

PHYSICS

DIVISION PLAN

FOR

QUALITY ASSURANCE

September, 2003

Prepared by _____
Physics Division Quality Assurance Representative

Approved by _____
Physics Division Director

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**Physics Division
Quality Assurance Plan**

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INTRODUCTION

The Physics Division performs basic research addressing a broad range of current problems in nuclear physics with some interdisciplinary applications. Our program currently emphasizes experimental nuclear physics research in heavy-ion physics centered at the Argonne Tandem-Linac Accelerator System (ATLAS) which is operated as a designated National User Facility. The Division also has strong programs in medium-energy nuclear physics (carried out at a number of major national and international facilities), accelerator development, and nuclear theory.

The Physics Division recognizes the Laboratory's commitment to quality assurance. This document, the Physics Division's Quality Assurance Plan, interprets Laboratory Quality Assurance policy establishing a quality assurance program relevant to the needs of the Physics Division. It implements the requirements in DOE Order 5700.6C, "Quality Assurance" and is consistent with the basic program requirements defined in the Argonne National Laboratory Quality Assurance Program Plan. The guidance contained in two DOE documents has been considered in the preparation of this plan: (1) the *Quality Assurance Program Implementation Guide* (Attachment 1 to DOE Order 5700.6C), and (2) the *Implementation Guide for Quality Assurance Programs for Basic and Applied Research* (DOE-ER-STD-6001-92).

This plan is designed to provide the basis for the management practices, deemed appropriate by Division management, for the majority of the Division's quality-affecting activities. The Division Director may at his discretion determine that a specific project or activity is beyond the scope of this plan. In such a case, the Principal Investigator or designated alternate will be directed to develop a supplement to this plan or an individual plan that will satisfy the Quality Assurance requirements of the Physics Division.

Records of QAR review and Quality Assurance requirements for a specific quality-affecting acquisition are maintained in the Division Office requisition file. The only exceptions to this rule are bulky specifications or requirements which are indicated on drawings. Those records are maintained in the Principal Investigator's project files.

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CRITERION 1 - Program

This Quality Assurance Plan (QAP) for the Physics Division describes the implementation of quality practices within the Physics Division. This plan has been developed in accordance with the Argonne National Laboratory (ANL) Quality Assurance Policy, the ANL Quality Assurance Program Plan (QAPP), DOE Order 5700.6C and the Implementation Guide for Quality Assurance Programs for Basic and Applied Research (DOE-ER-STD-6001-92). It establishes a graded approach for determining level of formality and rigor the Division's activities consistent with the Laboratory's defined quality levels found in QAPP section 2.2.

The Physics Division's Quality Assurance program is designed to cost-effectively monitor those activities affecting the quality of research, safety, programmatic fiduciary responsibility, the reputation of the Division and the Laboratory, and other potential risks which may be incurred in the course of normal operations of the Division. This program provides the basis for the management practices deemed appropriate by Division management. In the event that a specific activity exceeds the scope of this plan, a supplement shall be issued addressing the requirements of that specific activity.

1.1 Mission

The mission of the Physics Division is to conduct basic research in the field of nuclear physics which includes the operation of advanced facilities with the support of experienced and talented scientists, engineers, technical support and administrative personnel. The Division's mission is fulfilled in two ways: first, through the direct publication of the results of staff research in refereed journals or conference proceedings, and secondly, through the design, fabrication, and maintenance of experimental facilities. The Physics Division has a strong tradition of close interaction with the nation's universities. We have many visiting faculty members and we encourage students to participate in our programs for both practical training and thesis research.

1.2 Organization

The Physics Division, in order to foster a stimulating research environment, maintains an open organizational structure (see Figure 1 for Organizational Chart). The purpose of this open structure is to encourage collaborative efforts between researchers, thus avoiding channeling personnel into narrow areas of specialization. The Physics

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Division is structured so that all Ph.D.-level research staff report directly to the Division Director. In recognition of the fact that the Division is too large to be effectively operationally administered this way, there are chiefs including Associate Directors, who act as group or program leaders providing appropriate degrees of scientific guidance to their programmatic areas. Principal investigators report programmatically through their chief to the Division Director. It should be noted that research staff within the Physics Division frequently participate in multiple research projects. Consequently, a given staff member may be a Principal Investigator on one or more projects and a research staff member on several others.

Each activity within the Physics Division has an assigned Principal Investigator. Typically, quality assurance records and documentation shall be maintained in laboratory notebooks and project files retained by the Principal Investigator. The records retained shall be those required to satisfy the applicable individual elements of this plan or applicable supplemental plan.

Note: For the purposes of this plan a "Principle Investigator" is a term that is applied to a Program Manager, Facility Manager, Operations Manager, Chief, Scientist, or Supervisor assigned by Physics Division management to be responsible for the outcome of an activity or event.

