CATEGORIES IN THE IAEA SAFETY SERIES

A new hierarchical categorization scheme has been introduced, according to which the publications in the IAEA Safety Series are grouped as follows:

Safety Fundamentals (silver cover)

Basic objectives, concepts and principles to ensure safety.

Safety Standards (red cover)

Basic requirements which must be satisfied to ensure safety for particular activities or application areas.

Safety Guides (green cover)

Recommendations, on the basis of international experience, relating to the fulfilment of basic requirements.

Safety Practices (blue cover)

Practical examples and detailed methods which can be used for the application of Safety Standards or Safety Guides.

Safety Fundamentals and Safety Standards are issued with the approval of the IAEA Board of Governors; Safety Guides and Safety Practices are issued under the authority of the Director General of the IAEA.

An additional category, Safety Reports (purple cover), comprises independent reports of expert groups on safety matters, including the development of new principles, advanced concepts and major issues and events. These reports are issued under the authority of the Director General of the IAEA.

There are other publications of the IAEA which also contain information important to safety, in particular in the Proceedings Series (papers presented at symposia and conferences), the Technical Reports Series (emphasis on technological aspects) and the IAEA-TECDOC Series (information usually in a preliminary form).
The following States are Members of the International Atomic Energy Agency:

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world".

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QUALITY ASSURANCE
FOR THE SAFE TRANSPORT
OF RADIOACTIVE MATERIAL

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 1994
FOREWORD

The 1985 edition of the IAEA Regulations for the Safe Transport of Radioactive Material extended the requirements for quality assurance programmes to cover all aspects of transport.

A number of standards or codes specifying requirements for quality assurance have gained international recognition, including the IAEA Code on the Safety of Nuclear Power Plants: Quality Assurance. This Code was used as the basis for the previous guidance on the application of quality assurance published in the Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (1985 edition). More detailed advice is given in this publication for persons needing to develop quality assurance programmes that meet the requirements of regulations governing the safe transport of radioactive material.

All activities related to the safe transport of radioactive material should be covered by a quality assurance programme. This publication recognizes that a single transport operation often involves several different organizations, each having specific responsibilities. Hence, it is unlikely that the operation will be covered by a single quality assurance programme. Each quality assurance programme should be tailored to the specific organizational structure for which the programme is prepared, with account taken of the particular transport activities of that organization and the interfaces with other organizations. Furthermore, many small companies have business transporting radioactive material, frequently staffed by personnel who have no specialist training in quality assurance. The aim of this publication is to give a detailed interpretation of what must be done by whom to produce a quality assurance programme for radioactive material transport. A flexible approach is promoted such that, by selecting appropriate elements, readers can tailor a quality assurance programme for their particular application.

The IAEA wishes to acknowledge the contribution of C.J. Pecorer in preparing the original draft of the text.
This publication is no longer valid
Please see http://www-ns.iaea.org/standards/
1. INTRODUCTION

BACKGROUND

101. The importance attached to quality assurance (QA) was significantly increased in the 1985 edition of the IAEA Regulations for the Safe Transport of Radioactive Material [1] in recognition of the value of QA programmes in enhancing safety. Previously, the application of QA to the transport of radioactive material had been restricted to the manufacture of packaging whereas the 1985 edition of IAEA Safety Series No. 6 broadened the applicability of QA to all aspects of transport. When QA principles are applied to radioactive material transport operations it becomes possible to have all relevant aspects of the operations clearly identified, controlled and documented to ensure that those operations are carried out safely and in compliance with the Regulations.

102. It must always be recognized that the basic responsibility for achieving quality in performing a particular task (e.g. in design, manufacturing, consignment or carriage) rests with those assigned the task and not with those seeking to ensure by means of verification that it has been achieved.

103. The transport of radioactive material is often carried out by a large number of organizations; for example, the movement of one package alone may involve a designer, a test facility, a packaging manufacturer, a consignor, shipping agents, carriers and a consignee. Therefore it is likely that more than one separate QA programme will apply during a complete transport operation. Likewise, for the life cycle of a reusable package, which is similar to many other items or pieces of equipment, it is unlikely that a single QA programme will cover all of initial design feasibility work, design, testing (regulatory or other), manufacture, use, modification, servicing, maintenance and disposal.

104. Sometimes it is possible to identify one party or organization that is responsible for the whole transport operation. In this case it will be feasible to establish an overall QA programme. When it is not possible to clearly identify one responsible party or organization, then the interfaces between the QA programmes must be clearly understood and agreed by all parties.

105. If a package is to be used in a safe manner and in compliance with the Regulations throughout its life, QA needs to be appropriately applied during all phases of the life cycle, so that the approved design work, intent and definition are not later compromised, for example by subsequent misuse or incorrect maintenance operations. Each organization concerned should have an individual QA programme covering its activities. Contractual arrangements between organizations should not dilute or relieve organizations of their responsibilities.
OBJECTIVE

106. This publication provides guidance on methods and practical examples to develop QA programmes for the safe transport of radioactive material. It draws upon IAEA Safety Series 50-C-QA (Rev. 1) [2], which is extant, and Appendices IV and V of Safety Series No. 37 [3], which are superseded by this publication. The extent of the QA programmes will depend on the type of transport activities being considered, ranging from minor requirements for the infrequent consignor of excepted packages to extensive detailed requirements for regular consignors of packages subject to competent authority approval. This publication gives guidance on how to address each QA element for various types of transport activities.

SCOPE

107. This Safety Practice provides detailed advice for persons wishing to produce QA programmes that meet regulations for the safe transport of radioactive material. It promotes a flexible approach to the development of a QA programme and may be used to prepare such a programme for a specific application by selection of appropriate features.

STRUCTURE

108. Following the introduction (Section 1) this publication provides information on how to develop the programme (Section 2), the standards that could be used (Section 3) and the common features of a QA programme (Section 4). In addition, further details for users, with samples of specimen documented QA programmes and implementation procedures, are provided in the annexes, which cover: programme development (Annex I), references to standards (Annex II), QA programme descriptions for infrequent consignors and carriers (Annex III and IV), document control procedures (Annex V and VI), an internal audit procedure (Annex VII), a flask maintenance procedure (Annex VIII) and examples of poor interface control (Annex IX).
2. DEVELOPMENT OF
A QUALITY ASSURANCE PROGRAMME

GENERAL

201. This section introduces the considerations necessary to develop an appropriate QA programme for the transport of radioactive material. Such programmes are needed to meet national and international regulations applying to the individual organizations participating in the different phases of transport, namely:

— establishment of a transport need,
— design/use feasibility studies,
— design/specification engineering and product development,
— testing,
— procurement,
— manufacture,
— inspection, testing and examination,
— package preparation and despatch,
— transport operations (distribution, carriage, storage in transit),
— servicing and maintenance, including technical assistance,
— preparation for disposal of the packaging after use.

202. The different phases of transport are recognized and some comparisons are made between the types of organizations as well as the frequency/volume of their transport operations, to assist in the development of individual QA programmes.

203. As mentioned in Section 1, there can be several separate QA programmes in effect during transport (see Fig. 1). For the purpose of this section the development of a single typical QA programme will be covered. The starting point is the recognition by senior management that it is necessary to have such a programme. Only by such recognition and commitment on the part of management will it be possible for any QA programme to be successfully developed and maintained.

204. Following the necessary management decision to develop a QA programme, there is a need to study and review the organization’s objectives and the way in which they are achieved. The organization may acquire appropriate QA knowledge or expertise (either by initial QA awareness training of selected personnel or by engaging a suitable consultant) to ensure that the correct perspective of the application of QA is maintained.

205. Most organizations already have procedures (written or otherwise) covering the work that they do and the way that they do it. These procedures can be identified as administrative or technical implementing procedures associated with QA programmes.
FIG. 1. Application of QA programmes throughout the life of a package. Whilst this diagram illustrates the potential for several QA programmes to apply during the life of a package, some organizations may be involved in more than one activity and accordingly their QA programmes will cover those multiple activities. There may be more than one organization carrying out this activity, in which case each will have its own appropriate QA programme.

206. The next consideration should be the QA standard with which the QA programme should comply. It is good practice to declare in the policy statement or foreword of the QA programme exactly what standards that particular QA programme meets.

207. An initial draft description of the QA programme can now be produced. The documented QA programme for transport, which can be the whole or part of the
prescribed QA programme depending on the size and structure of the organization, should describe the methods and procedures used to achieve quality for all stages in the transport of radioactive material or the life cycle of a package relevant to the business of the organization. The organization should then have the appropriate parts of the documented QA programme (sometimes called the quality manual and procedures) issued to management, employees, suppliers and customers.

208. The long term success of the QA programme will depend on whether all personnel have an appropriate awareness and understanding of the objectives, principles and benefits of the QA programme functioning in their organization, and support its initial development. The programme should provide for training, as necessary, of personnel performing activities affecting quality to ensure that suitable proficiency is achieved and maintained.

209. After a predetermined period, the prescribed and functioning QA programme should be reviewed by management to establish the effectiveness of implementation. This is normally fulfilled by addressing the internal auditing criteria and the management review features found in most QA programme specifications or standards. It is particularly important that in the early stages of application and development of the QA programme these auditing functions and management reviews are carried out promptly and thoroughly so that (a) the overall programme can benefit where change is identified as necessary and (b) the programme can be seen to function in the desired manner. In some Member States, it may be necessary at this stage to obtain approval for the prescribed QA programme from the competent authority.

210. An example of time-scales for the development and implementation stages of a QA programme is given in Fig. 2.

211. The QA programme itself should be assisting in the control of all normal functions of the organization related to the assigned task by ensuring that:

(a) The management system, structure, organization and responsibilities are all prescribed;
(b) There are agreed written specifications of the standard of work to be done;
(c) There are written procedures covering how the work will be done to the required standard;
(d) Adequate records of objective evidence are produced to demonstrate that the required standards have been achieved;
(e) Audits are carried out confirming that the procedures are being complied with, the QA programme is creating the necessary objective evidence, and faults and deviations in a system or product are being investigated; and
(f) Feedback arising from investigation of audit findings, deviations, concessions, etc., is used to improve the QA programme and prevent the recurrence of problems.
212. By applying QA to the transport of radioactive material (or any other transport operation), the whole cycle of transport (of a package) can be examined and carefully managed by those carrying out the tasks (in part or whole) so that it is achieved in a safe and compliant manner. It also means that, by the creation of appropriate QA records, safety and compliance can be demonstrated to others.

213. Quality assurance will assist the management of any organization to have a better understanding and control of its business and operations, and thus more easily prevent the following examples of degraded transport safety or non-compliance:

- failure of packages in transport with potential loss of containment, shielding, etc.;
- failure to package a radioactive material properly;
- poor condition of packaging owing to lack of maintenance, especially in the case of exposure devices and source changers used for radiography purposes;
- failure to prepare, label or document packages properly;
- incorrect declaration of Transport Index for packages;
- failure to placard a vehicle correctly;

![Activity Diagram]

*FIG. 2. Example of implementation stages of a QA programme.*
— improper removal of placards and labels from vehicles;
— insecure stowage or improper handling of packages, resulting in loss and/or damage to packages;
— improper stowage of packages, inhibiting adequate heat dissipation;
— improper application of exclusive use shipment controls;
— failure to comply with conditions for special arrangement.

214. When a package develops a previously unknown or unexpected type of defect in service, the user’s QA programme should assist in:

(a) Early detection of the defect (by providing meaningful and effective in-service handling instructions, inspection and testing);
(b) Determination of the most appropriate corrective action;
(c) Review of the appropriate aspects of design, manufacture, use, testing, servicing, maintenance and transport operations to see what changes, if any, are necessary to identify and prevent similar occurrences;
(d) Implementation of any changes necessary in a controlled and recorded manner.

MINIMUM REQUIREMENTS FOR A QUALITY ASSURANCE PROGRAMME

215. Irrespective of the size of the organization or the scale of its activities, there are certain minimum requirements that must be addressed in any QA programme. Table I gives some guidance on the applicability of various QA criteria to the different types of organizations and their QA programmes.

216. With widely differing activities to carry out, a carrier’s management system will be different from that of, for example, a designer of packages. Each of their QA programmes should address some common QA criteria. It can be seen from Table I that all QA programmes need to have certain elements, such as organization and document control, addressed and described in a QA programme document, but that other elements do not always need to be featured. For example, in a carrier’s QA programme, design control is not usually relevant.

217. Where an organization is involved in more than one activity, e.g. design and manufacture, or is both user and carrier, the QA programme should reflect that multiple involvement and address the appropriate criteria. The types of organization or elements quoted in Table I are not intended to be exhaustive, but merely a general guide. Other organizations involved, such as test facilities or shipping agents, may possibly align themselves with one of the types mentioned or should consider their activities separately.
TABLE I. COMPARATIVE ELEMENTS OF A QA PROGRAMME

<table>
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a Care should be exercised in the interpretation and understanding of these elements. Reference should be made to the appropriate standard to ensure that all the requirements of the elements are clearly understood and included in the organization's QA programme.

QUALITY ASSURANCE AND THE DIFFERENT PHASES OF TRANSPORT

218. As mentioned earlier, an organization may be involved in more than one basic transport activity, e.g. design and manufacture, use and carriage, or even all phases from design through to carriage. The QA programme for any particular organization must be specially designed/developed to suit its needs and total activities, but for the sake of convenience individual phases of transport and applicable QA criteria are discussed in the following paragraphs.

