Compliance Assurance and Regulatory Agency's Co-operation in the UK (Benefits Resulting from Co-operation Between the UK Regulatory Enforcing Agencies and the Use of Quality Assurance as a Method of Assuring Compliance)

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INTRODUCTION

The impact of the 1985 Edition of IAEA - REGULATIONS FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL - SAFETY SERIES NO 6 (1985) on the transport of radioactive material scene in the UK has been gradual but very significant. This paper attempts to describe the particular impact of the two paragraphs (209 and 210) which have arguably had the most significant impact on the United Kingdom's Competent Authority and other Government Agencies notably the Health and Safety Executive.

ASPECTS OF COMPLIANCE ASSURANCE

The Competent Authority now has a clear responsibility stemming from para 210 of IAEA Safety Series No 6 to assure compliance with these Regulations and is expected 'to provide evidence that the provisions of these Regulations are being met in practise'. The change of emphasis concerning Compliance Assurance (CA) in the most recent edition of the Transport Regulations compared with the previous edition, poses considerable problems and in some cases imposes greater responsibility and a larger workload than previously experienced. This has certainly been the case in the UK. It has been necessary to develop a Compliance Assurance programme which, not only addresses all the relevant guidelines established in IAEA-TECDOC-413 COMPETENT AUTHORITY REGULATORY CONTROL OF THE TRANSPORT OF RADIOACTIVE MATERIAL (1987) but also recognises the existing modally based regulation of transport. It is also very important that the national industry is not placed at a commercial disadvantage during the development and application of the Compliance Assurance programme. The UK Compliance Assurance programme has therefore had to take account of the responsibilities and actions of other Governmental Departments and Agencies including their legislation and modal regulations.

MODALLY RELATED ENFORCEMENT AGENCIES

It was necessary, in the interests of good CA to not just recognise the different National modal regulations but to maximise liaison and co-operation between these various responsible Departments who are, for Sea - the Marine Directorate of Dept of Transport (DTp); for Air, the Civil Aviation Authority; for Rail, Railways Inspectorate of DTp; and for Road, the Traffic Area Co-Ordination Division (DTp). It is argued that only by having effective and appropriate co-operation between the departments involved, can full compliance with the transport regulation begin to be assured in the UK.

NON MODALLY BASED ENFORCEMENT AGENCIES

In the UK safety regulations for employees and others affected by their work are made under the Health and Safety at Work Act 1974. This Act applies to all sections of employment. The Act allows regulations to be made and in 1986 the 'Ionising Radiations Regulations 1985 (IRR85)' were introduced. These regulations include requirements which are binding on the UK by virtue of its membership of the European Community. The requirements are contained in the Euratom Directives of 1980 and 1984 and are traceable to International Commission on Radiological Protection (ICRP) publications 26(1977) and 30(1979).

All the IRR 85 apply to transport. In particular Regulation 21 "Transport and Moving of Radioactive Materials" has requirements for containment, labelling, information and dose limitation. However, this regulation does not apply where and to the extent that 'The Radioactive Substances (Carriage by Road) Regulations (1974) and Amendment (1985)' apply. Guidance on Transport given in the "Approved Code of Practice for the protection of persons against ionising radiation arising from any work activity" relies heavily on IAEA requirements.

Enforcement of IRR85 is the responsibility of Health and Safety Executive (HSE) inspectorates ie Factories and Agricultural, Mines and Quarries and Nuclear Installations. Railways and Offshore installations are inspected by the Railway Inspectorate and the Department of Energy respectively under an agency agreement with the Health and Safety Commission. Technical advice on the application of the regulations is given to these inspectorates by HSE Technology Division.

ENFORCEMENT AGENCY LIAISON

It was recognised at an early stage in the development of IRR85 that there would have to be close liaison between the HSE enforcement agencies, the Competent Authority and those involved with emergency arrangements. An Enforcement Liaison Committee for the Transport of Radioactive Materials (ELCTRAM) was set up under the joint chairmanship of the DTp and HSE. The committee meets 2-3 times per year. Its present DTp membership comprises of representatives of the Radioactive Materials Transport Division, Marine Directorate, Civil Aviation Authority, Traffic Area Co-ordination Division and Railways Inspectorate. HSE is represented by the Factory and Agricultural Inspectorate, Nuclear Installations Inspectorate, Technology Division and Radiation Protection Policy Branch. The Police are also represented.

The main terms of reference are:

(i) To discuss and review current issues and difficulties with a view to ensuring consistent interpretation of regulatory/code of practice provisions.

(ii) To keep enforcement procedures under review and working interfaces agreed in order to promote consistent and efficient standards.

(iii) To provide a forum for the discussion of instructions and advice to inspectors with a view to seeking uniformity where appropriate.

