting quality within the purview of the PI's activities. The PI will verify that such activities have been correctly performed and appropriately documented. For new and existing activities, the PI will develop the QA requirements and procedures by giving consideration to the following topics:

- The technical requirement for the work and the activities, and items that can affect the ability to achieve these requirements. These may include processes; process parameters; designs; procedures; non-radioactive materials; radioactive materials or sealed sources; systems; equipment items; computer codes; or sensitive, limited-life, or high-value items.
- The risk or consequences if these activities or items do not perform as expected. For example, the PI must evaluate the seriousness of the effects and of the risks and consequences of the attendant exposure of the Division or the Laboratory in case the identified activities or items fail, create unsafe conditions, or provide insupportable or unacceptable results. Specific consideration should be given to

- 4 Injury to project participants,
- 4 Injury to Laboratory personnel not involved in the project,
- 4 Injury to the public,
- 4 Negative effects on the reputation of the Division or the Laboratory,
- 4 Negative effects on the schedule of the project or other projects,
- 4 Negative effects on project status or costs,
- 4 Negative effects on the reputation of the researcher, and
- 4 Monitoring of the radioactive materials or sealed sources used.

The Division will take advantage of the resources and technical expertise within EQO for assistance and coordination where needed.

4.1.1.3 Collaborative Activities

When a Division activity involves an organization outside the Division, whether internal or external to the Laboratory, the responsibility and authority of the Division must be clearly defined and documented by the DD. This documentation must specifically include descriptions of internal and/or external interfaces and the responsibility and authority of the Division with respect to areas affecting QA, such as inspection, assessment, verification, review, and approval.

4.1.2 **Criterion 2 - Personnel Qualifications and Training**

All Division personnel must have the qualifications and training required to perform their assigned work with the proficiency needed to achieve the mission, goals, objectives, and performance requirements of the organizational unit.

4.1.2.1 Personnel Qualifications

Personnel qualifications for each activity in the Division are defined in the position description (PD) for that activity. The PD includes a summary of the basic purpose of the position; typical activities; the work environment; required knowledge, skills, and experience; measures of effectiveness; decision-making authority; work relationships; work direction to others; and the financial dimensions of the position. The PDs for all staff members in the Division are maintained by the DD. Opportunities to revise PDs are provided annually.

4.1.2.2 Personnel Training

The policy of the Division is to advance the training of its staff through formal education, seminars, training programs, and participation in professional society activities and other activities considered to be of mutual benefit to the Division and the staff. Such training will allow each employee to perform his or her job in an efficient and effective manner and in compliance with existing regulations. These training activities must be documented, with records maintained in the Training Management System (TMS).

Support for formal education will be in accordance with the Division's Educational Assistance Policy. General programmatic training (e.g., project management, administration, and word processing) will be provided to individuals as needed. Training that addresses special needs of a program will be provided, when appropriate, to ensure that the employee understands the processes and tasks being used, the extent and sources of variability in those processes, and the degree to which the employee has control over the variability. Such training may include demonstrations of correct work performance, the necessity for quality requirements, problem recognition, and the potential consequences of improper work.

Each Division employee must complete the Environment, Safety and Health (ES&H) training courses listed on the Employee Training Profile generated for him and her by the TMS on the basis of the employee's Job Hazard Checklist (reference Human Resources Policy and Procedures Manual, Policy/Procedure 5100). Line managers, from the DD through and including PIs, must understand that certain ES&H courses are "operationally required." That is, these courses are of such a nature, either by law or by direct safety implication, that the training is absolutely required. TMS will identify such courses, perhaps a list of those courses, distribute the list to all staff, and ensure that the training requirements are met. Formal ES&H courses, or alternative means of training, must be completed before employees are permitted to work at these functions. The Division Training Management Representative will maintain all ES&H training records for the Division. In addition, QA training will be provided where necessary (for example, for the QAR).

4.1.3 ***Criterion 3 - Quality Improvement***

Quality improvement is a line responsibility. Management at all levels will foster a "no-fault" environment, and the correction of quality problems will involve personnel at the lowest possible decision-making level. All personnel are encouraged to identify and report any unsafe working conditions and/or performance problems, along with suggestions for improvement to their supervisor or to Division management so that corrective action can be taken. Abnormal conditions or problems, commonly called nonconformances, are deficiencies in characteristics, documentation, or procedures that render the quality of an item or activity unacceptable or indeterminate, so that it will not

meet requirements. Such nonconformance will be documented by an Inspection/Disposition Report (IDR, form ANL-267).