219. Irrespective of the type of organization involved or the kind of activity it engages upon, there will be a need for the interfaces between that organization and others to be identified and controlled. Such interface identification and control should
be achieved during the application of QA and the development of the relevant QA programmes by the organizations involved. More information concerning interfaces is given in Section 4.

Package designers and testers

220. The designer of a transport package should be able to assure the manufacturer, user and certifying body as appropriate that all necessary steps and design processes have been addressed during all phases of design. For example, the designer needs the means to ensure that the final design specifications, drawings and procedures have been produced with account taken of regulatory requirements, design bases, codes and standards. The designer should also demonstrate that any proposed changes, modifications or deviations from the accepted design are carefully considered, justified, controlled, documented and implemented in a quality assured manner, as well as being consistent with, or better than, the controls applied to the original design.

221. If the designer is responsible for prototype manufacture and testing, the QA programme should ensure that any prototype packages, including perhaps scale models, are specified correctly and made exactly as required, and are consistent with the materials and fabrication methods used for production packages. The actual testing (regulatory proof testing) should also be accomplished in a quality assured way, using appropriate equipment and calibrated instruments working within their recognized capabilities and limits of accuracy. Only by controlling all design related activities can any subsequent manufacturer, user or certifying body have a reasonable assurance that the finished package complies with the designer's intent, and that any prototype package physically tested against the regulatory requirements is actually related to the finished product.

Package manufacturers

222. The manufacturer should have a QA programme which is capable of clearly demonstrating that the packaging has been manufactured strictly in accordance with the agreed specification prescribed by the designer or customer. All relevant aspects of manufacturing or production control should be addressed, including the planning of production, timely acquisition of necessary equipment, expertise, planned and sequential manufacturing and inspection arrangements, traceability and verification of materials and components throughout the manufacturing process, individual process controls and final product verification. Also, where production has deviated from the agreed specification, or modifications have been embodied, it should be ensured that this has been done in a controlled and authorized manner with appropriate reference to the designer or design authority, and with the necessary QA records being created.
Consignors

223. The consignor has to ensure that the package used for the transport operation is the correct one and is appropriate for its intended contents. The consignor should also ensure that the package is in a fit state to transport the material. A re-useable package should be properly serviced and maintained. The next maintenance should not fall during an actual transport operation. The user should ensure that a new package has been correctly made and prepared for transport.

224. The consignor very often prepares the material for loading/filling and carries out that operation, which for materials such as uranium hexafluoride or spent nuclear fuel must be done under carefully controlled conditions in accordance with detailed procedures. Similarly, the preparation of an industrial gamma radiography unit requires strict adherence to prescribed procedures to ensure radiological safety and compliance with the Regulations.

225. The consignor is also responsible for appropriate monitoring of the package before despatch as well as correct labelling of the package, overpack, freight container or tank. The consignor has to prepare the necessary transport documents and be aware of the difference between various national regulations when conducting international transport movements. If a separate carrier is to be used, the consignor should be satisfied that the carrier knows how to transport radioactive material safely and in compliance with the Regulations.

Users

226. Users of packages, who are frequently the owners/consignors of packages containing radioactive material, have a variety of tasks to perform in order to dispatch a package safely, and their QA programme should be appropriately designed with sufficient flexibility to achieve this.

227. Alternatively, the user sometimes prepares the material for loading/filling and conducts that operation under carefully controlled conditions in accordance with detailed procedures.

Carriers

228. There can be considerable differences in the type of work carriers engage in and consequently their QA programmes should be developed so as to be appropriate for their type of business.

229. Apart from a very few nuclear transport specialists, most carriers handle a variety of goods including many different categories of dangerous goods. Nevertheless, for the transport of radioactive material, the carrier has to ensure that the driver
(for road transport) is adequately trained and knows the regulatory requirements and how to comply with them.

230. The carrier should know what transport documents are required, what information they contain, what action to take in an incident or emergency, and how the vehicle or container should be placarded or labelled. Segregation distances frequently need to be determined to limit radiation exposures to people and undeveloped film.

COMPARISONS IN THE ESTABLISHMENT OF QUALITY ASSURANCE PROGRAMMES BETWEEN LARGE AND SMALL ORGANIZATIONS

231. Quality assurance requirements are independent of the size of a company, but a small company may be able to meet the QA requirements with a simpler organization and with less administration than a larger company. It does not matter whether the organization or company employs two or three people in the occasional transport of a few packages a year, or whether it employs hundreds of people and transports many thousands of packages a week. The differences will be only in the scale and type of QA programme to be developed and used. For example, a large company may need to have a relatively elaborate, well defined procedure for document control for work instructions or drawings. In contrast, a small company that only infrequently transports radioactive material may only need a simple procedure to issue up to date work instructions to one or two places of work. Similarly, a large manufacturing plant will need complex, well defined arrangements to ensure that up to hundreds of items of different measuring equipment are calibrated and capable of giving accurate measurements, whereas a small company using two or three different instruments may only need a brief procedure for their control. In all cases, safety is the fundamental consideration in determining to what extent the QA programme is to be developed.

232. It is not considered appropriate to provide specimen QA programmes for large organizations, since these will need to address many complex issues and responsibilities. However, it is possible to provide more practical guidance for the infrequent consignor as well as the infrequent carrier (see Annexes III and IV), who may not initially have access to expertise in QA at appropriate levels.

3. QUALITY ASSURANCE STANDARDS

301. Standards establish the fundamental requirements for QA programmes to achieve a common understanding and approach.
302. A competent authority may specify the acceptable standard or standards to be used in the development of QA programmes by industry. A number of different standards are compared in Annex II.

303. In developing or amending a QA programme for the transport of radioactive material, the user should seek guidance and direction from the competent authority concerning acceptable standards. It is acceptable for a user’s QA programme to be designed to meet the requirements of more than one QA standard. Some organizations develop their QA programmes to meet a range of relevant QA standards in order to obtain transport approvals.

304. A number of standards address the subject of QA. Some international standards are widely recognized, such as the IAEA Safety Series No. 50-C-QA (Rev. 1) and the ISO 9001 of the International Organization for Standardization [4]. There are also a number of national standards [5-7].

305. The various standards use different numbers of main sections or elements. The differences are not so significant, however, when the wording of the standards is compared, since one standard may well include more than one QA programme element within a main section whereas another standard will treat these elements separately.

306. These differences in the style and treatment of QA programme elements are usually traceable to the origin of the particular standards.

307. Some Member States have issued specific requirements for QA programmes in radioactive material transport, e.g. the Nuclear Regulatory Commission in the USA has issued its 10 CFR Part 71 Subpart H, Quality Assurance [8], which specifically addresses such transport related QA requirements. Other Member States have adopted Appendix IV of IAEA Safety Series No. 37 or other suitable national and international QA standards.

4. ELEMENTS OF A QUALITY ASSURANCE PROGRAMME

401. This section describes the activities which are typically covered in a QA programme in order to ensure compliance with applicable standards and regulatory requirements. Users will formulate their QA programme from elements of a chosen standard to meet specific requirements.
QUALITY ASSURANCE PROGRAMMES

Organization and structure of a QA programme

402. Management is ultimately responsible for establishing the quality policy and for the development and maintenance of the QA programme.

403. The organizational structure pertaining to the QA programme should be clearly established within the management of a company. The lines of authority and communication should be defined.

404. Activities contributing to quality, whether directly or indirectly, should be identified and documented, and the following actions taken:

(a) General and specific quality responsibilities should be explicitly defined;
(b) The responsibility and authority delegated to each activity contributing to quality should be clearly established; authority and responsibility should be adequate to ensure the assigned quality objectives with the desired efficiency;
(c) Interface control and co-ordination measures between different activities should be defined;
(d) Management may choose to delegate to nominated persons or other groups the responsibility for conducting some or all of the QA monitoring activities; however, the persons responsible for monitoring QA should not be engaged in the activities reported on, and should be provided with the necessary organizational authority to function effectively;
(e) In the organization of a well structured and effective QA programme, emphasis should be placed on the identification of actual or potential quality problems and the initiation of remedial or preventive measures.

405. Management should provide sufficient and appropriate resources for the implementation of quality policies and the achievement of quality objectives. These resources may include, but need not be limited to, the following:

— human resources and specialized skills,
— design and development equipment,
— manufacturing equipment,
— inspection, test and examination equipment,
— instrumentation and computer software.

406. Quality assurance is required to be applied to all packages, particularly packages as presented for transport, and also to shipping controls, including pre-dispatch checks and maintenance of packages, in order to ensure a state of continued compliance with requirements.

407. The design requirements and operational requirements of packages are interrelated and it is essential to identify the safety features of the items and components
that collectively comprise a package to ensure that appropriate QA procedures are applied and hence to minimize the probability of failure or malfunction of these items or components.

408. If appropriate, the structure of the QA programme can make due allowance for a ‘graded approach’ in the application of QA measures to both packages and contents, and can ensure that such measures are sufficiently stringent to ensure adequate control without being excessively severe. Any system for grading packages or components of packages should be based on their safety significance. An example of a three-tier grading system is given in the Appendix: Grade 1 items are those essential to safety, Grade 2 items are those with a significant impact on safety; and Grade 3 items are those with minor or no impact on safety.

**Documenting the QA programme**

409. All the elements, requirements and provisions adopted by a company for its QA programme should be documented in a systematic manner in the form of written policies and procedures. Such documentation should ensure a common understanding of quality policies and procedures (i.e. QA programmes/plans/manuals/records). An example of a documentation structure is given in Fig. 3. Care should be exercised in documenting the QA programme and its attendant procedures so as to keep documentation to a minimum and avoid creating a cumbersome or unnecessarily complex structure and set of procedures.

410. The size and complexity of the organization will have considerable influence on its QA programme and hence its documentation system. For example, a small, infrequent carrier of radioactive material may be able to condense or combine some of the levels to prescribe its QA programme more accurately; whereas a large, multi-divisional organization may need to have all the levels prescribed separately, with perhaps an additional level added to assist with divisional management.

411. To demonstrate that a documented QA programme has been fully implemented by appropriate written procedures and is contained in QA manuals, a master index of QA procedures related to all activities important to safety should be established. Those QA procedures should be consistent with the size/complexity of the organization involved. Measures should be included to ensure that current issues of applicable documents are available at the location where the activity is being performed to preclude the use of obsolete or superseded documents.

412. The typical form of the main document used in drawing up and implementing a quality programme is a quality manual, as shown schematically in Fig. 3. The primary purpose of a quality manual is to provide an adequate description of the QA programme while serving as a permanent reference in the implementation and maintenance of that programme.
413. Depending on the size of the company/organization and the scale of its transport related activities, and consistent with the requirements of its QA programme, individual plans (sometimes called quality plans) as shown in Fig. 3 may be produced which relate specifically to packages, products, services, processes or contracts. Quality plans should define:

(a) The quality objectives to be attained;
(b) The specific allocation of responsibilities and authority during the different phases of the project;
(c) The specific procedures, methods and work instructions to be applied;
(d) Suitable testing, inspection, examination and audit programmes at appropriate stages (e.g. design and development);
(e) A method for making changes and modifications as projects proceed;
(f) Other measures necessary to meet quality objectives;
(g) Records pertinent to the transport activity.

FIG. 3. An example of a documentation structure for a QA programme.
414. Quality records and charts pertaining to all aspects of the functioning QA programme are themselves important constituents that should be adequately documented and retained.

**Review and evaluation of the QA programme**

415. Provision should be made by the company management for periodic independent review and evaluation of the QA programme. Such reviews should be carried out by appropriate members of the company management or by competent independent personnel as decided on by company management. Reviews should consist of well structured and comprehensive evaluations which include:

(a) Findings of audits centred on various elements of the QA programme;
(b) The overall effectiveness of the QA programme in achieving stated quality objectives;
(c) Considerations for updating the QA programme in relation to changes brought about by new technologies, quality concepts and environmental conditions.

Findings, conclusions and recommendations reached as a result of review and evaluation should be submitted in documentary form for necessary action by the company management.

**ORGANIZATION**

**Management responsibility**

416. The responsibility for and commitment to a quality policy belongs to the highest level of management.

417. The management assigned to the task should develop and state its quality policy. This policy should be consistent with other company policies. Management should take all necessary measures to ensure that its quality policy is understood, implemented and maintained.

418. The quality policy can be defined in a separate document or as a foreword to the formal prescription of the QA programme. Objectives pertaining to key elements of quality such as fitness for use, performance, safety, reliability and compliance should be addressed in the quality policy statement.

419. Following from the quality policy and the statement of objectives is the definition or delineation of the QA programme. The QA programme must be structured and documented according to the needs of the tasks assigned. It should also take account of the appropriate elements of the chosen QA recommendations or other applicable recognized QA standards, as stated in Section 3.
420. The QA programme should function so as to confirm that:

(a) The programme is well understood and effective,
(b) The products or services actually do satisfy requirements,
(c) Emphasis is placed on problem prevention rather than on detection after occurrence.

Contract review

421. Procedures should be established to ensure that contracts placed with a supplier by a purchaser (usually the operator of the QA programme) are reviewed to verify that:

— the requirements and responsibilities are clearly defined,
— any requirements differing from those submitted to the client at tender have been identified and agreed on,
— the supplier has the capability to meet the requirements.