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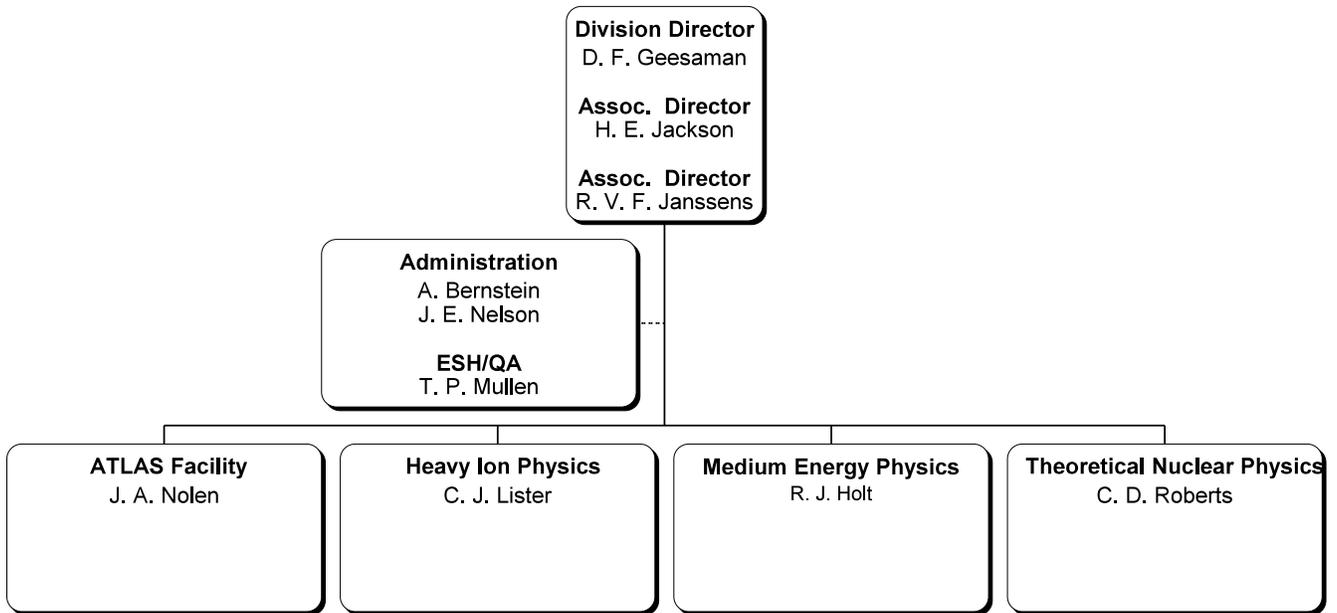


Figure 1
Organizational Structure

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1.3 Sponsors and Users of Physics Division Research and Facilities

The primary sponsor for the Physics Division work processes is The US Department of Energy (DOE) Office of High Energy and Nuclear physics, Division of Nuclear Physics

The primary customers (users) of the Physics Division research and facilities are scientists throughout the world, from scientific affiliations including National Laboratories, universities, and private industry.

1.4 Authority and Responsibilities

Division Director

Ultimate responsibility for quality assurance within the Physics Division resides with the Division Director. The Principal Investigator has the primary responsibility for prescribing and ensuring implementation of appropriate quality assurance provisions for his or her research or construction projects. The Quality Assurance Representative (QAR) is responsible to the Division Director for ensuring compliance within the Division to applicable portions of this QA Plan, the ANL-East Quality Assurance Policy and Procedure, and to act in the best interest of the Laboratory.

The Director shall establish the organizational structure, functional responsibilities, levels of authority, lines of communication, and overall QA policy within the Division. The QA responsibilities of the Division Director also include the following:

- Directs, guides and assists Principal Investigators, ESH Coordinator, and QAR in the administration and implementation of this QA Plan;
- Directs and approves planning and documenting of work, including the establishment of justified budgets and cost estimates, and establishes priorities for resource commitments;
- Directs periodic management assessments measuring the execution of the Division work processes against stated goals and objectives and taking appropriate action to achieve and further the missions of the Division;

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- Ensures that meaningful quality objectives and performance indicators are established and reviewed periodically for continuing adequacy;
- Designates a Quality Assurance Representative for the Division.

Quality Assurance Representative (QAR)

The QAR has the principal responsibility of coordinating the quality assurance related activities within the Division. The QAR is appointed by and reports to the Division Director. The QAR provides independent overview for the Division Director by reviewing quality assurance planning documents and assisting the Principal Investigators in carrying out their quality assurance responsibilities. The QAR is trained by the Office of Quality Assurance (OQA) and serves as a focus for quality assurance matters within the Division. In addition to the above, the QAR has the following responsibilities and functions:

- Conducts periodic monitoring of the Physics Division Quality Assurance program to insure it's adequacy and effectiveness;
- Is aware of the QA status of major Divisional projects;
- Reports unresolved quality assurance problems to the Division Director for appropriate action and verifies completion of corrective action;
- Works in cooperation with OQA on quality-related matters;
- Participates in management assessments of the Physics Division's quality assurance program.

Quality Assurance Coordinators (QAC) may be appointed by the Division Director to assist the QAR or to assume quality assurance responsibility, typically for a specific project.

Principal Investigators

Primary responsibility for determining the applicability of individual elements of this QA Plan to specific projects resides with the Principal Investigator or designated alternate. In addition to the responsibilities delineated in other criteria of the plan, the Principal Investigators have the responsibility to implement the applicable requirements and practices of this QA Plan and related quality documents in their

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operations. Principal Investigators are responsible for determining the quality levels associated with activities for which they are responsible using the grading matrix of Quality Levels A (high consequences), B (moderate consequences) or C (low consequences) in Table 2.2 of the ANL-E Quality Assurance Program Plan (QAPP.) This table is available on the web. It is in the web version of the QAPP. A link to Chapter 2 of that plan, which contains the definitions of the Quality Levels, is provided on the Physics Division's ESH page. That page is reached from a link on the Physics Division's Home Page.

Physics Division Personnel

Employees are responsible for conducting daily activities in accordance with the principles and requirements of this plan. Each individual is responsible for the quality of his/her work and for being attentive to the opportunities for improvement. Employees are responsible for the following. Employees shall:

- Take appropriate action to remediate any unsound or out-of-compliance conditions with Division and Laboratory policies, procedures, and instructions;
- Utilize only proper, maintained, and safe equipment; report all accidents, occurrences, and unsafe conditions to their supervisor;
- Maintain knowledge of emergency plans and procedures, alarms, and responses for their locations;
- Discontinue any activity that poses a threat to their or others well-being, the Division's mission or the environment, and notify management.

CRITERION 2 - Personnel Training and Qualification

2.1 Selection and Hiring Process

All the steps, from posting of a job opening through extending a job offer, are performed according to the *ANL Human Resources Manual*.

2.2 Personnel Position Descriptions

Position descriptions (PDs) are developed and maintained for each employee in the Physics Division. Each PD is reviewed as part of the performance evaluation process to assure that it reflects the current assignment. Generic PDs may be developed for each grade category.