Quality improvement goals for individual activities will be established by the PI and discussed with the DD or with supervisors during program and performance reviews. These reviews will facilitate the analysis of recurring problems, identification of corrective actions, and communication of lessons learned to other segments of the Division.

4.1.4 ***Criterion 4 - Documents and Records***

The Division will comply with the requirements of the Argonne Records Management Program and the Records Inventory and Disposition Schedule (Form DOE 1324.10), which indicates the retention period for various documents. Detailed information on records disposition is contained in DOE Order 1324.2A or the Laboratory Records Coordinator Manual. In general, the records of a particular program, project, or task will be retained in the Division for five years after their completion; they will then be transferred to the Records Center for permanent storage and retrieval.

4.1.4.1 Programmatic Documents

For programmatic activities, the PI is responsible for ensuring that documents and records are created, maintained, and stored. The PI will identify documents requiring retention and will specify the procedures for their retention. In establishing any documentation or record system, consideration will be given to the purpose, retention period, reproducibility, and impact and probability of error or loss. Documentation might include laboratory notebooks; computer software; data acquisition charts, tapes, disks, or other original media; design documents; project review documentation; description of quality-affecting systems; purchase requisitions, service requests, and related documents; and project management plans.

4.1.4.2 Divisional Documents

For activities of the Division administration office, the DD will identify documents requiring retention and will specify the procedures for their retention. Such documents might include procurement records, financial records, personnel training records, QA reports, administrative correspondence, publications, and other documentation that may be pertinent to the operation of the Division.

4.1.4.3 Controlled Documents

Documents may be specified as controlled by the DD (for documents affecting all or part of the Division staff) or by a PI (for documents affecting a specific activity). When a revision or other update of a controlled document is issued, the DD or the PI, as appropriate, will advise each recipient to use only the current issue and destroy older versions. The date of the document will be updated to note the latest version. The DD or the PI, as appropriate, will be the only individual to maintain archival copies of controlled documents.

Division documents are controlled through the HEP Operations Practices Manual and are distributed to group leaders and project managers. A record is kept by the Safety Coordinator of the date when each addition or update is distributed.

For specific documents under control, refer to the Table of Contents in the HEP Operations Practices Manual.

4.2 *Performance Criteria*

4.2.1 **Criterion 5 - Work Processes**

Work processes are defined as activities, actions, or operations that involve personnel and/or materials in the conduct of laboratory or field experiments, creation of samples, development of computer software, performance of analyses, delivery of services, or generation of any other type of product. Processes that significantly affect the quality of the work produced must be clearly identified and documented.

4.2.1.1 Personnel

Line management should, when needed, provide documentation about the expectations, guidance, or specific procedures that are appropriate to a given activity. Personnel performing work must be knowledgeable about the requirements of the work. Management must also ensure that personnel are knowledgeable in their assigned tasks and are capable of performing these tasks, and that the performance of the tasks has produced results of the required quality.

The qualifications and training of personnel are addressed in Section 4.1.2.2. The core competency requirements and expectations are given in the PD. If special knowledge is required for the performance of work, the requirements must be specified in sufficient detail so that the scope of the task is completely understood by the worker. Written procedures for complex or hazardous work will be prepared when appropriate. Such requirements will be identified in planning documents for the program. The degree of specificity of instructions will be commensurate with the identified risks.

The criteria for acceptable performance must be specified, and the annual performance evaluation of personnel must reflect the degree of acceptability. These criteria and the measures of effectiveness of performance are usually contained in the PD. Unacceptable performance may affect quality and should be discussed during the annual performance evaluation.

4.2.1.2 Materials and Processes

Materials and items that significantly affect quality must be identified and controlled to ensure their proper use; maintained to prevent their damage, loss, or deterioration; and properly handled, shipped, and received. Equipment used for data collection must be calibrated and maintained as required by the PI to achieve the specified performance requirements.

The principal work processes in the Division are scientific data analysis, experimentation, and engineering for detector development. These processes are addressed below:

Identification and Control of Items

When made necessary by programmatic requirements, procedures must be established to ensure that only correct and accepted materials and items are used in the conduct of work. Identification must be maintained either on the items or in documents traceable to the items. For example, quantities and locations of general chemical supplies are controlled by the Division's chemical inventory system; hazard communications associated with these chemicals are provided by the Material Safety Data Sheets (MSDS's). Each laboratory or work area has a binder of its MSDS's. Additional records and MSDS's of Division chemicals are accessible through the Site Chemical Database System.