422. Contract reviews should be performed by the purchaser and should take account of the following:

— availability of staff and equipment,
— existing commitments,
— programme delivery,
— special requirements,
— special conditions, technical regulations and standards,
— previous problem areas.

Records of contract reviews should be maintained. (See also the discussion on records in paras 4106–4110.)

Organizational interfaces

423. The QA programme and associated procedures should provide for the recognition and control of interfaces (internal and external) wherever they occur; they should be sufficiently detailed that the transfer points for responsibility and operational physical control are clearly established and known.

424. It is vital that all people and organizations concerned in the transport of radioactive material have a clear understanding of their own interfacing responsibilities and limits of operation and control and also those of others. Such an understanding can be achieved by definition of responsibilities. Where internal interfaces occur, the organization should clearly identify them within its QA programme, possibly in the documentation/procedures for a particular activity. Where external interfaces occur, they should be identified and agreed upon and care should be taken to ensure that
responsibilities have been clearly defined in appropriate documents such as purchase orders, specifications and contracts.

425. Correct interface recognition and definition of responsibilities enable one organization or part of an organization to pass on a package or design knowing not only that its responsibilities and actions have been fully completed but also that the recipient of that package or design understands clearly what has and has not been done. Within a large/medium sized organization, correct definition and understanding of interfaces can prevent, for example, a package being dispatched before all the necessary checks such as package closure, leak test or labelling have been completed. Similarly, failure in design can result from inadequate communication (interface control) between the designer and user, with a package not meeting specified or regulatory requirements during test or use. This may occur because both parties have assumed, but not confirmed, that all necessary requirements have been taken into account by the other party in their interfacing activities.

426. Such actions will confirm that all aspects of the transport operation are under appropriate control, with no shortfalls in actions or responsibilities when a design, package or shipment is passed from one organization to another. Relevant interfaces may also exist between, for example, those involved in design and in carrying out modifications.

427. Interfaces between groupings such as design, testing and manufacture or consignor, user, carrier and consignee will frequently occur; however, other more infrequent interfaces should not be overlooked as these often create or add to problems and misunderstandings in transport.

Internal interfaces

428. Internal interface control is as important as external interface control. It is important within an organization that there be minimal overlaps but no gaps in responsibility or activity. It may be desirable in some aspects of package preparation and dispatch to have some deliberate overlap of activity serving as a verification check. Essential but unassigned tasks should not be carried out where no responsibility and hence no formal control exists. Therefore each of the different sections or departments of an organization should ensure not only that its internal interfaces are clearly understood, but also that they are recognized and described in procedures and instructions pertinent to that particular section or department.

External interfaces

429. External interfaces have wider implications and are analysed more carefully than internal interfaces as a result of pressures arising from considerations of commerce or prestige, etc. However, there is far more potential for external breakdowns
in communication and interface control than within a single organization. Different working methods and practices can create wider gaps in responsibility and control between organizations. Compliance with the Regulations can only be achieved in transport if the points at which responsibility and control are passed from one organization to another are clearly understood and agreed, and clearly defined in appropriate documented form (contractual documents, purchase documents, specifications, agreements).

430. The determination of and agreement on external interfaces is sometimes more complicated because several parts of one organization may be dealing with another organization simultaneously, e.g. a procurement section may be placing orders with a supplier while the design office may be negotiating specification details and the inspection section may be defining acceptance criteria with the same supplier. Unless all of these different external interfaces are recognized and controlled, problems could arise that could eventually compromise transport safety.

431. In consignor and carrier relations, definition and control of interfaces are of particular importance since the carrier must not only be provided with the necessary information as specified in para. 453 of the Regulations, but must also know whom to contact and how to contact them in the event of an emergency or incident. If there are two or more carriers concerned, as for example in a multimodal transport operation, the consignor, through the effective functioning of the QA programme, should ensure that there is sufficient understanding on the part of all the carriers and shipping agents of the normal and any special requirements applicable, including emergency arrangements and contacts.

432. External interfaces may also include relations with the competent authority and other approving/enforcing agencies. Such interfaces should be recognized, established and maintained by inclusion in the relevant QA programme to ensure that formal notifications required by the Regulations are correctly received within specified time-scales. They should also provide for the timely acquisition of information concerning changes to regulatory requirements and other issuances of the competent authority.

433. Some examples of poor interface control and attendant problems are given in Annex IX.

DOCUMENT CONTROL

Document preparation, review and approval

434. Consistent with the size and complexity of the organization and its QA programme, there should be a procedure or procedures for controlling all relevant
documents. The preparation, issue and control of documents should be such as to limit documentation to a minimum consistent with the degree of control necessary.

435. Document control measures should include the unique identification of each document, an indication of the document revision or issue status, and identification of the individuals or organizations who have the authority for:

- preparation of documents
- review of documents
- approval of documents
- changes to documents
- issue and distribution of documents.

Document control should be carried out on (but should not be limited to) the following:

- design documents (e.g. drawings, specifications and computer codes)
- procurement documents
- QA manuals
- operating, maintenance and modification procedures
- inspection and test procedures
- non-conformance reports
- design change requests
- corrective action reports.

Document release and distribution

436. Control of the release and distribution of documents should be in accordance with the appropriate procedure, using up to date distribution lists. The procedure used should ensure that persons needing the documents are made aware of, and use, the appropriate and correct documents.

Document change control

437. When documents are changed, the changes should be reviewed and approved as described in a documented procedure. The organizations reviewing the document should have access to appropriate background information and possess an adequate understanding of the requirements of the original document. Changes to documents should be reviewed and approved by the original review and approval organization or, alternatively, by a qualified organization that has been specifically designated for this purpose.

438. Information on document revision and status should be given to all persons affected by the change. Arrangements should be made to prevent the use of outdated and inappropriate documents.
DESIGN CONTROL

General

439. Control measures for the design process should provide for the translation of specified requirements (customer/user/regulator) into technical specifications, drawings, procedures or instructions for materials, products and processes. Measures should be established to ensure that: all design parameters, e.g. criticality physics, cooling and decontamination of an item, have been properly considered, reviewed and approved by the responsible design organization; that the parameters are in accordance with the applicable performance codes, standards and regulatory requirements; and that maintenance, repair, in-service inspection, handling, storage and cleaning requirements are specified in design documents. The final design specification should be such that the product or service is producible, verifiable and controllable under the relevant transport conditions.

440. The designer should consider the requirements relating to safety, environmental and other regulations, and design base codes and standards, including items in the company's quality policy which may go beyond existing regulatory or statutory requirements. Measures should be established to ensure that appropriate codes and standards are used in the design of the packaging. In the absence of such codes and standards for the formulation of design activities, alternative approaches should be identified.

Design planning

441. Management should specifically assign responsibilities for various design duties to activities inside and/or outside the organization and ensure that all those who contribute to design are aware of their responsibilities for achieving quality.

442. In its delegation of responsibilities for quality, management should ensure that design activities provide clear and definitive technical data for procurement, the execution of work and verification of conformance of products and processes to specification requirements.

443. Where two or more departments or organizations are involved in design, responsibilities should be clearly identified and defined in writing. Measures should be established to ensure that there is adequate communication of design information, including that relating to changes, in a controlled and documented manner between departments and organizations.
Design input

444. The quality aspects of the design should be unambiguous and should adequately define characteristics important to quality, such as acceptance and rejection criteria. Both fitness for purpose and safeguards against misuse should be considered.

445. The methods of measurement and testing and the acceptance criteria applied to evaluate the product and processes during both the design and production phases should be specified. Parameters should include the following:

- performance target values, tolerances and other attributes;
- acceptance and rejection criteria;
- test and measurement methods, equipment, bias and precision requirements, and quality of computer software.

Design output

446. The final design should be appropriately documented in specifications and drawings that define the design baseline. The total document package that defines the design baseline should undergo approval at appropriate levels of management within the organizations affected by, or contributing to, the product. This approval, which may also include appropriate competent authority approval, constitutes the production release and signifies agreement that the design can be realized.

Design verification

447. The design process should provide for periodic evaluation of the design at significant stages (ideally predetermined). Results from regulatory or proof testing that may be necessary should be incorporated into these evaluations. The results of all tests and evaluations should be documented regularly throughout the development and verification stages of the design.

448. At the conclusion of development of the design, a formal, documented, systematic and critical review of the design results should be conducted by the designer or designing authority. Participants in the design review should include representatives of all functions affecting quality. The design review should identify and anticipate problem areas and inadequacies and initiate corrective actions to ensure that the final design and supporting data meet the original design target specifications, as well as the requirements of the customer and the regulatory requirements. Such corrective actions should be documented and their implementation verified.

449. Design verification methods to be applied should be identified by the design organizations.
450. Design verification action may be taken independently or in support of design reviews by applying the following methods:

(a) Alternative calculations, to verify the original calculations and analyses.
(b) Testing, for example, by model or prototype tests. If this method is adopted, the test programmes should be clearly defined and the results documented, including any failures.
(c) Independent verification of the original calculations and/or other design activities.

451. Design activities should be documented to permit adequate evaluation by technical personnel other than those responsible for the original design.

Design changes

452. The QA programme should provide a procedure for controlling the change, release and use of documents that define the design baseline and for authorizing the necessary work to be performed to implement changes that may affect the product during its entire life cycle. The procedures should provide for various necessary approvals, specified points and times for implementing changes, removal of obsolete drawings and specifications from work areas, and verification that changes are made at the appointed times and places. Consideration should be given to instituting formal design reviews and validation testing if the magnitude, complexity or risk associated with the change warrants such actions.

453. During a design verification phase, changes to the final design may result. Consequently, measures should be established for ensuring that drawing and specification changes are reviewed and approved by the same individuals or organizations that reviewed and approved the original documents. Changes in design that could result in conditions different from those prescribed on the approval certificate should be approved by the competent authority before implementation. The changes should be subjected to the same design control measures as those applied to the original design.

454. The QA programme should ensure that any production and field experience indicating the need for design change is fed back for analysis. Care should be taken that design changes do not cause product/quality degradation and that proposed changes are evaluated for their impact on all product characteristics in the design baseline definition.

PROCUREMENT CONTROL

455. Purchased materials, components, assemblies and services become part of the company’s product (package contents, packaging or transport operation) and directly
affect the quality of this product. The quality of services such as calibration and special processes should be considered. The procurement of supplies should be planned and controlled. The purchaser should establish a close working relationship and feedback system with each supplier.

456. The purchasing procedures should include measures to control the following elements as applicable:

- requirements for all purchase documents including specifications, drawings and purchase orders;
- selection of qualified suppliers;
- agreement on QA levels;
- agreement on verification methods;
- provisions for settlement of non-conformances and corrective actions;
- receiving inspection plans;
- receiving controls;
- receiving quality records.

457. Systems and procedures should be established by which disputes concerning non-conformances and corrective actions can be resolved between suppliers and other organizations.

Supplier evaluation and selection

458. The purchaser should confirm that each supplier has a demonstrated capability to provide supplies which can meet all the requirements of the specifications, drawings and purchase order. Measures should be established to ensure that designated individuals or organizations evaluate proposed suppliers on the basis of the following criteria as applicable to the type of procurement:

- technical ability
- conformance to QA requirements
- production capability
- past performance.

459. Those responsible for procurement should develop appropriate methods to ensure that the requirements for the supplies are clearly defined and communicated and, most importantly, are completely understood by the supplier. These methods may include written procedures for the preparation of specifications, drawings and purchase orders, vendor/purchaser conferences before purchase order release, and other methods appropriate for the supplies being procured.
Purchasing data

460. The successful procurement of supplies begins with a clear definition of the requirements. Usually these requirements are contained in the contract specifications, drawings and purchase orders which are provided to the supplier.

461. Purchasing documents should contain data clearly describing the product or service ordered. Purchasing data may include the following:

- the type, class, style, grade or other precise identification;
- the title or other positive identification, and applicable issue of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;
- QA standards to be applied.

462. A clear understanding should be developed with the supplier on the QA levels for which the supplier is responsible.

Purchasing verification

463. Clear agreement should be reached with the supplier on the methods by which conformance to the purchaser's requirements will be verified. Such agreement can minimize difficulties in the interpretation of requirements as well as inspection, test or sampling methods.

464. Appropriate measures should be established to ensure that supplies which have been received are properly controlled. These procedures should include the use of quarantine areas or other appropriate methods to prevent unqualified supplies from being inadvertently used.

Purchaser supplied material

465. Any material, equipment or components supplied by the client to the supplier for incorporation into the final product should be suitably controlled. Procedures should be established to ensure that such material is verified for acceptability on receipt and suitably stored and maintained. Any such material that is lost, damaged or otherwise rendered unsuitable for incorporation into the final product should be recorded and notified to the purchaser.

MATERIAL CONTROL

466. All materials and parts should conform to appropriate specifications and quality standards before being introduced into production/service. Materials should be
appropriately stored, segregated, handled and protected during production/service to maintain their suitability. Special consideration should be given to shelf-life and deterioration control. Where in-plant traceability of material is important to quality, appropriate measures should be maintained throughout the production/service process to ensure identification of the original material and quality status.

467. The planning of operations should ensure that these proceed under controlled conditions in the specified manner and sequence. Controlled conditions include appropriate controls for materials, production equipment, processes and procedures, computer software, personnel and associated supplies. Operations should be specified to the necessary extent by documented work instructions.