(iv) To identify the need for and produce where appropriate further publicly available guidance and to provide a route for consultation on drafts within and between the organisations concerned.

It was agreed by committee members that joint enforcement exercises would be required in order to meet these objectives. The exercises were designed principally to :

(a) highlight the roles of each agency;

(b) identify areas of common concern and possible conflict of interests;

(c) provide employers and trade associations with the opportunity to discuss issues with all agencies at one time and

(d) to obtain information which would be used as a practical input to the making of policy and regulations.

JOINT ENFORCEMENT EXERCISES

So far exercises have been held at a major airport, a dock, a nuclear power plant and the national low-level waste disposal site at Drigg in Cumbria. The results of the visits to the airport and dock are discussed here to show their value.

The transport of radioactive materials through airports is complicated by the presence of a number of different operators each with their own premises on a site under the control of the airport owner. Emergency services such as the fire brigade are usually employed by the latter. During the enforcement exercise a number of operators premises were inspected to establish what arrangements had been made for handling and storing of packages, and emergency arrangements including liaison with road hauliers. It was soon evident that the quality of the arrangements varied greatly from operator to operator and that emergency arrangements were generally inadequate.

Subsequently operators were required to remedy these matters. They did so by appointing radiation protection advisers who in consultation with HSE and DTp drew up common radiological safety rules. These included handling methods for dose limitation, requirements for storage, contingency plans for local accidents and incidents including cooperation with the airport fire brigade for large scale emergencies. It is interesting to note that a dosimetric survey of package handlers showed that one handler was receiving a dose much greater than that of other handlers. Investigation showed that this was due to the system of work and only minor changes were necessary to alleviate the problem.

At the dock where a wide range of radioactive materials were handled, conditions governing the movement of packages did not comply with the present requirements of IRR85 and the 1985 IAEA Regulations. As a result of the exercise, the following arrangements were introduced:

(a) controlled areas for the storage of packages and containers,

(b) written rules for handling of packages,

(c) monitoring of packages to establish surface dose levels and transport indices,

(d) contingency plans for dealing with accidents and incidents, and

(e) cooperation with carriers.

The exercise and resulting actions created considerable interest throughout the UK. Subsequently the British Ports Federation assisted by HSE Technology Division and Factory and Agricultural Inspectorate produced notes of guidance on IRR85 for its members. These were launched at a national seminar attended by representatives of port employers.

These examples show that formal liaison between enforcement agencies is essential and that such liaison produces significant benefits for both the agencies and employers involved in the transport of radioactive materials. Since transport is an international business the authors believe that more formal international cooperation between enforcing agencies is required. The UK experience is that joint enforcement exercises are an essential element in the cooperation process and should always be provided for.

THE IMPORTANCE OF QUALITY ASSURANCE

In parallel with the development of ELCTRAM has been the increasing use by the Competent Authority of QA techniques in assuring compliance with the Regulations. The requirement in para 209 of IAEA Safety Series No 6 which effectively states that QA programmes shall be established for all packages, and all aspects of transport, was seen by the UK Competent Authority as being of considerable significance. Additionally, where Competent Authority approval is needed, the Competent Authority is virtually required by that para 209 to consider the appropriate QA programme and not issue an approval unless it is satisfied with the adequacy of that QA programme.

It was readily recognised that QA has an important part to play in assisting the UK Competent Authority towards full CA in as much as:-

(i) It is, or can be, a common denominator in the transport of RAM.

(ii) All aspects of RAM transport need appropriate QA programmes.

(iii) It is a management tool or management control system.

(vi) It can be used to demonstrate compliance.

(v) It can assist in self-correction or self improvement.

(vi) Its techniques can be used by Competent Authorities.

(vii) Its application and use can promote public confidence in RAM Transport operations.

Quality Assurance can be applied by large, medium or small organisations with equally good effect, all that is necessary is the determination to apply it successfully by those concerned, supported by appropriate expertise in the subject. The advisory material contained in appendices 4 & 5 of IAEA - ADVISORY MATERIAL FOR THE IAEA REGULATIONS FOR THE SAFE TRANSPORT OF RADIOACTIVE MATERIAL (1985 EDITION) THIRD EDITION - SAFETY SERIES NO 37 (1987) gives useful information and guidance about the development content and application of QA programmes in transport; and it can be seen that the QA programme developed by a large organisation regularly designing, manufacturing and transporting many or large packages will need to be a much more comprehensive programme than an infrequent consignor of small or excepted packages. In response to the enhanced QA requirements of the Regulations the Department has developed its CA programme to take account of the higher levels of demonstrable QA now required from all those involved in RAM transport.