Training utilizes a graded approach. Training needs are met based on the level of risk inherent in tasks, i.e., the risk to the individual (and/or other personnel), the Physics Division Facility and/or its mission, and to the Laboratory. High-risk positions, and associated tasks, require special qualifications, certifications, and/or training of the persons holding those positions.

2.3 Special Positions

Special training, qualification and certification is required for certain positions within the Division such as laser operators and accelerator operators. Specific training, qualification, and certification requirements and procedures are documented in the facility documents.

2.4 Job Hazards Checklist

A job hazards checklist will be completed by each new employee with the assistance of his/her supervisor. After the completed checklist is submitted to the Division's Training Management System (TMS) Representative, a training profile will be generated for and forwarded to the new employee.

Required and supplemental training is arranged and coordinated by the Physics Division TMS Representative. All training records are periodically reviewed and distributed to the Division employees by the TMS representative.

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2.5 Training Management System (TMS)

ESH training requirements are determined using ANL's Training Management System. The TMS is used to generate a training profile that will provide for a listing of the appropriate level of ESH related training for Division personnel. Supplemental training may be required at the direction of individual supervisors and Division management.

The Physics Division participates with the Training Group in assuring that required training is obtained in a timely manner for each employee. Within the Division, the TMS is administered by the Physics Division TMS Representative.

2.6 Training for Temporary Employees and Users

Physics Division management ensures that required prerequisite ESH training is provided to temporary employees and users in accordance with the requirements in the Argonne ESH Manual and Divisional procedures.

2.7 Work at Non-ANL Facilities

When reciprocity for ESH training is accepted by non-ANL facilities, the training record of the employee will be sent to the host facility. In general, determining requirements and providing related training is the responsibility of the host facility.

2.8 Continuing Education and Professional Development

Employees are encouraged to prepare for and to seek professional degrees, certification, and recognition by ANL approved universities, colleges, training institutes, or associated professional societies.

2.9 On-the-job Training

The managers are responsible for providing appropriate on-the-job training. This may consist of orientation training for new employees, or may be required to

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temporarily meet ESH training needs until formal training can be obtained, or to supplement classroom training.

2.10 Work Process Changes

Employee qualifications and training needs will be evaluated by the employee's supervisor whenever the work they are assigned is changed by the employee, the group, and/or manager. A new Job Hazards Checklist will be completed for any new job assignment by the employee's supervisor.

2.11 In-House Training Courses

Training requirements vary somewhat depending on the nature of the tasks associated with a particular job or position. Training that is not available through the ESH Training Section is provided in-house by Physics Division personnel. For example, special training is required to be designated a qualified ATLAS User or Accelerator Operator.

CRITERION 3 - Quality Improvement

3.1 Quality Improvement Policy

The Physics Division encourages all Division personnel to strive for excellence in their work performance. Personnel are encouraged to identify and report performance problems, deficiencies, unsafe working conditions, and improvement opportunities to the level of management at which corrective action can be taken.

Quality improvement is accomplished through:

- management assessments
- peer reviews
- safety inspections and reviews
- identification of deficiencies and non-conformances, and corrective actions that address their root cause.

Physics Division personnel may participate on boards and committees to achieve quality objectives, and to more effectively implement and achieve quality improvement goals.

3.2 Use of Performance Indicators For Quality Monitoring and Improvement

The Physics Division employs performance indicators to monitor Divisional performance and to assist in the goal of quality improvement. Performance indicators are used to measure the extent of achievement of quality improvement goals. Indicators are typically used for measuring the quality of research efforts and results, as well as budget and schedule performance.

Performance indicators in current use to measure Division performance are:

- Results of the University of Chicago Reviews
- Results of Physics Division management assessments
- Number of hours of beamtime available for research at ATLAS
- Number and percentage of proposals that receive funding

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- Absence (number) of Occurrence Reports
- Absence (number) and severity of injuries
- Number of publications
- Percentage of training completed and current

3.3 Control of Nonconforming Items and Corrective Action

Items that do not conform to specified requirements shall be clearly identified in a method deemed appropriate by the Principal Investigator to prevent inadvertent installation or use. Records of nonconforming items are retained by the Principal Investigator. Cognizant Laboratory personnel shall take the necessary actions to correct the nonconformity in accordance with established ANL policy and procedures. The Principal Investigator may, at his discretion, accept a nonconforming item. The resolution of the nonconformance shall be noted in the project file.

Upon identification of a nonconforming item or activity, the Principal Investigator shall promptly implement the appropriate corrective action. The identification, cause, and corrective actions for significant conditions adverse to quality shall be documented in the project files and brought to the attention of the appropriate levels of management for the purpose of disseminating information and devising strategy to prevent a re-occurrence of the nonconformance.

When requested, the QAR shall be involved in the resolution of nonconformances.

CRITERION 4 - Documents and Records

4.1 Policy

It is the policy of the Physics Division to maintain an effective and efficient documentation and records management system commensurate with the significance of the subject matter, the benefit, need, and/or requirement to document or record. The retention and disposition of documents and records is in accordance with the ANL Records Management Policy.

Within the Division, the records retention and retrieval processes are performed in a manner which maximizes effectiveness and minimizes cost. Records are stored in a manner that will minimize the risk of damage or destruction to the records.

4.2 Controlled Documents

The Division has no Controlled Documents

4.3 Authorities and Responsibilities

Principle Investigators (PI) and Facility Managers (FM)

Documents and records for quality-affecting activities are prepared by the PI, FM, as appropriate, or project support personnel with the review and approval of the PI or FM. The degree of control required is determined by the PI or FM. Documents and records for quality-affecting activities, including documentation of reviews and corrective action shall be maintained in the project files by the PI, FM, or project support personnel. The PI or FM provides a system for controlling the preparation, review, approval, revision, issue and distribution of quality-affecting documents. Document control by the PI or FM shall be structured to reduce the risks of using inappropriate, inaccurate or obsolete requirements documents.

Quality Assurance Representative (QAR)

The QAR, as appropriate, in accordance with the various elements of this plan, shall review the documents and records for adequacy.