468. All production equipment, including fixed machinery, jigs, fixtures, tooling, templates, patterns and gauges, should be tested for suitable accuracy and precision prior to use.

469. The handling, storage and shipment of materials, parts and components require proper planning and control and a documented system for incoming materials, materials in process and finished items including packages; this applies not only to initial delivery but also to use in transport operations. Provisions should be established to preclude damage or deterioration to the packaging and contents due to environmental conditions such as temperature and humidity.

470. Measures should be established to ensure adequate maintenance of packaging. Such measures should identify the items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection for each item.

PROCESS CONTROL

471. Consideration should be given to processes in which control is particularly important to product/service quality. Special consideration may be required for product/service characteristics that are not easily or economically measured, where special skills are required in operation or maintenance, or for a product/service or process which cannot be fully verified by subsequent inspection and test. Particular attention should be paid to computers used in controlling processes, and especially the maintenance of the related software. More frequent verification of special processes should be made to keep a check on:

(a) The accuracy and variability of equipment used to make or measure products/services, including settings and adjustments;
(b) The skill, capability, knowledge and certification, where appropriate, of operators to meet quality requirements;
(c) Special environments, age or other factors affecting quality;
(d) Certification records maintained for personnel, processes and equipment, as appropriate.
472. Those responsible for authorization of process changes should be clearly designated and, where necessary, appropriate approvals should be sought. As with design changes, all changes to production tooling or equipment, materials or processes should be documented. The implementation of such process changes should be evaluated to verify that the instituted change has had the desired beneficial effect upon product/service quality.

473. Inspections or tests should be considered at appropriate points in the process to verify conformance. Location and frequency will depend on the importance of the characteristics and ease of verification at the stage of production. In general, verification should be made as close as possible to the point of production of the feature or characteristic.

**Process control: transport**

474. There should be provisions for adequate control of packages and their radioactive contents during all relevant phases of transport operations.

475. Process control of transport operations may be accomplished, for example, by the use of a quality plan (as shown in Fig. 4) listing the sequence of actions/activities involved in the transport process, identifying responsibilities for those actions, referring to detailed procedures/specifications as appropriate, and identifying quality records to be produced at certain stages of the operations. Hold points may be identified within the sequence of actions to allow adequate verification at key stages of the process.

<table>
<thead>
<tr>
<th>Action/activity</th>
<th>Procedure</th>
<th>Responsibility</th>
<th>Records</th>
<th>Date, sign.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Check availability, maintenance status of equipment</td>
<td>Prd 02</td>
<td>OP</td>
<td>DOC/XX/...</td>
<td></td>
</tr>
<tr>
<td>2. Obtain approval</td>
<td>-</td>
<td>OP</td>
<td>Cert. of approval</td>
<td></td>
</tr>
<tr>
<td>3. Check approvals/package contents</td>
<td>-</td>
<td>EN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. HOLD - verify completion of 1, 2, 3 before proceeding to 5</td>
<td>-</td>
<td>RO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*FIG. 4. Example of part of a quality plan.*
476. Aspects of transports so controlled may include:
   - programming, co-ordination;
   - obtaining approvals;
   - regulatory formalities, notifications to competent authorities;
   - handling;
   - verification of package contents;
   - leak testing;
   - monitoring labelling;
   - preparation of transport documentation;
   - preparations for dispatch;
   - verification of maintenance status of packaging/vehicles.

477. All carriage, in-transit, storage and handling operations should also be appropriately controlled under documented QA programmes.

**Special processes**

478. Special process control should be applied to those processes where the required quality cannot be established solely by post-process inspection. Where such processes are to be performed, details of the process procedures should be submitted to the responsible group/organization for review/approval prior to commencement of work.

479. While commonly used in package manufacture, special processes such as welding, heat treatment or non-destructive testing are not normally performed by the users of packaging. However, if a packaging requires major repairs, the use of special processes may be necessary. Procedures should be established to ensure that the special processes are controlled in accordance with the following criteria:

(a) The process and procedures are capable of producing products of the specified quality;
(b) Procedures, equipment and personnel are qualified in accordance with applicable codes, standards and specifications;
(c) Where the processes are not covered by available standards or codes, the methods of qualification of personnel, procedures and equipment are defined;
(d) The operations are performed by qualified personnel and accomplished in accordance with written process sheets with recorded evidence of verification;
(e) Qualification records of procedures, equipment and personnel are established, filed and kept up to date.

480. In normal transport operations, all relevant aspects of contents and package preparation, servicing and maintenance, before-use inspection, packing methods, package closure and leak testing, contamination and radiation monitoring should be under appropriate documented control.
INSPECTION AND TEST CONTROL

481. All in-process and final inspections and in-service inspections associated with all prototype work, testing, manufacture, use, servicing and maintenance activities should be planned and specified. Documented procedures should be maintained, including the specific equipment to perform such checks and tests, as well as the specified requirement(s) and/or workmanship standard(s) for each quality characteristic to be checked.

482. Inspections of services provided should also be carried out and documented, and all relevant aspects of the service supplied should be verified against agreed specifications or other instructions.

483. Inspections of services and products should be carried out by people who, or organizations which, have no direct or conflicting responsibility for the activity under inspection, are suitably qualified to carry out such inspections, and can put into effect 'holding procedures' to prevent non-conforming items or services being used in transport.

484. Provisions should be made for appropriate testing of the package or its constituent parts during all phases of the package life cycle, in line with the applicable specifications, standards and regulatory requirements. Such testing, which may be carried out by one organization and hence under a QA programme, should include conceptual testing, regulatory proof testing for normal and accident conditions, material proving tests, manufacturing tests and in-service testing as well as servicing and maintenance tests. All such tests or test programmes should be fully documented and controlled with prescribed test conditions, equipment and acceptance criteria. All equipment used during testing should be appropriate to the parameters being checked, of known accuracy and calibrated.

485. The facilities of other qualified organizations may be used for measurement, testing or calibration services to avoid duplication or additional investment, provided that the necessary controls and traceability are maintained.

Programme of inspection

486. Measures should be established to ensure that inspection procedures, instructions or checklists include the following:

(a) Identification of characteristics and activities to be inspected;
(b) Acceptance and rejection criteria;
(c) Identification of the individuals or groups responsible for performing the inspection operation;
(d) Recording of objective evidence of inspection results;
(e) Identification of hold or witness points;
(f) Approval of data by the supervisor to ensure that all inspection requirements have been satisfied;
(g) The prerequisites to be satisfied prior to inspection, including operator qualification and equipment calibration.

487. Receiving measures should be established to ensure that items important to safety (i.e. those features under control of the QA programme and necessary to ensure the integrity of the packaging or its capability to prevent the release or mitigate the consequences of the release of radioactive material) meet the requirements specified. Also, provisions for the control of accepted items until they are placed in stock or released for use and provisions for the proper disposition of rejected items should be established.

488. In-process measures should be established to ensure that process specifications and their supporting documents provide for indirect control by monitoring processing methods, equipment and personnel if direct inspection is impractical.

489. Final inspection measures should be established to ensure that inspection provides for correcting non-conformances identified in earlier inspections, that the inspected item is identifiable and traceable to specific records and is adequately protected from physical damage, and that supervisors review inspection records to verify that all inspection requirements have been satisfied.

490. Measures should be established to ensure that: inspectors are qualified in accordance with applicable codes, standards and company training programmes; such qualifications and certifications are kept up to date; and inspection personnel are independent of individuals performing the activity being inspected.

**Test programme**

491. Measures should be established to ensure that applicable test programmes, including prototype qualification tests, production tests, proof tests and operational tests, are accomplished in accordance with written procedures. Measures should be established to ensure that modifications, repairs and replacements are tested in accordance with the original design and testing requirements.

The following items may be included in typical tests of transport packages:

- structural integrity
- leaktightness (on containment vessel as well as auxiliary equipment)
- component performance
- shielding integrity
- thermal integrity.
492. Measures should be established for ensuring that test prerequisites identified in the appropriate design disclosures (instrument calibrations, monitoring to be performed, mandatory hold points, suitable environmental conditions to be maintained, condition of the test equipment, methods for physical identification of test specimen, methods for documenting or recording test data and criteria for acceptance) are properly transplanted into test procedures.

493. Measures should be established to ensure that test results are documented and evaluated and that their acceptability is determined by a qualified individual or group.

**Calibration and control of measuring and test equipment**

494. Measures should be established for ensuring that measurement and test equipment (e.g. gauges, fixtures, reference standards and devices used to measure product characteristics) are calibrated, adjusted and maintained at prescribed intervals or prior to use. The measuring and test equipment should be labelled or tagged to indicate the planned date of its next calibration, and the calibration records should be identified and traceable. Measures should be established to ensure that in-house reference or transfer standards used in calibrating measuring and test equipment are traceable to nationally recognized standards. Calibrating standards should have known valid relationships to nationally recognized standards. If no known recognized standard exists, the basis for calibration should be documented.

495. Measures should be taken to validate previous inspection and test results up to the time of previous calibration when test and measuring equipment is found to be out of calibration. If any measuring equipment is consistently out of calibration, it should be repaired or replaced.

**NON-CONFORMANCE CONTROL**

496. Non-conformances may occur when an item, operation (manufacturing, transport, etc.) or service does not comply with specifications or applicable working procedures. Such procedures should clearly identify responsibilities for reviewing non-conformances and the use of non-conformance forms and may provide examples of markings to be applied to non-conforming items.

497. The steps for dealing with non-conformances should be set out in documented procedures. Non-conformances should be immediately identified and the occurrence(s) recorded. Whenever possible, provision should be made to examine previous production items or batches, or the conduct and results of previous operations or services.
498. The non-conforming items should be segregated, wherever possible, from conforming items and adequately identified to prevent further use until the appropriate action is taken. Similarly, non-conforming operations or services should be suspended until appropriate decisions are made.

499. Non-conforming items should be subject to review by designated persons to determine whether they can be used as they are or whether they will be accepted or repaired, reworked, reclassified or scrapped. Likewise, unsatisfactory operations or services should be reviewed to determine where changes or improvements are necessary. Consideration should be given to obtaining competent authority agreement if proposed changes or waivers affect existing approvals of packages, shipments, etc.

4100. Non-conforming items should be accepted, reworked or rejected as soon as practicable in accordance with the decisions made. Decisions on non-conformances should be documented, justified and authorized. Appropriate steps should be taken to prevent the recurrence of non-conformances. Consideration should be given to establishing a file listing non-conformances to help identify those problems having a common source, in contrast to those that are unique occurrences.

4101. The description of changes, waivers or deviations that have been ‘passed’ should be documented to denote the as-built condition of an item or the authorized change to a transport operation or service.

CORRECTIVE ACTIONS

4102. The implementation of corrective action begins with the detection of a quality related problem and requires measures to eliminate a problem or to minimize its recurrence. The responsibility and authority for instituting corrective action should be defined as part of the QA programme. The co-ordination, recording and monitoring of corrective action related to all aspects of the organization or a particular product or service should be assigned to a particular function within the organization. However, the analysis and execution may involve a variety of functions, such as design, production and quality control. The significance of a problem affecting quality should be evaluated in terms of its potential impact on such aspects as safety, production, quality, performance, reliability, compliance and customer satisfaction.

4103. In the analysis of a quality related problem, the root cause should be determined before the preventive measures are planned. Often the root cause is not obvious, and careful analysis is therefore required of the product or service specifications and of all related processes, operations, quality records, service reports and customer complaints, with subsequent reporting to appropriate levels of management for the initiation of change.
4104. In order to prevent a future recurrence of a non-conformance it may be necessary to change a manufacturing, packing, transport, transit or storage process, revise a quality document (e.g. procedure or plan) and/or revise the QA programme. Controls of processes and procedures should be implemented to prevent recurrence of the problem. When the preventive measures are implemented, their effect should be monitored in order to ensure that desired goals are met. Measures should be established to ensure that the acceptability of non-conforming items is verified by re-inspecting or retesting the item against the original requirements after designated repair or rework. The final disposition of non-conformances should be identified and documented.

4105. Permanent changes resulting from corrective action should be recorded in quality documents. It may also be necessary to revise the procedures used to detect and eliminate potential problems.

RECORDS

4106. The QA programme should include written procedures for identifying, collecting, indexing, filing, storing, maintaining, retrieving and disposing of pertinent quality documentation and records. Consideration should be given to records required from a supplier and to those which should be made available to customers. Records required from a supplier (and retention times if necessary) should form part of the procurement specification.

4107. The records should adequately demonstrate the achievement of the required quality of the product or service. Quality assurance standards require that certain activities be documented, such as management reviews, audits and non-conformances. Records of these should also be maintained in order to demonstrate the effective operation of the QA programme. All necessary records should be legible, dated (including revision dates), clean, readily identifiable and maintained in a good condition and in an orderly manner, so as to be readily retrievable.

4108. The following are examples of the types of quality records which may require control:

- inspection reports
- test data
- qualification reports
- validation reports
- audit reports
- material review reports
- calibration data
- fabrication records
— servicing records
— maintenance reports
— consignment documents
— training records
— radiation monitoring reports
— package approval certificates
— management review reports
— contract review records.

Where quality records need to be retained, this should be for a defined period. Record retention periods may vary according to importance and the need for future reference, e.g. package manufacture and modification records should be available for the life of the package whereas it may be appropriate to keep records of individual transport movements for shorter periods. Retention periods and the means of disposing of records should be included in appropriate procedures. Similar quality records may be required from subcontractors in order to demonstrate overall product or service quality.