SIZE OF THE INDUSTRY

There is a tremendous range of RAM transport activity in the UK which includes such large organisations as BNFL and Amersham International with considerable international business to conduct, the Central Electricity Generating Board and South of Scotland Electricity Board with a significant irradiated fuel transport operation to manage, the UK Atomic Energy Authority with its research and production support work, through to smaller companies involved in product irradiation, RAM transport package design and manufacturing, industrial radiography, non destructive testing, civil construction, carriers, etc. This wide range of activity means, obviously, that the scope and breadth of transport related QA programmes encountered by the Competent Authority varies considerably. Indeed, the written QA programme for a small, infrequent transporter may only amount to a few pages, not necessarily addressing all identified QA criteria, merely those appropriate ones shown in appendix 5 of IAEA SAFETY SERIES NO 37. On the other hand the QA programme/s produced by a large organisation may of necessity involve more than one level or tier of programme definition, reflecting the work done at, for example, one particular works or facility.

The UK Competent Authority has endeavoured to be sufficiently flexible, because of the size and variety of the industry, in its approach to satisfying itself about the QA arrangements being developed and/or operated within the industry, without compromising the Regulations or assurance of their being complied with. Part of this flexibility has been the DTp's refusal to insist on any one particular Quality Assurance standard being employed. It has instead, acknowledged that a number of nationally recognised QA standards are in use in the UK, and so it was declared that any of these standards (eg BS 5750/ISO 9000, BS 5882, AQAP 1, IAEA 50-C-QA) could be utilised in the development of an appropriate QA programme. Another example of this flexibility is the involvement by the Competent Authority of the Department of Transport's Traffic Examiners who have other responsibilities in road traffic enforcement. They are given the necessary instruction and information to enable them to visit (over 1000 locations) the smaller, infrequent consignor, consignee or carrier where with the aid of a detailed questionnaire which is reported back to the Competent Authority a reasonable understanding of compliance assurance can be achieved.

THE USE OF QA IN COMPLIANCE ASSURANCE

The UK Competent Authority has endeavoured to maximise on the QA practised by the industry in support of its own CA efforts. As applications for Competent Authority Approvals are received the references to the QA programme/s are taken up, examined, and verified. This may involve one relatively straight-forward QA programme or more complex interacting programmes where design, manufacture, testing, use, and maintenance are carried out by different organisations, each with their own separate QA arrangements. Matters can be further complicated by, typically, one organisation's singular QA programme applying to the design, testing or manufacture etc of a whole range of packages but with individual quality plans applicable to each separate package design or type. The UK Competent Authority confirms the adequacy of the QA arrangements by not only examining the actual written QA programmes and plans but also by auditing the arrangements to verify their correct functioning. When satisfactory QA arrangements are confirmed, the Department is then able to issue a full "85 IAEA" Approval Certificate, which of course, must specify the QA programme/s concerned. Obviously the Department's interest in QA does not finsih with the issue of a certificate, and further action is taken to ensure that the packages concerned continue to comply with the approved specification. In fact it is considered most important that the original design and its approval should not be compromised in subsequent use, consequently the Department takes a great deal of interest in the QA applied to all post manufacturing transport operations such as servicing, maintenance, modification and use.

Naturally, arising from an increasing awareness and use, by the UK Competent Authority, of QA in support of CA, it has been necessary to provide the appropriate resources including manpower. The increase however has been modest due to the Department's policy of engaging professional QA engineers who have, as anyone proficient in QA would recognise, taken the fact that all worthy QA programmes should provide for self audit and evaluation, and used that particular facet of QA to the Department's advantage. Basically, the principle is that any creditable QA programme should require the controller of that programme to carry out a series of self audits and reviews of the programme to test it for continued conformity and objectivity. The self audits should, over a period of time, examine and test all features of the subject QA programme and thus confirm and record its continued adequacy and effectiveness. Where non-conformances are found then appropriate corrective action should be identified, implemented and subsequently verified by the self audit process. The UK Competent Authority then periodically examines the records of the self audits, the performance of the auditors, and any other self checking mechanisms related to the QA programme, which enables it to then confirm, or otherwise pronounce on the overall continued acceptability of the QA arrangements, and hence provide evidence of regulatory compliance.

TECDOC 413 - A VALUABLE INFLUENCE ON CA

The publication of TECDOC 413 gave fresh impetus to the UK Competent Authority's CA programme with its valuable information and guidance material. It was possible to compare the provisions of Section IV and Appendix IV of TECDOC 413 in particular with the actions

or planned activities in CA in the UK; this comparison revealed that most aspects of CA were being addressed, some more formally than others. Some CA activities such as Design assessment, Criticality assessment, Approval Certificate issuance, witnessing of Regulatory Testing were well established and documented; however some other aspects such as control of maintenance, QA auditing, witness of package manufacture and observance of transport operations which were already carried out needed to be put on a more formal and planned basis.