The High Energy Physics Division Chemical Hygiene Plan ensures that adequate control methods are implemented to prevent unacceptable exposure to hazardous chemicals in laboratories. This plan applies to laboratory or the Bldg. 366 work area operations using hazardous chemicals.

Topics to be addressed regarding the identification and control of items will include the following, if appropriate:

- Identification or tagging of each item and its quality status.
- The traceability of items, samples, and materials.
- Inspection status of inspected items.

The PI is responsible for assuring that all items used in a project or program are adequately identified and controlled, where necessary, and that the appropriate records are maintained of the identification and control of quality-affecting items.

Handling, Storage, and Shipping

Instructions for adequate marking and labeling for handling, storage, and shipping of an item must be established as necessary to identify, maintain, and preserve the item. The presence of special environments or the need for special controls and safety or security precautions must be clearly identified. Standard and special tools and equipment will be used and controlled as required to ensure that their handling is safe. In addition, equipment and tools may require special handling or involve particular risk or safety hazards and will be dealt with according to standard safety practices.

The use of hoists or rigging equipment in handling items associated with research activities in the Division is subject to requirements specified in the Argonne National Laboratory Health and Safety Manual, Chapter II-15, and the Argonne National Laboratory Hoisting and Rigging Manual.

Handling, storage, and shipping of items must be in conformance with established work, inspection, shipping, and safety instructions; drawings; specifications; and/or other documents or procedures specified for these activities. Procedures will be in accordance with the requirements specified in the Division Chemical Hygiene Plan; the Argonne National Laboratory Health and Safety Manual; the Argonne National Laboratory Illinois Site Waste Handling Procedures Manual; and individual project Quality Assurance plans. Hazardous materials, critical materials, sensitive items, special samples, or perishable items must be handled, stored, and shipping in accordance with

the Department of Transportation Hazardous Material Regulation 49 CFR, Argonne East Hazardous Material Transportation Safety Manual and all other applicable special material procedures. For items not in one of these classes, special standards will be developed and implemented if required. In addition to standard procedures for normal operations, the required special containers, equipment, or protective environments will be specified, provided, and documented.

Calibration of Equipment

Tools, gauges, instruments, and other measuring and testing equipment (M&TE) used for activities identified as affecting quality will be controlled and, at specified periods, calibrated and adjusted to maintain accuracy within required limits. The PI must identify quality-affecting M&TE that requires calibration and control in order to ensure that the required precision and accuracy are achieved and documented, that reference standards are adhered to, and that prompt corrective action is initiated when M&TE is outside specified calibration limits. Procedures will be established by the PI so that M&TE designated as quality affecting is controlled, calibrated, adjusted, and maintained by authorized and qualified personnel at prescribed intervals or before use. Records of calibration must be maintained, and equipment must be adequately marked to identify its current calibration status.

The list of M&TE requiring calibration and/or repair must be maintained in the calibration control system by the person responsible for Division equipment records; new items, as determined by the PI, must be added as they enter the Division.

Purchased Software

Software purchased for business purposes in High Energy Physics is all standard commercial software. This software is from a broad commercial market, where millions of copies are sold and QA is accomplished by market forces.

Programmatic Software Development

The High Energy Physics Division identifies two classes of software development; both are done in the context of large collaborations. QA standards and procedures are set and evaluated by collaborators, generally as the basis of peer reviews.

- 1) software that will only be used by the collaborators writing it, usually for an evolving physics analysis for basic research; this is used for their own data analysis.
- 2) software components that become part of the general software of a large experiment, used by many or all collaborators. It is exempted from DOE software QA requirements under DOE Draft Order 203.X (undated) because it is used only for basic research. However, this class of software is subject to a rigorous process imposed by the collaboration, including design and coding standards, followed by extensive testing and peer review.

Experimental Work

Experiments in the Division intended to provide new knowledge of nature must be documented in a way that provides an accurate record of the investigation.

Experimental work aimed at developing new detector technology or testing procedures for a physics experiment should conform to the same guidelines to the extent that the results are relied on and that duplication is difficult or expensive. The requirements imposed on experimental work are not intended to abridge the spirit of experimental freedom or creativity.