4109. The owner or user of a packaging should establish and maintain appropriate service and maintenance records for each packaging. The records of QA measures for each individual packaging should be maintained and may be referred to in a log-book which should be available for inspection. The log-book should contain appropriate references to the following information and records (in parentheses):

(a) Competent authority approval of the package design and the individual packaging serial number (package design number and packaging serial number);
(b) Operating and maintenance instructions (instruction reference number);
(c) Certificate of conformance or commissioning certificate, including a summary of the applied test procedures (certificate number);
(d) Test procedure for reinspection tests (procedure reference number);
(e) Certificates of reinspection tests (certificate number);
(f) Movement or transport record of the package (actual record);
(g) Authorized modifications to the packaging (modification numbers or certificates);
(h) Record of significant damage and subsequent repairs (damage/repair certificate numbers).

4110. When a packaging is to be serviced or maintained at a point remote from the location of the detailed records mentioned, the owner or user should make available such information as may be required for satisfactory accomplishment of servicing or maintenance tasks.
STAFF TRAINING

4111. The need for personnel training should be assessed and a method for providing that training should be established. Consideration should be given to providing training to personnel at all levels within the organization. Particular attention should be given to the selection and training of recruited personnel and personnel transferred to new assignments.

4112. The need for quality should be emphasized through an awareness programme which may include induction and elementary programmes for new employees, periodic refresher programmes for long-service employees, provision for employees to initiate corrective actions and other methods.

4113. Care should be given to training which will provide management with an understanding of the QA programme together with the requisite skills and techniques needed for full participation in the operation of the QA programme. Management should also understand the criteria available for evaluating the effectiveness of the programme.

4114. Training should be given to technical personnel to enhance their contribution to the success of the QA programme. Training should not be restricted to personnel with primary quality assignments, but should include assignments such as procurements and process and product engineering. Where the complexity of the QA activities warrant it, particular attention should be given to training in statistical techniques, such as process capability studies, statistical sampling, data collection and analysis, problem identification, problem analysis and corrective action.

4115. All production supervisors and workers should be thoroughly trained in the methods and skills required to perform their tasks. The proficiency of the personnel should be maintained by retraining, re-examining and recertifying. Personnel performing functions important to safety, for example inspecting and testing, should be qualified on the basis of their abilities gained through education, training and experience. Records of persons performing functions important to safety should include the basis on which an individual is qualified to perform a required function.

4116. For personnel performing special processes, for example non-destructive examinations or welding, measures should be established for obtaining proof of their certification to perform the process, the period during which their certification remains in effect, and the conditions under which recertification would be required. Qualification and certification of non-destructive testing personnel should be accomplished on the basis of guidelines established by recognized authorities.
SERVICING

4117. Measures should be established for a servicing/maintenance/inspection programme for all packaging, transport related equipment, conveyances, materials, parts and components to ensure their continued suitability in the safe transport of radioactive material. The items or features to be serviced/maintained/inspected should be identified and the acceptance criteria, the replacement/repair criteria and the frequencies should be assigned in all cases. Procedures should be established for carrying out such servicing and should detail the method for verifying conformance to the specified requirements.

AUDITS

Elements of audit programme

4118. A comprehensive audit programme should confirm: the authority to audit and the organizational independence of the auditors; identification of audit personnel and their qualifications; provisions for reasonable and timely access of audit personnel to facilities, documents and personnel necessary for performing audits; use of checklists; methods for reporting audit findings to responsible management of both the audited and auditing organizations; provisions for access by the audit team to levels of management that have responsibility and authority for corrective action; and methods for verification that effective corrective action has been accomplished on a timely basis.

Scheduling of audits

4119. Schedules for internal and external audits should be established. Measures should be established to ensure that key activities of the QA programme are given priority. For internal audits, the schedules should identify the level of management designated to assess the overall effectiveness of the in-house QA programme described. The activities important to safety to be included in the audit programme should be identified.

4120. Internal audits of the applicable elements of the QA programme should be made at predetermined intervals.

4121. External audits of the elements of the QA programme of a major supplier should be audited on a predetermined basis. Auditing should begin when sufficient work is in progress to demonstrate implementation of a QA programme.
Team selection

4122. The responsibilities of the audit team members and the lead auditor with respect to evaluation and the issuance of audit reports should be specified. It is the responsibility of the auditing organizations to establish qualifications for prospective audit personnel and the requirements for the use of technical specialists to accomplish auditing activities important to safety. Specific guidance for determining qualifications for individual auditors and lead auditors is contained in Ref. [9].

Pre-audit meeting

4123. The nature and scope of the pre-audit meeting between the management of the organizations being audited and the team conducting the audit should be specified prior to an audit. The purpose of the meeting should be to confirm the scope and planned dates of the audit, to discuss the sequence of the audit, to set the time for the post-audit meeting and to establish channels of communication.

Post-audit meeting

4124. Measures should be established to conduct a post-audit meeting between the audit team and the management of the audited organization to present the results and clarify misunderstandings.

Reporting and response

4125. Measures should be established to identify the time constraints imposed for issuing audit reports and the requested date for corrective action response by the audited organization. The response should clearly state the corrective action taken to prevent recurrence of non-conformances. In the event that corrective action cannot be taken immediately, the response of the audited organization should include scheduled dates for initiation and completion of the corrective action.

Follow-up action

4126. The audit team leader should verify that the audited organization provides a timely response to the audit report, that the response is adequate, and that the corrective action has been accomplished within the prescribed schedule.
Appendix

GRADED APPROACH

The following examples of detailed requirements illustrate the application of a graded approach to QA.

*Grade 1* items would be those directly affecting package leaktightness or shielding, or for packages of fissile material, those directly affecting geometry and thus criticality control.

*Grade 2* items would be structures, components or systems whose failure could indirectly affect safety in combination with a secondary event or failure.

*Grade 3* items would be those affecting structures, components or systems whose malfunction would not affect the packaging effectiveness and so would be unlikely to affect safety.

For *Grade 1* items:

(a) The design should be based on applicable industrial standards or codes, and design verification should be accomplished by design review, by prototype testing or by the use of calculations or computer codes.
(b) The procurement documentation for materials or services should specify that only approved suppliers are used.
(c) The manufacturing planning should specify traceability of raw materials and the use of certified welders and processes.
(d) Test and inspection work should require the use of qualified test methods and qualified inspectors to verify conformance to specified standards and codes.
(e) Audits should be carried out only by qualified and nominated personnel.
(f) Acceptance after manufacture and authorization of use of such items should be made only by the consignor or a nominated representative of the consignor.

For *Grade 2* items:

(a) The design should be based on applicable industrial codes and standards; design verification may be through the use of calculations or computer codes.
(b) Specified processes need to be carried out by certified personnel.
(c) Tests and inspections should require the use of inspectors qualified to verify conformance to appropriate codes, standards or industrial specifications.
(d) The lead auditors need to be properly qualified and nominated personnel.

For *Grade 3* items:

(a) In general, the design needs to follow accepted engineering or industrial practice in which items would be standard ("off the shelf" or proprietary). All items would be subject to inspection to confirm acceptability for use.
RELATIONSHIP OF GRADING TO PACKAGE TYPE

The level of QA applied to a package can be commensurate with the hazard posed by the radioactive contents.

The following guidance applicable to each category of package listed is not intended to cover all situations. However, it gives a general indication of the level of QA to be aimed at. Clearly, higher grades than those suggested may be used, and should be considered especially for those packages designed for radioactive materials having other significant dangerous properties (subsidiary hazards), such as uranium hexafluoride.

Excepted packages and industrial package Type 1 (IP-1)

In the determination of the radioactive contents and package radiation levels, the instrumentation and processes used should be subject to QA at Grade 1. In all other aspects, such as design, manufacture, etc., Grade 3 should be applied.

Non-fissile Type A packages and industrial package Types 2 and 3

Matters affecting shielding integrity and containment should be subjected to QA at Grade 1. All other matters should be subjected to Grade 2 except where there is minimal effect on safety, in which case Grade 3 is appropriate.

Special form radioactive material

In all matters affecting compliance with the special form radioactive material requirements, QA at Grade 1 is appropriate.

Fissile packages (other than Type B packages)

In the case of criticality assessment and other factors affecting the assumptions in the criticality assessment, QA at Grade 1 is appropriate. All other aspects should be subjected to Grade 2 except where there is minimal effect on safety, in which case Grade 3 is appropriate.

Type B packages (non-fissile and fissile)

In all aspects contributing to the integrity of shielding and containment together with criticality safety (where applicable), QA at Grade 1 is appropriate. All other aspects should be subjected to Grade 2 except where there is minimal effect on safety, in which case Grade 3 is appropriate.
Shipments and special arrangements

Quality assurance should be applied to shipments and special arrangements according to the individual features of each case.
This publication is no longer valid
Please see http://www-ns.iaea.org/standards/
Annex I

TWO COMPARATIVE EXAMPLES OF QUALITY ASSURANCE PROGRAMME DEVELOPMENT

The table in this annex is intended to assist the developer of a QA programme to identify the appropriate scale and complexity of the programme.

Care should be taken in the interpretation of the table as the frequency of transport, package type and organization size all have an influence on the QA programme.

<table>
<thead>
<tr>
<th>QA elements (From IAEA Safety Series No. 50-C-QA)</th>
<th>Small industrial type packages, transported infrequently by small simple organizations</th>
<th>Larger Type B packages, transported frequently by large complex organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA programmes</td>
<td>Simple programme. Single-tier documented system</td>
<td>Comprehensive programme including an interrelated and detailed multitiered structure</td>
</tr>
<tr>
<td>Organization</td>
<td>Simple company structure/responsibility chart, key personnel/positions. Simple work instructions. Training measures and interface definitions</td>
<td>Multidivisional function and organization, corporate and divisional responsibilities. Specialist support departments, detailed internal/external interface definition, multilevel work instructions and a comprehensive training programme</td>
</tr>
<tr>
<td>Document control</td>
<td>Simple procedural system involving a small number of documents and simple controls</td>
<td>A more fully prescribed integrated system involving a large number of documents, formal controls, database management, filing and indexing, approval, review, internal interdepartmental and external release controls, departmental document interface controls and responsibilities</td>
</tr>
<tr>
<td>Design control</td>
<td>System of design verification relative to the complexity of the product</td>
<td>A comprehensive system of authorization/verification/interface activities and approval</td>
</tr>
<tr>
<td>QA elements</td>
<td>Small industrial type packages, transported infrequently by small simple organizations</td>
<td>Larger Type B packages, transported frequently by large complex organizations</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Procurement control</strong></td>
<td>Simple purchase orders, requisitions and supplier evaluation</td>
<td>A comprehensive system of supplier evaluation and auditing plus comprehensive purchase specifications</td>
</tr>
<tr>
<td><strong>Control of items</strong></td>
<td>Simple systems covering the identification, control, handling, storage and shipping of items. Simple maintenance instructions</td>
<td>A comprehensive system of controls covering the identification and control of all materials, parts and components, including handling, storage and shipping. Comprehensive programme of planned maintenance of packaging</td>
</tr>
<tr>
<td><strong>Process controls</strong></td>
<td>Single tier of control documents and instructions</td>
<td>Multitier documented system of procedures, work instructions and quality plans</td>
</tr>
<tr>
<td>(includes manufacturing and use of items)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inspection and test control</strong></td>
<td>Simple facilities and system of inspection/testing. Simple calibration system and controls</td>
<td>Comprehensive integrated systems under direct control and related to specific in-house test and calibration procedures</td>
</tr>
<tr>
<td><strong>Non-conformance control</strong></td>
<td>A simple system to carry out those controls affecting company activities</td>
<td>A comprehensive system describing in detail how to control company activities and systems</td>
</tr>
<tr>
<td><strong>Corrective actions</strong></td>
<td>Simple system of control to recover and prevent the continuance of non-conforming situations</td>
<td>A comprehensive integrated multilevel system of controls affecting internal and external systems and operations</td>
</tr>
<tr>
<td><strong>Records</strong></td>
<td>Simple system of collection, storage and retrieval of documented records</td>
<td>A comprehensive system of collection/collation/storage/retrieval of a wide range of appropriate documented records</td>
</tr>
<tr>
<td><strong>Audits</strong></td>
<td>A simple system of auditing quality activities</td>
<td>A comprehensive system of internal and external audits</td>
</tr>
</tbody>
</table>
Annex II

