IAEA Safety Standards Applications — TranSAS-2

Provision for the Application of the IAEA Safety Standards

Appraisal for Brazil of the Safety of the Transport of Radioactive Material

IAEA
International Atomic Energy Agency

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APPRAISAL FOR BRAZIL OF THE SAFETY OF THE TRANSPORT OF RADIOACTIVE MATERIAL

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IAEA SAFETY STANDARDS APPLICATIONS — TRANSAS-2

APPRAISAL FOR BRAZIL OF THE SAFETY OF THE TRANSPORT OF RADIOACTIVE MATERIAL

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FOREWORD

Within the family of the United Nations, the IAEA has the specific statutory function of establishing standards of safety for the protection of health against exposure to ionizing radiation. As a result, in 1959 the United Nations Economic and Social Council requested that the IAEA be entrusted with the drafting of recommendations on the transport of radioactive substances. Within its statutory mandate and pursuant to this request, in 1961 the IAEA issued the Regulations for the Safe Transport of Radioactive Material (the Transport Regulations). The Transport Regulations have been periodically reviewed and, as appropriate, amended or revised. Moreover, several guides and technical documents supporting the Transport Regulations have been issued by the IAEA. The latest version of the Transport Regulations was issued in 2000 by the IAEA as publication TS-R-1 (ST-1, Revised).

On 25 September 1998 the IAEA General Conference adopted resolution GC(42)/RES/13 on the Safety of Transport of Radioactive Materials. In adopting that resolution the General Conference recognized that "*compliance with regulations which take account of the Agency's Transport Regulations is providing a high level of safety during the transport of radioactive materials...*"

The IAEA's Statute also authorizes it to provide for the application of its standards at the request of any State. The IAEA discharges this statutory function through a number of mechanisms, including rendering independent peer review appraisal services to determine the status of compliance with its standards. Consistent with this statutory function, resolution GC(42)/RES/13 requested the IAEA Secretariat to provide for the application of the Transport Regulations by, inter alia, providing a service for carrying out, at the request of any State, an appraisal of the implementation of the Transport Regulations by that State.

In response to this request, on 10 December 1998 the IAEA offered to render such an appraisal service to all States. The service was termed the Transport Safety Appraisal Service (TranSAS). Since then the IAEA General Conference, through resolutions GC(43)/RES/11, GC(44)/RES/17, GC(45)/RES/10 and GC(46)/RES/9, has commended the Secretariat for establishing TranSAS, commended those Member States that have requested an appraisal, and encouraged other Member States to avail themselves of the appraisal service.

On 10 May 2000 the Head of the International Relations Office of the Brazilian National Nuclear Energy Commission (CNEN) requested assistance from the IAEA within the framework of the Transport Safety Appraisal Service. To lay the groundwork for the appraisal, a preparatory mission was

undertaken in August 2000. At that time a preliminary agreement was developed addressing the scope of the appraisal as well as the tasks and activities to be undertaken prior to and during the appraisal. Because of the difficulty in obtaining funding for the appraisal, the actual appraisal, initially planned for November 2000, was postponed until April 2002.

The TranSAS appraisal for Brazil involved five independent experts from the IAEA and Member States of the IAEA and was conducted between 15 and 26 April 2002. This report presents its findings.

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SUMMARY, FINDINGS AND CONCLUSIONS

BACKGROUND

S01. On 25 September 1998 the General Conference of the IAEA adopted resolution GC(42)/RES/13 on the Safety of Transport of Radioactive Materials. The General Conference recognized in adopting that resolution, inter alia, that compliance with regulations that take account of the IAEA's Regulations for the Safe Transport of Radioactive Material (the Transport Regulations) is providing a high level of safety during the transport of radioactive material. In addition, it requested the IAEA Secretariat to provide for the application of the Transport Regulations by, inter alia, providing a service for carrying out, at the request of any State, an appraisal of the implementation of the Transport Regulations by that State. In response to this request the IAEA has created and made available to all States the Transport Safety Appraisal Service (TranSAS).

S02. The objective of a TranSAS appraisal is to assist any requesting State to achieve a high level of safety in the transport of radioactive material by reviewing its implementation of the Transport Regulations and by making recommendations for improvement where appropriate.

S03. A letter dated 10 May 2000 from the Head of the International Relations Office of the Brazilian National Nuclear Energy Commission (CNEN) addressed to the Deputy Director General of the Department of Nuclear Safety of the IAEA requested assistance from the IAEA within the framework of the Transport Safety Appraisal Service. To lay the groundwork for the appraisal, a preparatory mission was undertaken from 21 to 24 August 2000. At that time a preliminary agreement was developed addressing the scope of the appraisal as well as the tasks and activities to be undertaken prior to and during the appraisal. Owing to the difficulty in obtaining funding for the appraisal, the actual appraisal, initially planned for November 2000, was postponed until April 2002.