All experimental activities are subject to the operating limits and conditions of the facility used for the experiment. The PI is responsible for developing an experimental plan that describes how and when an experiment is to be performed. The experimental plan may be documented in an FWP or other proposal. The plan may contain the following items, as appropriate:

- Test objectives
- Test requirements and conditions
- Design description and requirements
- Test operations plan
- Safety analysis
- Use of radioactive materials for building, testing, and QA
- Quality assurance
- Analyses
- Documentation
- Schedules
- Budget

When appropriate, operating procedures will be prepared that state the steps to be performed in the operation and conduct of the experiment. These procedures, at a minimum, will include the following:

- Checklists for starting up and shutting down equipment being used in the experiment, including emergency shutdowns.
- Detailed instructions for the operation of the experimental apparatus and the performance of the experiment. (The manufacturer's operations instruction manual may be sufficient.)
- Directions for performing analyses.
- Sample data sheets or other directions for gathering data.

The operating procedures must describe any safeguards required when the apparatus is idle. The calibration of instrumentation will be reviewed to determine whether calibration is up-to-date and provide for calibration of any new instruments.

All experimental work must be recorded in suitable logs to maintain a chronological history of significant events that affect the performance, operability, or safety of the experiment. Log books will be maintained as described in Section 4.1.4. The form and content of these records will be determined by the PI and may include items such as the following:

- Date and time of entry
- Identity of experiment
- Experimental conditions
- System calibration
- Special characteristics being investigated
- Parameters being measured
- Success or failure observation
- Total accumulated operating time and duty cycles
- Discrepancies noted during the experiment
- Repair and maintenance record
- Pertinent, unusual, or questionable occurrences
- Modifications made during the experiment
- Reference to supporting information or documentation

At the completion of each experimental program, a written report will be prepared describing the results of the experiment. The report may be in the form of a letter that provides the results of the research sponsor, an Argonne report or document, a peer-reviewed publication, or other appropriate document.

4.2.2 **Criterion 6 - Design**

All design activities must be performed with the level of QA and documentation required to ensure the adequacy and completeness of design information, so that the work performed will produce items that will perform as intended. The level of detail in design documentation for major items is different from that of smaller activities, although the level of quality and safety will be maintained commensurate with the scope, complexity, and risk associated with each item. The PI has the responsibility of defining the design measures and level of detail required for each task.

When required because of the complexity of an item, the PI may prepare a design plan describing the design effort to be accomplished in terms of components and assemblies. Such a plan may include the following:

- Statement of design approach and criteria

- Assignment of design responsibility to an individual
- Lists of specifications, drawings, analyses, and other documents to be prepared
- Lists of codes, standards, and quality assurance and safety requirements
- Design reviews
- Design schedule

In preparing the design criteria, the PI should consider characteristics such as the following for the item being designed:

- Functional requirements and design margin
- Operational environment which may include radioactive materials
- Space and weight limitations
- Safety requirements
- Maintainability
- Handling, storage, and shipping
- Design life
- Reliability
- Quality assurance requirements
- Demolition and disposal at completion of project.

Design reviews will be conducted, as appropriate to the quality and complexity of the task, in order to assure the following:

- That the design criteria are adequate, reliable, and complete
- That the design complies with the criteria
- That the design can be fabricated, inspected, and tested

For research activities, the detailed proposal for peer review will be the basic document defining project plans and objectives, procedures, organizational interfaces, and assigned responsibilities. The detailed proposal must satisfy the requirements of this criterion. Because of the nature of some activities, particularly those that involve field studies or basic research, the design may not be explicitly defined until an activity has begun. In such cases, the research and design are conducted in steps, with changes based on the results from a previous step. These particular cases will be identified at their initiation, and special care will be taken to assure that adequate attention is given to quality requirements at each step.

Some research projects within the Division involve the design and development of computer software. Such software design and development will be performed in an organized and planned manner. The methodology used will be appropriate to the software. Because software development is an evolutionary process, careful planning is necessary to assure that the deliverable item corresponds to the user's requirements.

The primary responsibility for design review, approval, concurrence, and/or change follows the designated management line. When required by the complexity of the design, special reviews should be conducted by qualified individuals other than those who performed the work.

4.2.3 **Criterion 7 - Procurement**

The procurement of quality-affecting items and services must conform to applicable Laboratory, DOE, and federal requirements commensurate with their complexity, risk, quantity, and programmatic significance. As appropriate, the guidelines and procedures described in the Argonne National Laboratory Procurement Policy and Procedures Manual will be used for procurement activities such as source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion. This procedure applies to requisitions for items and services from Laboratory organizations and outside vendors.

The PI is responsible for the review and approval of requisitions for all quality-affecting items and services. Applicable design bases and other requirements to assure adequate quality must be included or referenced in the procurement documents, including requirements to assure quality. Applicable codes and standards must be specified. Statement of work and technical specifications will be prepared, when necessary, in accordance with the Argonne National Laboratory Guide for Preparation of Statements of Work and Technical Specifications.