REFERENCES TO EXAMPLES OF QUALITY ASSURANCE STANDARDS

<table>
<thead>
<tr>
<th>QA elements and subelements from this publication (see Section 4)</th>
<th>Referenced QA standards and their paragraph numbers</th>
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<tbody>
<tr>
<td></td>
<td>IAEA SS No. 37 [9]</td>
</tr>
<tr>
<td>QA programmes</td>
<td>IAEA SS 50-C-QA [1]</td>
</tr>
<tr>
<td>Organization and structure of a QA programme</td>
<td>ISO 9001 (EN29001) [2]</td>
</tr>
<tr>
<td>Documentation of a QA programme</td>
<td>BS 5882 [5]</td>
</tr>
<tr>
<td>Review and evaluation of the QA programme</td>
<td>ASME NQA-1 [6]</td>
</tr>
<tr>
<td>Organization</td>
<td></td>
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<tr>
<td>Management responsibility</td>
<td>2.1 2 4.2 4.2 2</td>
</tr>
<tr>
<td>Contract review</td>
<td></td>
</tr>
<tr>
<td>Organizational interfaces</td>
<td>2.1 2 4.1.3 4.2 2</td>
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<td>Document control</td>
<td></td>
</tr>
<tr>
<td>Design control</td>
<td>4 4 4.5 9 6</td>
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<tr>
<td>Procurement control</td>
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<tr>
<td>Purchaser supplied material</td>
<td>6 6 4.6 7 4</td>
</tr>
<tr>
<td>Material control</td>
<td>6.3 6 4.7 10 7</td>
</tr>
<tr>
<td>Process control</td>
<td>7.1 7 4.8, 4.12 11 8, 13</td>
</tr>
<tr>
<td>Inspection and test control</td>
<td></td>
</tr>
<tr>
<td>Control of measuring and test equipment</td>
<td>8 8 4.9 12</td>
</tr>
<tr>
<td>Non-conformance control</td>
<td>9 9 4.10 13, 14 10, 11, 14</td>
</tr>
<tr>
<td>Corrective actions</td>
<td>11 10 4.13 18</td>
</tr>
<tr>
<td>Records</td>
<td>12 11 4.14 19</td>
</tr>
<tr>
<td>Staff training</td>
<td>13 12 4.16 20</td>
</tr>
<tr>
<td>Servicing</td>
<td>14 3 4.18 5.3</td>
</tr>
<tr>
<td>Audits</td>
<td>9 9 4.19 13.5 13S1</td>
</tr>
<tr>
<td></td>
<td>15 13 4.17 21</td>
</tr>
</tbody>
</table>

* Care should be taken in the use of this table; in particular the wording of elements differs between the standards.*
Annex III

EXAMPLE OF A DOCUMENTED QUALITY ASSURANCE PROGRAMME DESCRIPTION FOR AN INFREQUENT CONSIGNOR

<table>
<thead>
<tr>
<th>Prepared:</th>
<th>Ref:</th>
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<tr>
<td>Checked:</td>
<td>Issue:</td>
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<tr>
<td>Approved:</td>
<td>Page</td>
</tr>
</tbody>
</table>

POLICY

It is the policy of ABC Ltd to consign radioactive material (RAM) in a safe manner in accordance with the QA programme.

NATURE AND SCOPE OF ACTIVITIES

ABC is a consignor of radioactive sources at infrequent intervals throughout the country. The actual transport of the RAM is carried out using our own vehicles or is contracted out to specialist transport organizations.

ORGANIZATION

The company employs two staff in the consignment of RAM. The two staff are the manager-director (who is responsible for these operation) and in his/her absence the assigned deputy. The management structure diagram shows the two above persons and their responsibilities in the RAM transport business. The services of consultant or professional advisers are sought as and when required and a current listing of professional experts is maintained.

DOCUMENT CONTROL

Each document pertinent to the operation of this QA programme is controlled and is designated as a ‘CONTROLLED DOCUMENT’. Each such document is maintained in a control file. Procedures and work instructions are approved for use by the managing director and are controlled by date and issue number.

1 In this and other annexes, where appropriate, it is understood that the check box or check list should appear at the top of each page of the document.
PROCUREMENT CONTROL

ABC Ltd controls the purchases of all relevant goods and services in a manner designed to ensure compliance with regulations. ABC Ltd only uses companies recognized as competent suppliers of goods or services whose QA arrangements are subject to third party assessments. We specify in our purchase orders that suppliers should supply their goods/services in a quality assured manner (either by working to their own independently verified QA system or by an agreed QA plan). A list of the suppliers is maintained for reference.

MATERIAL CONTROL

Packaging material is controlled according to identified procedures. These procedures cover the identification of packaging codes and specification, and the storage, use, inspection, test, servicing, maintenance, opening and closure of packaging and packages. Materials for consignment are similarly treated.

INSPECTION AND TEST CONTROL

The packaging used for consignment may remain in store and unused for extended periods. The packagings are inspected and where appropriate tested according to the schedules of the manufacturers/suppliers during storage or before use to confirm their continued acceptable condition. Any defects found are recorded and assessed to ensure that the packaging is acceptable for use. Should repair or reconditioning be required, the packagings are normally returned to the manufacturer or supplier for the work to be done. Alternatively, the work may be undertaken by an acceptable repairer. Prior to the despatch of any item containing RAM, the package is monitored to determine the transport index and assign the category label. Measurement and test equipment used by this company is subject to regular calibration. This calibration is controlled by the requisite procedures as defined by the manufacturer, at intervals not exceeding fourteen months. Records of instruments are kept, including their serial numbers, calibration status and usage.

CONTROL OF USE AND CARE OF PACKAGES

Packages are subject to control at all stages to comply with regulations to prevent deterioration and any hazard to the safe transport of RAM. Procedures for preparation, servicing/maintenance, opening, filling, closure and use/operation of packages are available as supplied by the relevant manufacturer, the agent of the manufacturer or this company as appropriate.
NON-CONFORMANCE CONTROL

Procedures for the control of items, services and documents that do not conform to specified requirements should be subjected to the reporting, segregation and identification of the non-conforming aspects.

CORRECTIVE ACTIONS

Procedures for the provision and implementation of corrective actions (which may stem from errors found at internal audits, deviations and non-conformance in consignment, carriage, use, inspection and test) are put into effect by designated personnel.

RECORDS

Records to support and demonstrate compliance with regulatory requirements and the satisfactory functioning of this QA programme are filed and maintained. Mandatory shipping certificates and other quality related documents, such as calibration, test, inspection and audit data, are included within these records.

STAFFING AND TRAINING

It is the policy of this company to employ persons of the requisite skills, knowledge, education and training to carry out their specific tasks safely and in compliance with the regulations. To achieve this, those staff directly concerned with activities involving radioactive material transport receive specific training in the regulations and in the arrangements for this QA programme. All staff are trained in company procedures as and when required. Training may either be in-house, on the job, or by a specific external course depending on need. Training procedures are formulated and records are maintained of each individual’s training and proficiency.

AUDITS

Internal audits are conducted on all of our operations at specified times and intervals depending on the volume of business. The aim of these audits is to determine any deficiencies and non-conformances and recommend and implement corrective actions.
Annex IV

EXAMPLE OF A DOCUMENTED
QUALITY ASSURANCE PROGRAMME DESCRIPTION
FOR AN INFREQUENT CARRIER

Prepared: Ref:
Checked: Issue:
Approved: Page

POLICY

It is the policy of our company to provide a transport service to our customers and to perform this in a safe manner in compliance with the regulations.

NATURE AND SCOPE OF ACTIVITIES

The service we provide is a wide ranging and diversified transport operation to carry packages and items of many types employing vehicles and drivers and office staff. This is shown on our management structure diagram. There are occasions when we are required by a customer to transport radioactive material (RAM), approximately ... times per year. This is deemed to be an infrequent operation and an irregular aspect of our business. It is, however, our policy to apply quality assurance (QA) to this area of our activities.

ORGANIZATION

The responsibility and authority of the personnel who manage, perform and verify work in relation to the RAM transports are defined.

Measures are taken to identify and record quality problems and to implement solutions through designated channels, by verification, inspection and auditing of our documented programme.

Responsibility for implementation and maintenance of the quality programme is defined.
CONTRACT REVIEW

Procedures exist for the verification of incoming contracts/orders, to verify that responsibilities and requirements are clearly defined and that we have the capability to meet these requirements.

DOCUMENT CONTROL

There are procedures for the control of documents used by this company. Most of these documents (or copies thereof) are maintained for reference purposes, but for RAM transport operations records will be separately or clearly identified and any statutory or regulatory records will be similarly maintained.

The procedures provide for all aspects of control of documents, including review, approval, issue/distribution and modification.

PROCUREMENT CONTROL

Procedures control the procurement of items and services used in relation to RAM transport which may directly or indirectly affect the safety of this transport and compliance with the regulations.

PROCESS CONTROL

All activities of the transport are controlled through the use of quality plans.

INSPECTION AND TEST CONTROL

Procedures for the examination of packages are produced as required in the execution of our business but are normally limited to the following aspects: (1) correct labelling — the presence or absence of requisite labels; (2) ensuring that packages are undamaged, correctly sealed and fit for transporting.

CONTROL OF USE AND CARE OF PACKAGES

There are procedures for the control of use and care of packages but they are currently limited to the following: stowage, tie-down and prevention of damage.
NON-CONFORMANCE CONTROL

There are procedures for the control of packages or other aspects that do not conform to specified requirements such as damaged packages, incorrectly labelled packages and inadequate paperwork.

CORRECTIVE ACTIONS

There are procedures for correcting errors or discrepancies in our transport and handling operations but these may require reference to the consignor.

RECORDS

Documents relevant to the carriage of radioactive material are kept on file; other records are kept for a specified time dependent on their nature and customer requirements.

STAFFING AND TRAINING

It is the policy of our company to employ staff of the requisite education, experience and training to perform specific activities. Training of our staff is undertaken in matters pertaining to RAM transport. Drivers are required to undergo a specific recognized training course; records of their training and proficiency are maintained.

AUDITS

There are procedures for conducting internal audits to ensure that the operation of our system and business is functioning to specified requirements. External audits on other companies are not conducted. Records of audits are kept and any corrective actions are implemented with agreed time-scales.
Annex V

EXAMPLE OF A DOCUMENT CONTROL PROCEDURE FOR A SMALL ORGANIZATION

<table>
<thead>
<tr>
<th>Prepared:</th>
<th>Ref:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checked:</td>
<td>Issue:</td>
</tr>
<tr>
<td>Approved:</td>
<td>Page:</td>
</tr>
</tbody>
</table>

DOCUMENT CONTROL PROCEDURE

Introduction

It is the policy of this organization to implement a system of control of documents which are vital to our operations and which, if they were not subject to control, would adversely affect the quality of our product or service. This procedure describes the working of that system, including the receipt and control of external documents as well as the development, approval and continuing control of internal documents.

Types of document

Documents held by us comprise the following:

(1) Reference documents

Those international and national standards, regulations and other similar documents which we have to comply with or take cognizance of in the general conduct of our business.

(2) Third party documents

Those documents supplied to us by our clients and customers to enable us to fulfil their requirements.

(3) In-house documents

Those documents generated by us as and when necessary in the course of our business to meet our or our customers’ requirements or legal and statutory responsibilities.

52
METHOD OF CONTROL

(1) Reference documents

The company has all reference documents listed on forms DOC 1. Upon initial receipt copies are assigned to the appropriate nominated holders, who are responsible for: their upkeep by ensuring correct issue status, amending the list accordingly, subsequent issue, return and withdrawal as well as circulation to other staff who may need to see them. Where it is necessary to have more than one controlled copy of a reference document, each copy must be listed on the form DOC 1 and controlled. When other uncontrolled copies are made of such documents they shall be clearly marked as 'UNCONTROLLED COPY' and a record made on form DOC 1 of the copy and its recipient.

(2) Third party documents

These documents usually comprise correspondence, drawings and specifications. Drawings and specifications are held within a project filing system and all copies are listed on form DOC 2. It is the responsibility of the recipient and/or the office clerk to locate them within the appropriate file(s) and to update form DOC 2. The internal reproduction of such documents is also controlled on form DOC 2. General correspondence, e.g letters, are held within the company filing system and are referenced to a particular client file and entered chronologically. At the completion of a project or contract the third party may request that drawings, specifications, etc. are returned. Before such requests are complied with, copies of such documents will be made and retained, to form part of our necessary QA records.

(3) In-house controlled documents

These documents, which usually consist of company working procedures/instructions, drawings, quality plans, record forms, etc., will be developed by nominated people in the company's preferred style, and before issue will be checked and verified by the manager, who will approve the document by signing in the appropriate place on the master copy. The manager will maintain a listing of all approved company procedures and their authors/controllers. No unapproved documents shall be used, except where the responsible manager has given specific written permission for such unapproved documents to be used.

The author of a controlled document is responsible for identifying the document by using an appropriate title, unique reference number, issue number and date of issue. The author is also responsible for initiating any amendments to such documents and controlling the issue of amendments using the form DOC 3 as well as ensuring that all obsolete copies are returned or destroyed. To avoid potential problems, our controlled documents will only be issued as complete documents.
Consequently, individual pages will not be issued when change is necessary. The author (or the office clerk) will maintain a record of all controlled copies of each document using form DOC 1. All controlled documents will be marked (in red) ‘CONTROLLED DOCUMENT’ and company personnel, other than the author or the office clerk, shall not photocopy or otherwise duplicate such company documents except as follows. Where a company produced report or record form, which is part of a company procedure or other controlled document, is used for recording information, such forms can be copied, when stamped ‘uncontrolled copy’, and retained as a QA record in the appropriate file.
Example of documents list (Form DOC 1)

Reference documents list DOC 1:
Controlled by:

<table>
<thead>
<tr>
<th>Title</th>
<th>Issue</th>
<th>Issued to</th>
<th>Returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>BS 5750</td>
<td>December 1987</td>
<td>K 2/2/92</td>
<td>5/3/92</td>
</tr>
<tr>
<td>ISO 1345</td>
<td>5</td>
<td>B 5/6/91</td>
<td></td>
</tr>
<tr>
<td>DIN 5678</td>
<td>2</td>
<td>D 3/5/91</td>
<td>23/5/91</td>
</tr>
<tr>
<td>EN 2345</td>
<td>1</td>
<td>X 3/3/90</td>
<td></td>
</tr>
<tr>
<td>EN 2345</td>
<td>1 uncontrolled</td>
<td>Y 6/4/91</td>
<td></td>
</tr>
</tbody>
</table>

Form DOC 1, issue 1 28/3/92
Example of third party document control (form DOC 2)

<table>
<thead>
<tr>
<th>Drawings/specification</th>
<th>Issue number</th>
<th>Issued to</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA 1234</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>SA 4321</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>Specification for paint abc</td>
<td>3</td>
<td>Company X, paint contractor</td>
</tr>
<tr>
<td>Specification for drop test</td>
<td>1</td>
<td>Test centre</td>
</tr>
</tbody>
</table>

Form DOC 2, issue 1 23/2/92
To .................................. Date ..........................
.................................. Reference ...........................