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It shall be the QAR's responsibility to periodically review the project's activities and records for conformance to this plan. The QAR shall retain records of findings of nonconformity and satisfactory resolution of any nonconforming activities.

The QAR is the custodian of the Physics Division QA Plan, which involves responsibility for coordinating yearly reviews of the plan with participating managers and group leaders, supervising revisions and reissues, and the overall maintaining of the plan as a current, applicable, and useful aid for assuring quality within the Division.

Assistant Division Director

All administrative documents and records are under the custodianship of the Assistant Division Director, including budget and planning records.

Division Property Representative

The Division Property Representative is responsible for maintaining records on, and an inventory of, Physics Division "property" and "capital equipment" per *DOE Order 1324.5A Records Management Program, dated 4-30-92*.

Division Records Coordinator

The Division Records Coordinator's responsibilities and related procedures are contained in the *ANL Records Coordinators Manual*.

4.4 Document Control

The preparation, issue, and change of documents that specify quality requirements or prescribed activities affecting quality shall be the responsibility of the Principal Investigator or Facility Manager. Prior to the start-up of a new activity (and on-going activities upon initial approval of this plan), the Principal Investigator or Facility Manager, with the assistance of the QAR, if requested, shall review the

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proposed project and make a determination of activities that are likely to be quality affecting.

CRITERION 5 - Work Processes

5.1 Process Descriptions

Organizationally, the Physics Division consists of an administrative unit, three basic research groups, the ATLAS facility with a strong research program in accelerator development, and the Dynamitron facility. In addition, a technical support group composed of technicians, designers, and engineers are dedicated to the technical support of the experimental program in the Division.

The three research groups are:

- Heavy-ion Research
- Medium Energy Physics
- Theoretical Nuclear Physics

Heavy-ion Research

Heavy-ion research addresses key questions about the structure and dynamics of the nuclear many-body system. Nuclear structure and reactions are studied in collision of complex nuclei with heavy-ion beams, mostly from the ATLAS accelerator. The program maintains state-of-the-art equipment to perform these experiments. Many of the projects are collaborative efforts with scientists from other institutions.

Medium Energy Physics

Medium Energy Physics explores nuclei, nuclear matter, and fundamental nuclear interactions between the constituents of nucleons and the manner in which they are modified in nuclei. To achieve programmatic goals, staff members lead and collaborate in research projects at a variety of major national and international research facilities and also design, develop, and construct innovative targets and detector systems to facilitate research.

Theoretical Physics

Our nuclear theory research spans a wide range of interests including nuclear dynamics with subnucleonic degrees of freedom, dynamics of many-nucleon systems, nuclear structure, and heavy-ion interactions. This research makes

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contact with experimental research programs in intermediate-energy and heavy-ion physics, both within the Division and on the national scale.

The theory group of the Physics Division is involved principally in investigations into intermediate- and high-energy nuclear physics, heavy-ion reactions, and nuclear many-body problems. The group has collaborations with other research institutes in the United States and throughout the world.

Argonne Tandem-Linac Accelerator System facility (ATLAS)

The ATLAS facility is a heavy-ion accelerator system designed for precision studies in nuclear physics and other areas of science. ATLAS is a National User Facility and is based on superconducting radio-frequency technology. The accelerator consists of several major components: three injectors, two positive-ion injectors, and an alternate tandem electrostatic accelerator, which serve as sources of low-energy ions followed by two stages of superconducting heavy-ion linear accelerator (linac), the BOOSTER section, and the ATLAS addition. ATLAS currently has approximately 200 active outside users of the facility including faculty, Ph.D. and graduate student researchers from universities and other laboratories worldwide.

A major effort involves research and development in the accelerator physics of superconducting linacs and related technologies. Much of this effort is related directly to upgrading or improving the technology of ATLAS with the continuing goal of enhancing its capability as a National User Facility.

Dynamitron

The Dynamitron accelerator located in the Physics Division provides intense and highly collimated beams of fast atomic or molecular ionic projectiles. It is currently used principally in experiments relating to the development of an exotic beam facility.

5.2 Control of Planning and Review for Hardware, Experiments, and Systems

The staff of the Physics Division are a group of highly-motivated, skilled professionals pursuing basic research activities. The nature of basic research is

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such that there is a significant degree of risk regarding the outcome of most of our research activities. The method used to control and minimize this risk is the peer review process. The peer review process takes advantage of the extensive professional expertise of both our in-house staff and external reviewers.

The overall quality of the Division's work is assured by both external and internal reviews of our research programs. The cognizant Department of Energy Program Offices review, on an annual basis, our research programs. The University of Chicago appoints an independent review committee consisting of scientists who are leaders in their field to carry out an in-depth review of the Division's research activities on an 18-month cycle. The U. of C. Review Committees transmit their reports to the President of the University, who in turn transmits them to the ANL Board of Governors and the Laboratory Director. Copies of all Review Committee reports are sent to the Associate Laboratory Director for Physical Research, and to the Division Director. The Division Director uses these findings as guidance to shape the future direction of the Division's activities. These reports are critical because, not only do they reflect on the reputation of the Laboratory and the Division, but because they support requests for both new and continuing funding for the Division's activities. In addition to the external reviews, both the Laboratory Director and the Associate Laboratory Director for Physical Research independently review the Division's activities, typically on an annual basis. In summary, these external and internal reviews provide oversight and guidance for the Division's major research activities.

The development and operation of the Division's experimental facilities receive similar scrutiny. New proposals receive extensive review and discussion within the Division. The Division Director reviews these proposals and forwards them through the appropriate channels to the cognizant funding agency. These agencies typically solicit independent reviewers for comment prior to further funding consideration. Upon approval of funding, the Division Director determines the appropriate management controls to be applied to projects.

Most projects are relatively small in scope. Management is delegated to the Principal Investigator when work projects are created. Review of these projects is incorporated in the normal performance review of the Principal Investigator. Large scale or critical projects are treated somewhat differently. The Principal Investigator reports regularly on the status of these projects to the Division Director and the Division staff on the whole. The Principal Investigator's work is thus subject to both peer and Division management review.