"Requester will verify that each requirement of the order is met, and the requester will retain records of verification, nonconformances (if any), and corrective actions for non-conformances."

Upon receipt of the order, the PI will perform the inspections and note on the specification sheet that the requirements have been verified or note nonconformances and corrective actions. The requester will initial the form, which then will become the QA document.

Procurement documents and associated records will be maintained in the Division administrative office. Additional records may be retained by the PI, as appropriate.

4.2.4 **Criterion 8 - Inspection and Testing**

Inspection and testing requirements to verify the conformance of quality-affecting items or services to specified criteria will be planned and executed as appropriate for the complexity and risk associated with the performance of the item or service. The PI is responsible for the establishment and documentation of these requirements.

The status of inspection and testing activities must be identified on the items or in documents traceable to the items when it is necessary to assure that required inspections and tests are performed and to assure that items that have not passed the required inspections or tests are not inadvertently installed, used, or operated. Nonconforming items must be reviewed by the PI to determine their disposition. Such nonconforming items must be discarded, returned to the vendor, or otherwise controlled by segregation or tagging to prevent their inadvertent use. Personnel who are responsible for evaluating nonconforming items to determine their disposition must have demonstrated technical competence, cognizance of technical requirements, and access to relevant background information. Justification of the acceptability of nonconforming items and their disposition (for example, to repair or use as is) must be documented with a clear identification of the degree of deviation from the requirements and its impact on performance. Repaired items must be inspected and tested in the same manner as the original item.

4.3 *Assessment Criteria*

4.3.1 **Criterion 9 - Management Assessment**

A QA assessment of all Division, project, and program activities will be conducted periodically by Division management or the responsible PI. The purpose will be to evaluate achievement relative to performance requirements and to appropriately validate or update performance requirements and actions, in order to provide confidence that the quality goals are being achieved. The management assessment process will also periodically include an evaluation of the effectiveness of this QA Plan in fulfilling the Division's mission.

When the performance in a particular area is found not to satisfy the expected and acceptable performance standards, Division management will, in conjunction with the PI, determine the cause of the lack of performance, identify the corrective action to improve performance, and then evaluate the effectiveness of the recommended actions. Management assessments will be conducted periodically or when considered necessary by the PI or Division management. These assessments will be performed to inform Division management of the effectiveness of the implementation of this QA Plan and will identify any activities where the quality of work needs improvement. Such QA assessments may be conducted along with the regular ES&H assessments described elsewhere.

Management assessment reports, responses to assessment reports, corrective action reports, and followup reports when put in writing must be retained as specified in Section 4.1.4. The DD is responsible for the review of all assessment reports and the review and approval of corrective actions initiated by the PI. The PI is responsible for initiating periodic assessments of activities, implementing appropriate corrective actions on the basis of findings and observations, issuing assessment reports, and retaining the assessment reports as quality records.

4.3.2 **Criterion 10 - Independent Assessment**

4.3.2.1 Internal Assessment

Independent assessments of Division activities are conducted in accordance with the requirements of the QAPP. The DD, with assistance of the QAR, is responsible for coordinating assessments of Division activities, and will participate in the assessments,

annually or as required to address the needs of the Division, and they will review and approve intended actions in response to assessment findings and observations, and will provide the ALD and Director for EQO with the results of the assessment.