Dear

Amendment No. to company QA programme

1. This company’s quality manual/working procedures/quality plan/drawing/instruction (delete as necessary) is issued/amended as shown below:

Remove and discard

Manual .......... issue ........

Procedure/
quality plan No. ........ issue ........

Drawing/
instruction No. ........ issue ........

Insert the attached amendment at

Manual .......... issue ........

Procedure/
quality plan No. ........ issue ........

Drawing/
instruction No. ........ issue ........

Front amendment sheet

2. Please return this sheet to the originator after you have amended your copy(s)

<table>
<thead>
<tr>
<th>Amendment approval</th>
<th>Manager</th>
<th>Amendment release</th>
<th>Originator</th>
</tr>
</thead>
</table>

I have incorporated amendment No. ...... and have destroyed the previous issue.

Signed ......................
Example of in-house form/records for consigning a package

<table>
<thead>
<tr>
<th>Number</th>
<th>Operation</th>
<th>Specification</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Consignment completed. Signature .................. Date ...... Position ......

Form DOC 4, issue 1

This publication is no longer valid
Please see http://www-ns.iaea.org/standards/
Annex VI

EXAMPLE OF A DOCUMENT CONTROL PROCEDURE FOR A COMPLEX ORGANIZATION

Prepared by:

............................ Date:

Reviewed by:

............................ Date:

Approved by:

............................ Date:

Ref. No. ..... Issue No. .....
Title: Document control

Prepared by:

Approved by: Date: Feb. 1992

QA manager

Scope

The document covers the procedures established and maintained to control approval, issue, review and modification of all documents relating to the requirements of applied standards.

It is the policy as stated in the Radiation Sources (RS) Departmental QA manual that all procedures, including document control, shall meet the requirements of applied standards.

Contents

(1) Introduction
(2) Procedural documents
(3) Quality records

Appendices 1–4
1. INTRODUCTION

For the purpose of this procedure the Radiation Sources Department’s key documents have been designated procedural documents or quality records.

Procedural documents cover standing procedures used to define and control specifications, manufacturing and testing methods and quality system definition. There are four types of procedural documents controlled directly by the QA department: raw material requirements (RMR), source product specifications (SPS), quality assurance procedures (QAP) and manufacturing procedures (MP).

Quality records are any records which demonstrate achievement of the required quality and effective operation of the system.

The QA department monitors the working of the document control system as part of its internal auditing programme. The QA manager nominates a document controller to operate and monitor the system, including the distribution of documents.

2. PROCEDURAL DOCUMENTS

2.1. Introduction

Procedural documents are drafted by a member of staff nominated by the local manager who is most closely involved with the procedure being prepared. They are defined as follows:

(a) Raw materials requirements (RMR)

A technical specification for certain products purchased outside RAM International and controlled by the QA department. It forms part of the purchase order placed with the supplier and is prepared by the QA department normally in conjunction with the production department. It includes the means by which the QA department approves the items specified. They are prepared when other forms of specifications (e.g. drawings) are not deemed adequate. (See Appendix 1.)

(b) Quality assurance procedures (QAP)

An internal control procedure which may be either a specific test method, e.g. leak testing, or a more general control system, e.g. product design. Appendix 2 indicates the sections that would normally be included in the document, although the exact content will depend upon the nature of the QAP.

These procedures are important for control proposes and to assist training, contribute to monitoring safety standards and ensure consistency.
(c) **Manufacturing procedures (MP)**

A detailed description of the method of manufacture. These procedures are generally in the same format as the QAPs. (See Appendix 3.)

(d) **Source product specification (SPS)**

A detailed technical specification for a particular customer requirement or particular source type. It is used where a clarification of specifications is required. Customers are asked to show acceptance by signing the document. (See Appendix 4.)

### 2.2. Issuing a new controlled procedure

2.2.1. The document controller in the QA department is contacted for a new number, which will be entered on the master list against the author’s name, together with the date of the request and the title.

2.2.2. Write the procedure using the general formats as indicated in Appendices 1–4 for guidance. The procedure number, issue number and page number must appear on every page.

2.2.3. Submit the draft for typing (using word processor for ease of updating) and send it to the responsible manager if appropriate and the QA manager for approval. The QA manager confirms the circulation list, which includes controlled files and occasionally individuals.

2.2.4. The QA manager will stamp the procedure ‘QC authenticated’. This is a red stamp and indicates the master copy.

2.2.5. The document controller will copy the master and place a copy in the appropriate controlled files. (See Section 2.4.2.) Controlled copies are stamped ‘Controlled’ on the reverse side.

2.2.6. The document controller will file the master copy and amend the indexes accordingly. The date of issue of the procedure will be recorded in the computer database.

### 2.3. Amendment of an existing controlled procedure

2.3.1. Controlled procedures may be updated by using the amendment procedure, QAP 228, or by re-issuing the entire document.

2.3.2. The QA manager or nominated deputy will check that the changes are valid and appropriate.
2.4. Control of procedures

2.4.1. All procedures mentioned above are controlled by the QA department, which holds the master file for each procedure.

2.4.2. Each work area holds a controlled copy of all relevant QAPs, RMRs and SPSs. The database holds a list of controlled files.

2.4.3. It is the responsibility of the QA department to maintain an updated copy of the procedures in the 'controlled files'.

2.4.4. It is the responsibility of the QA department to review each file at appropriate intervals as part of the internal auditing programme.

2.4.5. In certain circumstances uncontrolled copies of procedural documents are released to individuals. These are stamped 'Uncontrolled', which indicates that the QA department does not update the issue. In these cases it is the individual who is responsible for maintaining copies and for disposing of obsolete copies.

2.4.6. The master file is kept in a secure cabinet and controlled copies are available for examination.

2.4.7. Copying of all controlled documents is discouraged. However, when copies are required, it is the responsibility of the individual taking the copy to either maintain it at the current issue or dispose of it after use.

2.4.8. Information on document numbers, titles and circulation lists and cross-referencing information is held on a computer database maintained by the QA department. This database is the master record and index. Individual files may have an index of contents for convenience. The master record must always be used to check for currency of any document.

2.4.9. Occasionally it is necessary to issue controlled documents to individuals. An issue index is maintained either with the master copy or by references in the database.

2.5. Non-QA-authenticated procedural files

There are a number of procedural documents which are outside the radiation sources QA controlled document system. Reference to these files is made in the controlled procedures as appropriate.

For these, the master file and person responsible are clearly defined. The documents are all suitably identified, approved, stored, distributed and amended by the responsible manager.

Control of these files is monitored by the QA department as part of its internal auditing programme.
3. QUALITY RECORDS

3.1. Introduction

Quality records come in many different forms, the key one being identified below. They demonstrate achievement of the required quality and effective operation of the quality system. References are made to other QAPs, where appropriate, which give more details of specific quality records.

(a) Route card

This is a progressive record of key steps in a manufacturing process. It will include the following information:

(i) All interfaces to maintain traceability, i.e. goods received number, capsule numbers, work orders, despatch details, etc.
(ii) A sequential list of key operations that could affect the quality.
(iii) A statement of the specific standard that relates to a key operation of wipe test to QAP 130 or a weld specification number.
(iv) Reference to other test reports performed as part of manufacture, e.g. pressure test, heat treatment.
(v) Sufficient space for comments.
(vi) Sufficient space for each operation to be signed and dated by the operator.
(vii) Sufficient space at the bottom of the route card for the supervisor/team leaders to sign off the operations.

Route cards are approved by the QA department, which maintains a file of current forms, each of which is identified with a unique number. Also, part of this file are weld specification blanks.

(b) Supplier control reference QAP 048.

(c) Auditing reference QAP 037.

(d) Goods-in inspection reference QAP 100.

(e) Pre-despatch leak testing reference QAP 155.

(f) Testing of new source designs to standard applied reference QAP 053.

(g) MM 3000, this is a computerized production control system. Information to ensure full material traceability is stored. The system includes facilities to produce a wide range of reports on various aspects of manufacture.

(h) Test reports

These are despatched with every batch, giving details of the sources and all key tests. A copy is maintained by production staff. They are generated by a central
computer on the day of despatch following entry, by the production department, of the appropriate information. A production manager or nominated deputy check and sign the test reports.

(i) Other final reports

Measurement or calibration reports and certificates of conformity are prepared on request.

3.2. Storage of quality records

All quality records are stored and maintained such that they are readily retraceable in facilities that provide a suitable environment to minimize deterioration or damage.

Records are maintained indefinitely.
Appendix 1: Raw Material Requirement Procedure

RAM INTERNATIONAL RADIATION SOURCES (RS) DEPARTMENT
RAW MATERIALS REQUIREMENT (RMR)

Title: 
Prepared by: (Author) Date: 
Approved by: Production (signature as appropriate) Date: 
QA manager (signature required) Date:

Scope
A statement of the subject and limitations of this procedure

Contents
Specification
(Reference to national/international specification, e.g. BS 970, drawings, suppliers specifications are made when appropriate)

Sample procedure
(Details of what sample is required, if any for approval testing)

Test schedule
(Details of procedure)

Approval procedure
(Reference to general procedure QAP 100)
Appendix 2: Quality Assurance Procedure

QAP No.
Issue No.
Page of

RAM INTERNATIONAL RADIATION SOURCES (RS) DEPARTMENT
QUALITY ASSURANCE PROCEDURE (QAP)

Title:
Prepared by: (Author) Date:
Approved by: Production (signature as appropriate) Date:
QA manager (signature required) Date:

Scope

(Summary of procedure)

Contents

(Subsequent sheets as detailing following sections as appropriate)

Introduction
Reference — validation work included
Responsibilities
Flow chart
Equipment
Procedure
Non-conformance reporting
Records
Appendix 3: Manufacturing Procedure

Title:
Prepared by: (Author) Date:
Approved by: Production (signature as appropriate) Date:
QA manager (signature required) Date:

Scope

(Summary of procedure)

Contents

(As for QAP)
Appendix 4: Source Product Specification

Title:
Prepared by: (Author) Date:
Approved by: Production (signature as appropriate) Date:
QA manager (signature required) Date:

Scope
(List product codes or range of activities)

Customer approval

NAME

TITLE

COMPANY

SIGNATURE

DATE
1. **Details of design**

   (Capsule material (RMR); if appropriate capsule code)
   (Assembly drawings)

2. **Details of contents**

   (Purity)
   (Radioactive Material — Tolerance
    Form of activity content
    Output
    Nominal activity)

3. **Engineering**

4. **Special requirements**

   (Additional requirements, loading, etc.)

5. **Safety and performance testing**

   (ISO CLASS
    SFC Cert. No.
    R W Life)

6. **Application**

   (Specific use if known; if not, state laboratory environment or conditions)

7. **Manufacture**

   (General statements, e.g. the sources are manufactured according to general requirements of RAM International, Radiation Sources QA Manual. Specific procedures exist which contain the manufacture and testing of these sources)

8. **Quality control testing**

   (Reference to be made BS standards or QAPs if appropriate, e.g. vacuum bubble test to BS 5288, visual examination of weld to QAP03)
9. Documentation

(‘Handling instructions and test report supplied’. The test report gives code, source serial number, ISO Class, SFC wipe test results, leak tests, results, measurement data)

10. Packaging

(Package type
Assembly drawing
Unload procedure)

11. Additional information

(Leave blank if not required)
Annex VII

EXAMPLE OF AN INTERNAL AUDIT PROCEDURE
IN A SMALL ORGANIZATION

<table>
<thead>
<tr>
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<th>Ref:</th>
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</thead>
<tbody>
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<td>Issue:</td>
</tr>
<tr>
<td>Approved:</td>
<td>Page</td>
</tr>
</tbody>
</table>

INTERNAL AUDIT PROCEDURE

Introduction

It is the policy of this company to implement a system of internal quality audits. The purpose of these audits is to ensure that systems, procedures and company objectives set out in our quality assurance (QA) programme (QA manual) are being adhered to.

Frequency and responsibility

Audits will be scheduled and conducted on an annual basis by the manager who has been trained in auditing methods, and is, as far as possible, independent of the area/activity being audited.

Audit planning

Audits will be planned so that all aspects of the company’s QA programme are audited during the annual period. All relevant activities will be checked for conformance to the arrangements described in our manual or procedures. An audit plan stating the activity or operation, time and other pertinent details (Form AUD 1) will be issued to the staff concerned prior to the audit. Whilst internal audits will generally be planned in advance, unannounced or more frequent audits may be conducted where doubts exist concerning the effectiveness of the QA programme arising from customer complaints, or by evidence of faulty materials or services, or breaches of regulations.