Publications of research results in refereed journals and conference proceedings are the primary output of the Physics Division. Publications receive intensive peer

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reviews and verification, ensuring that they meet Physics Division and Laboratory standards. Figure 2 illustrates the flow of the peer review process for publications. A copy of the original manuscript and correspondence related to internal review of the manuscript is retained in Division files for a minimum of five years. This process ensures and documents the fact that each publication has been read, reviewed, and approved by a non-author Division staff member, the Program Manager, and the Division Director and/or Associate Division Director.

The ATLAS (Argonne Tandem-Linac Accelerator System) facility, operated as a National Collaborative Research Facility, maintains its own well-defined operating procedures, maintenance logs, operating logs, and data-acquisition system. In addition, training and qualification of operators is documented. ATLAS is a designated National User Facility.

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Review of Physics Division Publications

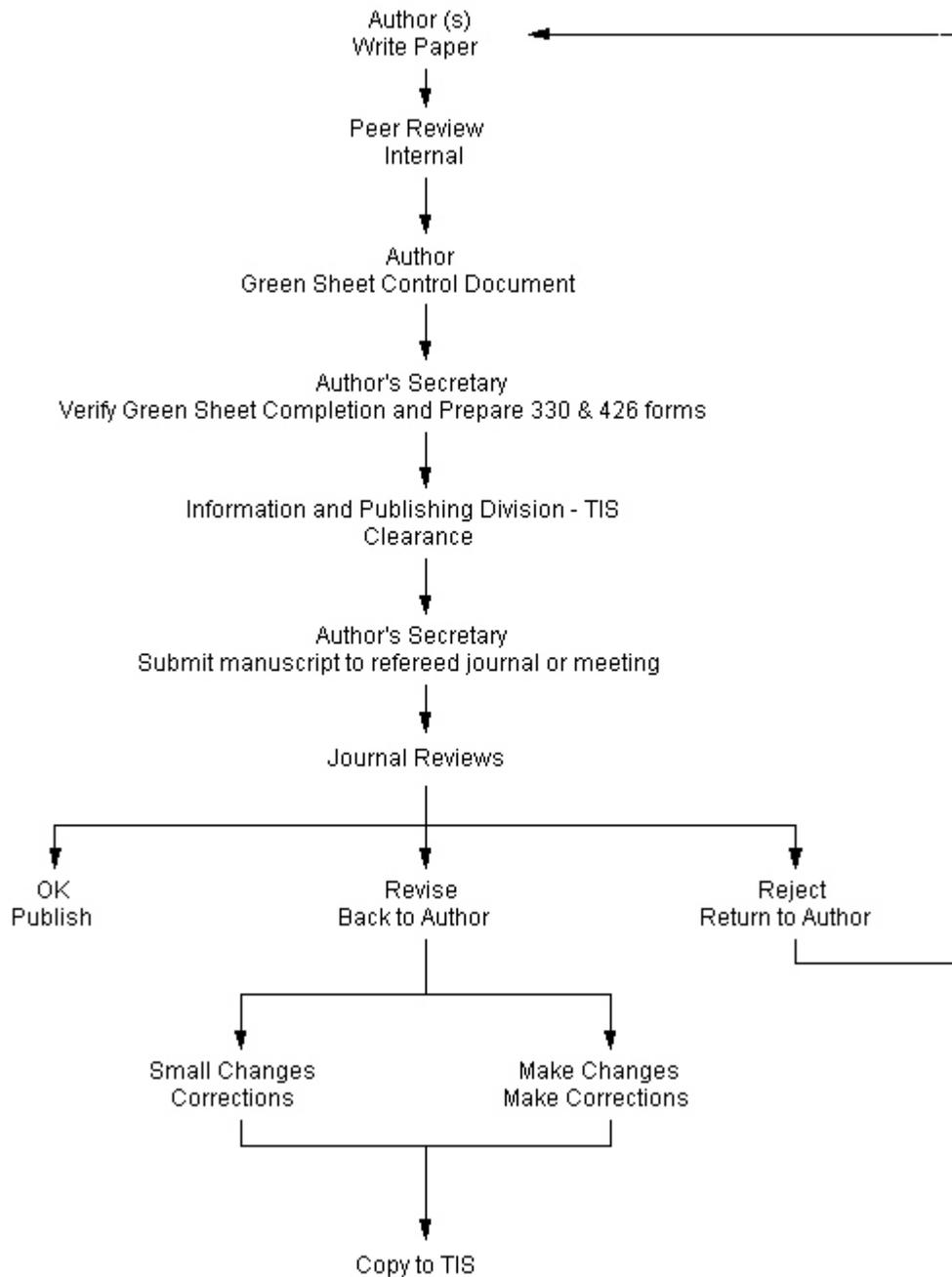


Figure 2

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The research program at ATLAS is selected with the advice of the ATLAS Program Advisory Committee (PAC). The ATLAS PAC consists of voting members made up of Physics Division staff scientists and representatives of the outside users community. In addition to the voting members, the PAC is chaired by the Scientific Director of ATLAS, and the User Liaison Physicist acts as Secretary. The PAC normally meets three times per year serving as a peer review panel reviewing competing proposals for experiments. Based upon scientific merit and technical feasibility, the PAC votes and recommends to the Scientific Director which experiments should be assigned running time. The overall quality of the research program at ATLAS carried out by ANL staff is subject to the same external and internal peer review process as the rest of the Division's activities. The ATLAS programs are carried out with the use of experimental equipment located in several target areas in building 203.

The status of studies and experiments are typically reported by project personnel in scientific publications and topical reports. The Division Director, based upon the normal managerial practices of the Physics Division, schedules reviews as deemed appropriate for critical projects.

The Dynamitron accelerator facility maintains its own operating logs. Operators (frequently experimenters) are pre-qualified to certify their ability to properly operate the instrument. They are trained by the technician responsible for operation and certified by the physicist in charge of the facility. A list of qualified operators is maintained at the facility. There is a printed set of operating instructions for the experimenter/operators to follow to ensure proper and safe operation.