It is interesting to note that every item mentioned in appendix IV of TECDOC 413 can be checked or verified by a Competent Authority during the course of a QA programme verification audit. Certainly the UK Competent Authority endeavours to follow this course, so as to derive maximum CA benefit from its resources. However there are some items mentioned in appendix 4 which should not be left to QA auditing alone to confirm compliance, and certainly the Department also carries out direct inspections of transport operations, package preparation and labelling, documentation, and handling.

COMPLIANCE ASSURANCE: FUTURE DEVELOPMENTS AND CO-OPERATION

There can be little doubt that RAM Transport both nationally and internationally causes a great deal of concern, mainly to those members of governments and the public, who do not always understand the reality of the situation, or who are mislead by an ill informed or mischievous media. Equally those responsible for producing and administering the international regulations must have an interest in knowing that those Regulations are in fact being recognised and realistically complied with. The UK Authorities are confident that through their mutual co-operation and joint enforcement activities a complete state of Compliance Assurance will be achieved and demonstrated.

However, it can be argued that there should be enhanced or more readily demonstrated levels of assurance on the international transport scene, which can only realistically come from closer contact between Competent Authorities. Citizens of one Member State often ask about RAM transport operations originating or controlled from another country. It may be possible, using the principles and methodology of ELCTRAM, to promote greater understanding and co-operation between Competent Authorities without impinging on sovereign Member States rights. The following ideas are proposed in an effort to promote further confidence and compliance assurance in International transport operations:-

(i) The International RAM transport industry and the IAEA could benefit by giving TECDOC 413 or the information contained within it more prominance or a higher status.

(ii) Competent Authorities ought to be encouraged to exchange details of their Compliance Assurance programmes, to promote greater understanding and mutual confidence in their industries, and their respective public.

(iii) Joint liaison/enforcement exercises involving concerned Competent Authorities and other appropriate National Authorities in the co-ordinated monitoring/ inspection of international RAM transport operations should be encouraged. /It is interesting to note that recently the UK Competent Authority has been co-operating closely with the Physikalisch-Technische Bundesanstalt (PTB) and the Bundesanstalt fur Materialprufung (BAM) of the Federal Republic of Germany in the matter of international movements of irradiated fuel and related flasks or casks./

(iv) Further initiatives and participation by the IAEA in promoting co-operation and exchanges between Competent Authorities. /This could be done on a regional basis, with perhaps advice and co-operation from the Standing Advisory Group on the Safe Transport of Radioactive Materials (SAGSTRAM) and the Radioactive Transport Study Group (RTSG)./

(v) The IAEA might care to consider what further steps it could take towards greater harmonisation in the application of its Regulations - possibly by establishing a Compliance Review Panel or similar body.

It is strongly suggested that in Member States where multiple enforcement agencies are involved in RAM transport such as the UK, total compliance assurance will not be possible until mutual co-operation and interface agreements between those agencies exist and can be clearly demonstrated. Only then can an "interested public" have a reasonable assurance of compliance. Similarly on the International scene individual Competent Authorities, their respective Governments, and general public will not be able to demonstrate, or have full confidence in, the effect of the International Regulations or the actions of an external consignor or carrier until appropriate mutual understanding and co-operation is a reality and clearly demonstrable. Indeed until international compliance can be more readily assured and demonstrated individual Member States and their industries are at greater risk from the over reactions of other Member States and geographical or ideological associations of States.

References

The Radioactive Substances (Carriage by Road) (Great Britain) Regulations 1974, Statutory Instrument No 1735, Her Majesty's Stationery Office, London (1974)

International Commission for Radiological Protection, ICRP Publication No 26, Pergamon Press, Oxford and New York (1977)

International Commission for Radiological Protection, ICRP Publication No 30, Pergamon Press, Oxford and New York (1979)

International Atomic Energy Agency, Regulations for the Safe Transport of Radioactive Material, 1985 Edition, Safety Series No 6, IAEA Vienna (1985)

The Ionising Radiations Regulations 1985, Statutory Instrument No 1333, Her Majesty's Stationery Office, London (1985)

The Radioactive Substances (Carriage by Road) (Great Britain) (Amendment) Regulations 1985, Statutory Instrument No 1729, Her Majesty's Stationery Office, London (1985)

International Atomic Energy Agency, Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (1985 Edition) Third Edition, Safety Series No 37, IAEA Vienna (1987)

International Atomic Energy Agency - TECDOC 413, Competent Authority Regulatory Control of the Transport of Radioactive Material, IAEA Vienna, 1987.