Method of audit

Audits will be carried out on time according to the established audit plan. The auditor will refer to the quality manual, procedures and specific work instructions,
and will audit each activity for conformance to those prescribed arrangements. The auditor may select aspects of current or past projects to ensure that objectives were or are being achieved to prescribed methods. Any deficiencies, discrepancies or deviations found will be noted on QA Audit Report Form AUD 2, together with corrective actions and time-scales noted for improvement/rectification. A summary report of each audit carried out which records the scope of the audit, its findings and recommendations with relevant QA Audit Report forms (AUD 2) attached, is prepared and provided to the responsible senior manager. Consistent with the agreed time-scales (which in no case will be longer than six months) the auditor will verify and record that the necessary corrections have been made and that they are effective. Only when all corrective actions have been satisfactorily implemented and verified will the auditor close the audit.

Audit records

Records of audits shall be maintained by the auditor for a period of five years and will be subject to management review.
<table>
<thead>
<tr>
<th>Activity/system</th>
<th>Reference document</th>
<th>Audit scheduled</th>
<th>Auditor and date of audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality manual, administration procedures</td>
<td>Quality manual, and administration procedure 2</td>
<td>January</td>
<td></td>
</tr>
<tr>
<td>Document control</td>
<td>Procedure 5</td>
<td>February</td>
<td></td>
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<tr>
<td>Inspection and test</td>
<td>Procedure 7/8</td>
<td>July</td>
<td></td>
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<tr>
<td>Transport activities</td>
<td>Procedure 3</td>
<td>May/November</td>
<td></td>
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<tr>
<td>Procurement activities</td>
<td>Procedure 4</td>
<td>March</td>
<td></td>
</tr>
<tr>
<td>Material control</td>
<td>Procedure 6</td>
<td>April</td>
<td></td>
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<tr>
<td>Control of use/care of packages</td>
<td>Procedures 9 and 10</td>
<td>June</td>
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<td>Non-conformance control</td>
<td>Procedure 11</td>
<td>September</td>
<td></td>
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<td>Procedure 11</td>
<td>September</td>
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<tr>
<td>Records</td>
<td>Procedure 13</td>
<td>October</td>
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<td>Training</td>
<td>Procedure 12</td>
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<tr>
<td>Audits</td>
<td>Procedure 14</td>
<td>December</td>
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**Note:** Additional audits including unannounced audits may be carried out, as described earlier in this procedure QP 9; such additional audits shall also be recorded using this form AUD 1.
QA Programme Audit Report Form AUD 2

Activity/Aspects audited ............................................

.......................................................................................... Date: ...........

Quality manual/Procedure reference .....................
Auditor ................................................................. Report No. ...........

Details of audit — Activities, documents, procedures, examined or verified

<table>
<thead>
<tr>
<th>Details of audit</th>
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Non-compliance(s)

<table>
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Auditor signature Auditee signature

Corrective actions and proposed time-scales

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Auditee signature

Actions confirmed and authorized

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Auditor closing statement

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Signature: Date: 

75
Annex VIII

EXAMPLE OF A FLASK MAINTENANCE PROCEDURE
IN A COMPLEX ORGANIZATION

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<tr>
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Prepared by:

..................  Date:

Reviewed by:

..................  Date:

Approved by:

..................  Date:

Contents

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<tr>
<td>7</td>
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</tbody>
</table>

Distribution

Original to:  File number QA 2A
Copies to:   Managing Director
             Group Quality Assurance Manager
             Manager

76
1. PURPOSE

1.1. The purpose of this document is to define the policy of maintenance of flasks in the Group of Companies.

2. SCOPE

2.1. The scope of this document covers the minimum requirements of the company to be applied to all flasks owned by the company.

3. REFERENCES

3.1. Group procedure — grading of components, equipment, services, activities and documents.

4. DEFINITIONS

4.1. Turnaround means each time the flask is unloaded or loaded.

4.2. Cycle means a transport shipment including loading and unloading.

4.3. Maintenance includes re-inspection and any subsequent repair.

4.4. Flask means all components which make up the packaging as described in the certificate of approval of package design.

4.5. Maintenance management means all activities in support of maintenance including records.

4.6. Approved supplier means an organization approved by the company to supply specified goods or services.

5. METHOD

5.1. Planned preventative maintenance shall be carried out on all company flasks as follows:

<table>
<thead>
<tr>
<th>Periodicity</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.1. Every turnaround</td>
<td>See the appropriate certificate of approval of package design;</td>
</tr>
</tbody>
</table>
5.1.2. Every 15 flask cycles within a maximum period of 3 years (Maintenance details may be contained in package design).

5.1.3. Every 60 flask cycles within a maximum period of 6 years Safety reports, package design Safety report supplements, maintenance schedules, Maintenance specifications or referenced from same.)

5.2. Some countries may have additional/different requirements over and above those covered in paragraph 5.1. Before maintenance in accordance with paragraph 5.1 of this procedure is carried out, the requirements of the country where the equipment is to be used shall be taken account of during the maintenance.

5.3. All maintenance shall be carried out in accordance with written procedures. The written procedures shall be supplied by the company or the ‘approved supplier’. Procedures supplied by an approved supplier shall be reviewed by the company prior to use.

6. RESPONSIBILITIES

6.1. The United Kingdom company shall be responsible for the flask maintenance management of United Kingdom registered flasks.

6.2. The French company shall be responsible for the flask maintenance management of French registered flasks.

7. RECORDS

7.1. A record of maintenance/repair shall be provided each time maintenance/repair is carried out in accordance with paragraph 5 of this procedure. Certificates shall make reference to the unique flask or package design and serial number, and to the maintenance/repair documents which have been applied.

7.2. Records of all maintenances shall be kept by the office designated as being responsible for that maintenance management in accordance with company procedures.
7.3. Records shall include a flask logbook which shall be compiled for each flask. The logbook shall contain the following as a minimum:

(i) Package design and unique serial number.
(ii) List of operating quality plan numbers.
(iii) List of commissioning certificate numbers or commissioning certificates.
(iv) List of commissioning tests carried out.
(v) List of maintenance quality plan numbers.
(vi) List of maintenance certificate numbers.
(vii) List of modification certificate numbers.
(viii) List of repair certificate numbers.
(ix) Table of shipments.
(x) List of non-conformance corrective actions outstanding.
Annex IX

EXAMPLES OF POOR INTERFACE CONTROL

(a) During the development of a package design the user identifies a need for the package to carry contents heavier than originally agreed with the designer. If the user’s or the designer’s interface controls are inadequate, the prototype package could fail during testing because the designer has not received the information concerning the desired change and has not reviewed and/or revised the weight carrying capabilities of the package. This may be prevented by clearly defining responsibilities for the transmission of documents and by engaging all appropriate parties in the design review activity.

(b) During the development of a design, adequate liaison occurs between the design office and the user, but the designer includes some design features which cannot be produced by the local production unit. Poor interface controls between the designer and the production unit in terms of inadequate liaison and design agreement or acceptance arrangements can result in a finished design incapable of being manufactured locally. Again, this may be avoided by including the appropriate parties in the design verification and design review processes.

(c) One section in a consignor’s organization is responsible for packing radioactive contents into the packaging and a different section is responsible for completing and attaching package labels. No section is made responsible for affixing package integrity seals, and each section thinks that the other one carries out the task. This situation can result in the package being dispatched without the integrity seals in place. The lack of definition of responsibilities would be detected by internal auditing and responsibility for affixing the seals would be assigned to one of the sections.

(d) To make maintenance operations easier, a maintenance section decides to use a shorter, more readily available containment lid closure bolt on a Type B package. The maintenance section has good interface controls with the user but it fails to communicate the change to the design office or design authority. In a subsequent accident the containment lid bolts pull out of the package body owing to insufficient thread engagement of the shorter bolts. With good communication between the maintainer and designer, information could have been made available to the maintainer and a suitable alternative bolt could have been agreed on and used with no adverse effect on transport safety.

(e) A consignor has been sending large industrial irradiation sources for many years to various international customers who had in part to organize the transport operation within their own countries. The consigning company, however,
supplied the sources ‘ex works’ (meaning that the supplier relinquishes ownership and responsibility of items as soon as they leave the premises) which made the consignees in part responsible in law for subsequent transport operations, a situation of which some of them were not aware. Consequently, some international movements were being carried out with no formal responsibility in place, each organization thinking that the other was responsible. The establishment of a formal definition of responsibilities cures the problem.
DEFINITIONS

The following definitions are intended only for the interpretation of the terms used in this publication.

applicant. Any person or organization who applies to a competent authority for the issue of an approval in accordance with the Regulations [1].

assessment. The act of reviewing, inspecting, testing, checking, conducting surveillance, auditing or otherwise determining and documenting whether items, processes or services meet specified requirements. Assessments are performed by or for senior management.

audit. A documented activity performed to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, established procedures, instructions, specifications, codes, standards, administrative or operational programmes and other applicable documents, and the effectiveness of implementation.

carrier (as defined in Ref. [1]). Any individual, organization or government undertaking the carriage of radioactive material by any means of transport. The term includes both carriers for hire or reward (known as common or contract carriers in some countries) and carriers on their own account (known as private carriers in some countries).

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

competent authority (as defined in Ref. [1]). Any national or international authority designated or otherwise recognized as such for any purpose in connection with the Regulations [1].

compliance assurance (as defined in Ref. [1]). A systematic programme of measures applied by a competent authority which is aimed at ensuring that the provisions of the Regulations [1] are met in practice.

consignor (as defined in Ref. [1]). Any individual, organization or government which presents a consignment for transport and is named as consignor in the transport documents.

controlled document. A document that has been designated as controlled in accordance with a quality or administration programme or procedural requirement. Controlled documents generally include documents that ensure technical adequacy, documents containing or specifying quality requirements, and documents that prescribe activities affecting quality.

corrective action. Measures taken to correct conditions adverse to quality and, where necessary, measures to preclude repetition.
design (as defined in Ref. [1]). The description of special form radioactive material, package or packaging which enables such an item to be fully identified. The description may include specifications, engineering drawings, reports demonstrating compliance with regulatory requirements and other relevant documentation.

design input. The criteria, parameters, bases, data or other design requirements upon which the detailed final design is based.

design output. Documents, such as drawings and specifications, that define technical requirements necessary for manufacture, installation and operation of structures, systems and components.

examination. An element of inspection consisting of investigation of materials, components, supplies or services, to determine conformance with those specified requirements which can be determined by such investigation. Examination is usually non-destructive and includes simple physical manipulation, gauging and measurement.

inspection. Actions which by means of examination, observation or measurement determine the conformance of materials, parts, components, systems, structures, as well as processes and procedures, with defined requirements.

item. A general term covering materials, parts, components, systems or structures, including computer software.

maintenance/servicing. The actions which include reinspection and any subsequent repair with appropriate records for traceability.

measuring and test equipment. Devices or systems used to calibrate, measure, gauge, test or inspect in order to control or to acquire data to verify conformance to a specified requirement, or to establish characteristics or values not previously known.

non-conformance. A deficiency in characteristics, documentation or procedure that renders the quality of an item or service unacceptable or indeterminate.

objective evidence. Qualitative or quantitative information, record or statement of fact, pertaining to the quality of an item or service, which is based on observation, measurement or test and which can be verified.

procedure. An element that specifies how a requirement, task or activity is to be accomplished.

procurement document. A procurement document may include any or all of the following: purchase requisitions, purchase orders, letters of intent, work authorization letters, drawings, contracts, specifications, instructions or any other document that provides a means for acquiring possession or ownership of items or the right to use services by providing payment.

qualification. The characteristics (or abilities gained through education, training or experience) which are measured against established requirements, standards or tests, to qualify a process, component or individual to perform a stated function.
quality. The totality of features and characteristics of an item or service that bear on its ability to satisfy a defined requirement.

quality assurance (as defined in Ref. [1]). A systematic programme of controls and inspections applied by any organization or body involved in the transport of radioactive material which is aimed at providing adequate confidence that the standard of safety prescribed in the Regulations [1] is achieved in practice.

quality elements. The major elements of the governing quality assurance requirements documents such as document control and design control.

quality assurance programme. The overall programme established by an organization to implement stated requirements. The programme generally defines responsibilities and authorities, policies and requirements and provides for the performance and assessment of work.

quality plan. A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, service, contract or project.

repair. The process of restoring a non-conforming item to a condition such that the capability of this item to function reliably and safely is unimpaired, even though that item may still not conform to the prior specification.

services. The performance by a supplier of activities such as design, fabrication, inspection, non-destructive examination, repair or installation.

specification. A written statement of requirements to be satisfied by a product, a service, a material or process, indicating the procedure by means of which it may be determined whether the specified requirements are satisfied.

supplier. An individual or organization under contract for furnishing items or services. This includes various levels or kinds of procurement, for example as undertaken by vendors, sellers, contractors, subcontractors, fabricators and consultants.

traceability. The ability to follow the history, application, material or location of an item/service and similar items or activities by means of documentation or by other means.

user. A person who, or an organization which, designs, tests, assesses, manufactures, services, maintains, handles, consigns, carries or otherwise uses a package in connection with the transport of radioactive material.

verification. The act of reviewing, inspecting, testing, checking, assessing, auditing or otherwise determining and documenting whether or not items, processes, services or documents conform to specified requirements.
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