The Target Development Laboratory maintains a record of all targets fabricated, including material certifications for isotopes, proper identification of containers, and target request forms that ensure proper completion and identification.

Controls for Software

The Division operates several clusters of computers for general computing and data analysis purposes. Commercial software for these clusters is first subject to the vendor's quality assurance program. A log book is maintained to indicate when the software is installed on the system. The operations group enters into software maintenance agreements with the vendors which assures that periodic updates are received. Also, the maintenance agreements provide for telephone assistance.

In-house designed software is carefully controlled. The computer operations group maintains developmental versions distinct from production versions. Extensive

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debugging is done prior to release of new software and updates. The computer operations group maintains a fall-back position, testing new versions against tried-and-proved earlier versions. After a new release, programmers monitor use independently from users to assure reliable operation. The programmers respond to bug reports from experimenters and correct any defects detected. A log is kept on when versions are installed. As a final precaution, the introduction of new software is staged to aid in the identification of problems.

Computer codes used in a quality-affecting activity shall be documented. The current version of a computer code shall be identified in each print-out of the computer code and on computer output runs.

5.3 Identification and Control of Items

Controls shall be established to assure that only correct and accepted items are used and installed whenever necessary to insure quality. A method of identification (by physical markings whenever possible) shall be implemented to ensure that only correct or acceptable items are used or installed in quality-affecting activities. It shall be the Principal Investigators' responsibility to specify and implement these controls. A notation of the controls established shall be retained in the projects records.

5.4 Processes

This element applies to quality-affecting processes and special processes required to assure the integrity of scientific equipment. Examples of quality-affecting processes include but are not limited to: special welding requirements, heat treating, cleaning, and non-destructive testing. Special processes are those quality-affecting processes which cannot be adequately verified after the process is completed.

The Principal Investigator shall determine, prior to the creation of an acquisition document, any quality-affecting processes required to reduce risks to an acceptable level for goods or services required. Any such processes shall be identified in

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writing within the acquisition documents either on the requisition or service request, fabrication drawings, specifications, or acceptance criteria in a method conforming to standard commercial or engineering practices. Performance instructions shall include responsibilities, prerequisites, acceptance criteria in process controls, data collection, and record-keeping requirements necessary to verify that the requirements specified have been met. Records of performance instructions and verification of successful completion shall be retained in the project files.

5.5 Measuring and Test Equipment

The QAR, or QAC if one is responsible for these duties, shall review all measuring and test equipment within the Physics Division as identified by the Division's property records with the Principal Investigator to whom the equipment is assigned. A determination shall be made by the QAR in cooperation with the Principal Investigator identifying those measuring and test equipment items which are critical to quality affecting activities in pursuit of the Division's research mission. A log shall be developed, retained, and maintained by the QAR uniquely identifying each piece of critical measuring and test equipment, its location, the cognizant staff member responsible for its operation and maintenance, the appropriate calibration standards, a schedule for calibration consistent with the manufacturer's recommendations, and records of calibration thereby attesting to the accuracy of calibration.

Principal Investigators using measuring and test equipment shall maintain in project notebooks records of measurements taken using this equipment that are consistent with standard research practices.

5.6 Handling, Storage and Shipping

Handling, storage and shipping shall be conducted so as to prevent damage or loss and to minimize deterioration. It shall be the responsibility of the Principal Investigator to prepare written instructions when there is significant risk of damage or loss.

Handling, storage and shipping of hazardous items or toxic materials shall be performed in accordance with ANL procedures specified in:

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1. *The Illinois Health and Safety Manual, Chapter III and Chapter V.*
2. *Supply Policy/Procedures Manual, (Chapter on Shipping of Hazardous Materials Off Site).*
3. *ANL Transportation Safety Manual.*

The control and disposal of any chemicals or other hazardous materials shall be controlled for environmental protection purposes in accordance with the *ANL Waste Handling Policy and Procedures Manual*.

5.7 Hoisting and Rigging

Divisional hoisting and rigging equipment shall be operated and maintained in accordance with the Argonne National Laboratory - East Hoisting and Rigging Manual. Maintenance and testing of Divisional hoisting and rigging equipment is performed by the Plant and Facility Services Division. Records related to those activities are maintained by Plant and Facility Services. It shall be the responsibility of the Divisional Training Management Representative to ensure that operators of such equipment receive appropriate training in its use and operation and retain records in the safety coordinator's files regarding such accreditation. Records of required daily inspections and monthly rigging inspections are maintained in the respective facilities.

5.8 Lockout/Tagout

The Physics Division Lockout/Tagout Policy is consistent with the policy and procedure listed in the ANL ESH Manual. Lockout Tagout authorities, responsibilities, and inventory list is described in this Policy.

5.9 System Components, Status, and Access

Maintenance and status of system components, including structures, facilities and equipment, shall be controlled to the extent that activities can be performed safely and effectively. Access to system components shall be controlled through administrative procedures, signs and physical barriers, according to the item's associated risk. Signs and labeling shall be consistent with signs and labels approved for Laboratory-wide use by the ES&H Division. Labeling, the marking of

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equipment and piping, shall be consistent with the labels used and approved by the Plant Facilities and Engineering Services and ESH Divisions.

5.10 Work Instructions

The level of formality of work instructions shall be commensurate with the complexity and risks associated with the activity. Written procedures are prepared and used to direct the work associated with activities that are sufficiently complex, impact multiple organizations, or have significant ES&H or programmatic impact.

The PI will, when necessary, prepare written requirements for processes, and ensure that the work is performed by qualified personnel using qualified procedures. These written requirements will include responsibilities, prerequisites, acceptance criteria, data collection and record keeping, as appropriate. The QAR shall review process QA requirements for adequacy, when specified by the PI.

CRITERION 6 - Design

6.1 Policy

The Physics Division design and engineering activities shall be defined, controlled, and verified in a manner commensurate with the complexity and risk associated with the design and intended use of a system.