4.3.2.2 Peer Review

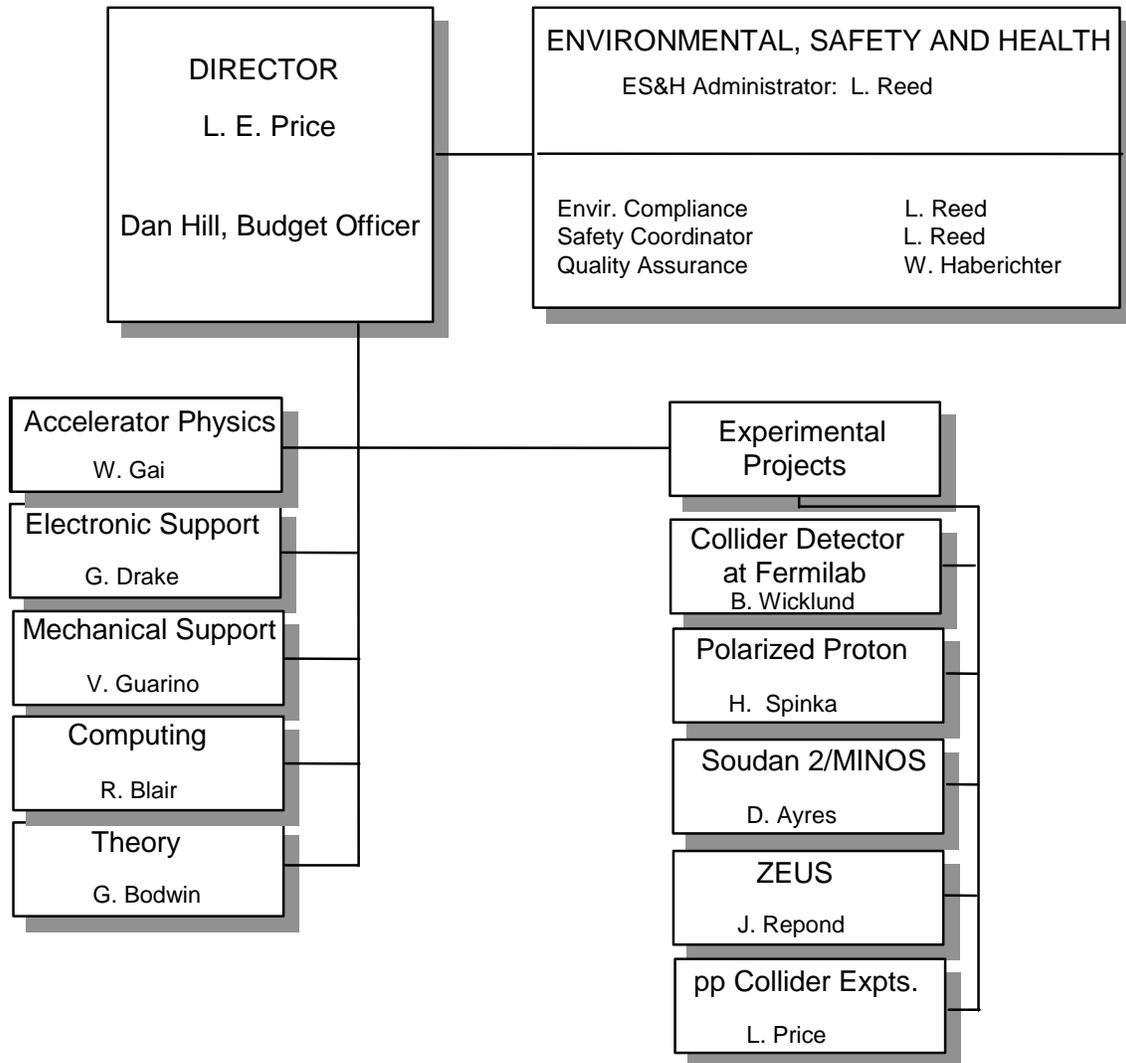
The Division recognizes that the peer review is the highest element of independent assessment to assure the quality of research. Peer review may be used during all phases of the scientific/engineering process, including review of research proposals, review of work in progress, review of results prepared for publication in professional journals, and review and evaluation of programs for both quality and adherence to missions, goals, and objectives. A periodic review of the Division's activities is conducted by the University of Chicago, and also by the DOE. In addition, the DOE, on occasion and at its discretion, organizes special reviews focused on specific activities. All of the above are organized as peer reviews.

The HEP Division encourages internal review of papers for publication prior to submission for publication. The majority of publications for the Division are refereed by independent peer groups selected by the publisher.

Appendix A

High Energy Physics Division Organization Chart

High Energy Physics Division



Appendix B

High Energy Physics Division Responsibility Matrix for Quality Assurance Criteria

Appendix B

High Energy Physics Division Responsibility Matrix for Quality Assurance Criteria

Criterion	Responsibility ^a of Individual ^b		
	DD	PI	QAR
Division QA Policy	P/A		R
Division Organization	P/A		R
Training	A	P	R
Quality Improvement	A	P	R
Documents and Records	A	P	R
Work Processes	A	P	R
Design		P/A	R
Procurement		P/A	
Inspection and Testing		P/A	R
Management Assessment	A	P	R
Independent Assessment	P	R	R

^a Abbreviations for responsibilities:

- A, Approval
- P, Principal responsibility for preparation
- R, Review

^b Abbreviations for individuals:

- DD, Division Director
- PI, Principal Investigator
- QAR, Quality Assurance Representative