Design is also an integral activity in the development of computer programs and codes, computer network hardware/software configuration in support of operation and control of the running of Physics Division Facility experiments, and for collecting and analyzing experimental data. Design controls, including verification and validation of computer software and configuration controls, shall be performed as appropriate for the application.

6.2 Design Controls

Design verification shall be planned, conducted, and documented in a graded manner to assure that the design meets prescribed requirements. The verification shall provide assurance that necessary studies, calculations, and analyses that support design conclusions have been documented and reviewed by technically qualified personnel.

The design process should include consideration that materials and design interfaces are compatible; that maximum use is made of qualified, standardized or approved parts, materials, components, and processes; that accessibility for in-service inspection, maintenance, or repair is adequate; and that acceptance criteria for inspections and tests are delineated. Discussions among the responsible organizations should be held to resolve technical problems concerning design adequacy.

Design verification should be independent to the extent necessary so that the reviewers have no direct responsibility for the design under review. Reviewers shall be technically competent, and, in keeping with the philosophy of a graded approach, may be from the same organization that prepared the design as long as they did not participate directly in the design.

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Design verification should be documented. Where necessary to improve quality, any design review reports should identify problems, decisions, and resolution actions.

6.3 Design Changes

Changes to final designs, as-built field changes, and modifications shall be subject to design control measures commensurate with the original design. The design change process should assure that analyses and calculations that support the design are still valid and that the design change is reflected in associated engineering, operation and maintenance documents.

6.4 Software and Computing Systems Design Configuration

Configuration design documentation is required for certain software systems as determined by the Principle Investigator in collaboration with the QAR.

6.5 Authorities/Responsibilities

Principal Investigator

The Principal Investigator (PI) is responsible for the preparation of instructions, procedures, and/or drawings, as necessary to bring a design activity, or procured design, to a successful conclusion.

The PI is responsible for arranging for design reviews, as appropriate, for the activity or task under consideration. Any instructions, procedures, drawings, and results of reviews will become part of the project files maintained by the PI.

Quality Assurance Representative

The QAR is responsible for reviewing any instructions and/or procedures relative to activities affecting quality to determine if they are properly described.

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6.6 Special Provisions for Experimental Pressure Vessels

It shall be the responsibility of the Principal Investigator to apply the appropriate elements of this Quality Assurance Plan to the design and fabrication of all experimental pressure vessels. All new (and not-approved existing) experimental pressure vessels must be approved by the Divisional Safety Committee before being pressurized. It shall be the responsibility of the Divisional Safety Committee to verify that the experimental pressure vessel conforms to the applicable requirements of the *ANL Health and Safety Manual*.

It shall be the responsibility of the Principal Investigator to retain records for experimental pressure vessels in accordance with the applicable elements of this Quality Assurance Plan. It shall be the responsibility of the Physics Division Safety Committee to retain documentation of conformation of experimental pressure vessels to the requirements of the *ANL Health and Safety Manual*.

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CRITERION 7 - Procurement

7.1 Policy

The Physics Division procurement activities shall be conducted according to the *ANL Procurement Operations Manual*, where appropriate.

It shall be the Physics Division's responsibility to assure that adequate quality controls are established for goods and services, provided by Laboratory service agencies and outside vendors, required in pursuit of the Physics Division's mission. The determination of adequate quality control is made prior to a request for goods and services. All procurements that are determined to be Quality Level A or B must be approved by the QAR to be processed through the PARIS system.

Adequate quality control may run the full spectrum from a manufacturer's normal commercial practices in furnishing goods and services for common commercial applications to complex quality assurance specifications, certifications, witnessed tests, etc. Responsibility for determining technical criteria for goods and services rests with the Principal Investigator.

7.2 Procurement Control

When applicable, Division personnel shall prepare procurement packages containing the following: statements of work, specifications, and drawings, which define the criteria for acceptance and delivery of the product to the Physics Division. The information in a procurement package may also address the need for supplier QA programs, the right of Physics Division access for inspection, and the requirements for documentation, including fabrication, production, acceptance and testing criteria.

7.3 Authorities, Responsibilities

Principal Investigator (PI)

Principal Investigators either initiate requests for goods and services themselves or delegate the authority to initiate requests to their collaborators or Divisional technical support personnel. The initiator of a procurement document is responsible

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for the accuracy of the document and the appropriateness of the goods or services requested for the intended application.

Goods and services shall be checked by the PI, or his designee, for correctness before acceptance and use. This activity shall include formal inspection and/or testing only when it is specified by the PI.

For important major items or when specified by the PI, provisions for ANL verification that contractual requirements are met shall be listed in an acceptance criteria document, which is only for ANL use.

For important major items or when specified by the PI, documentation supporting acceptance shall be maintained for records purpose, including required inspection reports and material certifications.

Quality Assurance Representative (QAR)

The Physics Division QAR shall ensure that the control of purchased items and services is implemented and that related requirements are met.

When formal QA is required, (e.g., important, complex, and/or one-of-a-kind procurements), the Division QAR will review the documents required for compliance with ANL procurement regulations, and for quality assurance adequacy of the specifications prepared by the PI. The QAR, in cooperation with the Requisitioner, shall determine the appropriate controls necessary to verify conformance to the specification. This may include, but is not limited to, certificates of conformance, inspection upon receipt, verification at the supplier's facility, and/or post-installation testing.

For all quality affecting goods and services, the requisitioner shall invoke the ANL invoice certification system to ensure that final payment is withheld until all requirements are satisfied. Additionally, the QAR may solicit comments or advice from OQA or other technical specialists in the process of reviewing the documentation. QAR concurrence of adequacy is indicated by signature on the procurement document.

7.4 Provisions for Complex Acquisitions

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The initiator of a complex acquisition (the Principal Investigator or requisitioner) generates a procurement requisition or service request which includes appropriate quality assurance provisions (inspection, test, certification, calibration, etc.) in the body of the acquisition document or specification. The statement of work defines the objectives and specific tasks to be performed. The specification describes how the objectives are to be accomplished.

CRITERION 8 - Inspection and Testing

8.1 Policy

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.

8.2 Requirements

The PI is responsible for establishing and documenting inspection and testing requirements. The Division QAR will assist in these matters when requested.

Inspection and testing must be performed by qualified persons. When appropriate, such inspection and testing will be performed by persons who are not directly involved with the work or purchase.

Inspection results including any follow-up or remedial action shall be documented and retained in the project files when appropriate.

For fabrication by Central Shops (SSD-CS), form *ANL-492, Central Shops Fabrication Request*, is prepared by the requestor and attached to the Service Request. If there should be a "Blanket Order" for a year's request, this form needs only to be generated in those situations where it is warranted, which is determined by discussion with the QAR who makes the evaluation based on current conditions and situations. The PI ensures that appropriate controls are in place, and that inspection requirements are effectively fulfilled.

8.3 Test Control

Tests required to verify conformance of an item or activity to specified requirements shall be planned with the concurrence of the QAR and executed by the Principal Investigator when necessary. An inspection test plan prescribes what is to be tested, by whom, when, by what methods, and includes the criteria for acceptance. The plan shall include the identification of potential sources of uncertainty and error in testing and the needed precision and accuracy.

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The QAR reviews test documentation for quality assurance adequacy as part of his or her overview activities. The PI ensures appropriate controls are in place and that testing requirements are effectively fulfilled.

Test results including any follow-up or remedial action shall be documented and retained in the projects files.

8.4 Authorities and Responsibilities

Any inspections required to verify conformance of an item or activity to specified requirements shall be planned and executed by the Principal Investigator or his designee. An inspection plan prescribes what is to be inspected, by whom, when, by what methods, and the criteria for acceptance. The formality of the inspection plan is determined by the Principal Investigator. The inspection plan shall be reviewed by the QAR for adequacy when requested.

It shall be the responsibility of the Principal Investigator to identify and maintain a record in the project's file of the current status of any critical quality-affecting goods and services. The Principal Investigator with the concurrence of the QAR shall determine appropriate methods of identifying and tracing the goods and services.

The QAR reviews verification documents for quality-assurance adequacy as a part of the QAR's overview activities for inspections.

8.5 Measuring and Test Equipment

Prescribed measuring and test equipment used for inspection and testing activities are adjusted and calibrated at prescribed intervals by qualified personnel to maintain accuracy and precision within the prescribed limits. Records will be retained by the PI.

8.6 Nonconforming Items and Activities

The reporting of significant nonconformance in major projects shall be the responsibility of the PI. The PI is responsible for the interim control, and ultimate correction of significant nonconformance. Records of such activities will be retained by the PI, as well as documented follow-up evaluation of the corrective action.

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If a procurement should involve a nonconformance condition before shipment of items by the supplier, it should be documented on the ANL Form, *Form ANL-366, Supplier Disposition Report (SDR)*.

Nonconforming items must be reviewed by the PI or his designee to determine their disposition. Such items must be discarded, returned to the vendor, or otherwise controlled by segregation or tagging to prevent their inadvertent use.

8.7 Correction of Nonconforming Conditions

The resolution of unusual operational occurrences shall be based on evaluation of safety and programmatic impacts and on lessons learned to prevent future similar incidents from occurring.

The correction of significant nonconformance in projects is the responsibility of the PI. The PI is responsible for the interim control, and ultimate correction of significant nonconformance.

CRITERION 9 - Management Assessment

9.1 Policy and Purpose

Management self-assessments are conducted periodically to evaluate whether the Physics Division programs are achieving the Division's missions. The assessments evaluate facility conditions, effectiveness of management programs, and the adequacy of performance. Conditions identified as adverse to quality or performance are to be investigated and reviewed to determine the root cause. The problems are then resolved.

The purpose of these assessments will be to evaluate the Division's performance relative to its missions and goals, to validate performance indicators, requirements, and actions, to provide confidence that the Divisional goals are being met. The formality and rigor associated with these self-assessments will depend on the administrative, programmatic, and ESH/QA risk.

9.2 General Requirements

Assessments shall be performed periodically of the Division's administrative and programmatic efforts to determine if the Division's quality standards and expectations are being satisfactorily applied, and whether the Division's missions, goals, and performance objectives are being effectively and efficiently met. The Physics Division's management assessment program consists of:

- (1) Monitoring of performance indicators,
- (2) Peer reviews of programs and experiment proposals,
- (3) Reviews of work in progress,
- (3) Root cause analyses and corrective actions of observations and findings of review bodies,
- (4) The annual ESH/QA Self Assessment for the Laboratory Director.

9.3 Authorities, Responsibilities

The QAR for the Physics Division conducts ongoing overview, surveillance, and training to ensure that Physics Division staff understand and implement provisions of this plan for quality-affecting activities. The responsibility for applying the elements of this plan to the specific project rests exclusively with the Principal Investigator.

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The QAR shall periodically review this plan for currency and adequacy and will revise this plan as required to meet the changing needs of the Physics Division. Any revisions to this plan require the concurrence of the Division Director prior to implementation.

CRITERION 10 - Independent Assessment

10.1 Types of Independent Assessments

Independent assessments of the Physics Division are appraisals initiated outside of the Physics Division's line management.

Quality-related assessments are conducted periodically to determine the efficacy of the Physics Division's programs. Among those outside organizations conducting such assessments are the following:

1. ANL Internal Appraisal programs
2. U. S. Department of Energy
 - Argonne Area Office
 - Chicago Operations Office
 - Headquarters
3. The Nuclear Science Advisory Committee (NSAC) to the DOE
4. The Department of Energy (DOE) Inspector General
5. The Office of Management and Budget
6. The General Accounting Office
7. The University of Chicago
8. Experiment review bodies at external user facilities

The University of Chicago reviews are of the technical experimental program. In addition, the Laboratory Director and the Associate Laboratory Director conduct functional reviews of the Physics Division Facility operation and experimental program.

The Physics Division Director shall formally respond to assessment results, and take corrective actions as necessary. The actions for the resolution of assessment results shall be documented and maintained by the QAR.