SCOPE OF THE APPRAISAL

S04. A TranSAS appraisal covers all modes of transport (i.e. road, rail, maritime and air). In accordance with the request from Brazil, specific attention was given to the evaluation of the national transport legislation and

regulations, the inspection and enforcement programme and the co-operation arrangements in areas of overlapping responsibilities. The appraisal considered in detail all relevant aspects of the regulation of the transport of radioactive material in Brazil with regard to the requirements specified in the Transport Regulations [1], the guidance provided in other IAEA publications [2–5] and other relevant international regulatory documents.

TRANSAS QUESTIONNAIRE

S05. A detailed TranSAS questionnaire was developed by the IAEA early in 1999 in order to facilitate the appraisal process in a consistent manner. The questionnaire has detailed questions in the following eight key areas:

— Legislative and governmental responsibilities;
— The authority, responsibilities and functions of the regulatory body;
— The organization of the regulatory body;
— The authorization process;
— Review and assessment;
— Inspection and enforcement;
— The development of regulations and guides;
— Emergency preparedness for transport.

The completed TranSAS questionnaire is a working document for the appraisal and may be used by representatives of the host organization to prepare for interviews and to develop presentations.

TASKS AND ACTIVITIES PRIOR TO THE APPRAISAL

S06. Brazil provided the IAEA with working papers and information papers relevant to the implementation of its transport regulations. In addition, they completed the TranSAS questionnaire. The IAEA assembled a team of experts for the appraisal, the members of which were subject to approval by Brazil. The approved experts were provided with the working papers, the information papers and the completed TranSAS questionnaire submitted by Brazil.

APPRAISAL TEAM

S07. The team for the TranSAS appraisal was composed of five independent experts. The members of the team represented regulatory authorities responsible for the transport of radioactive material in three States, a legal expert with experience in the transport of radioactive material and a transport safety expert from the IAEA. The expertise of the appraisal team was broad and covered all aspects of the implementation of regulations for the safe transport of radioactive material. Specific experience was taken into account for the assignment of the lead responsibilities for appraising the eight areas addressed in the TranSAS questionnaire.

APPRAISAL PROCESS

S08. The appraisal process included the following:

- A preparatory session for the appraisal team;
- An entrance meeting involving presentations by key representatives from the CNEN and other authorities concerning their responsibilities for the safe transport of radioactive material;
- Discussions to obtain clarifications and additional or more detailed information;
- Updating of the questionnaire and the preparation of the draft report of the findings;
- Ongoing feedback on the updated questionnaire and the draft report of the findings;
- A visit to the fuel manufacturing facilities of Indústrias Nucleares do Brasil (INB);
- An exit meeting to present and discuss the findings.

APPRAISAL REPORT

S09. The appraisal report includes, in Section 4, the findings for each area considered in the appraisal, together with a background discussion and a basis for any finding (tied to an international regulatory requirement or recommendation). The findings are presented as recommendations, suggestions and good practices, which for the purposes of a TranSAS appraisal have been defined as follows:

— A recommendation is advice on improvement in the reviewed area. It can be, but need not necessarily be, an indication of shortcomings either in the national statutory legislative and regulatory regime or in the methods of fulfilling the regulatory requirements.
— A suggestion is either an additional proposal in conjunction with a recommendation or it may stand on its own. A suggestion should stimulate the regulatory body's management and staff to consider ways and means of enhancing performance.
— A good practice is a recognition of a current practice well above the norm. It has to be superior enough to be worth bringing to the attention of other nuclear regulatory bodies as a model in the general drive for excellence.

FINDINGS OF THE TRANSAS APPRAISAL FOR BRAZIL

S10. The background information and the basis for the findings are presented, together with the findings, in Section 4 of this report. Each finding has a basis in the Transport Regulations, in the modal international standards and/or in other relevant international regulatory documents and standards.

S11. The listing of findings presents for each key area of review first the recommendations, then the suggestions and finally the identified good practices, as applicable.

S12. The findings of the appraisal include 22 recommendations and seven suggestions for areas in which the transport regulatory practice can be streamlined or improved. The appraisal also identified four good practices that can serve as a model for other competent authorities in the radioactive material transport sector to emulate.

S13. The findings are presented for the eight key topical areas of review in the TranSAS questionnaire, after which the general conclusions are given.

S14. General conclusions concerning the findings are also presented in Section 5 of this report.

Legislative and governmental responsibilities

S15. Recommendation: harmonization of the requirements of the various national and international regulations should be pursued so as to eliminate legal discrepancies.

S16. Recommendation: the legislation should, to the extent possible, harmonize the keywords in the field of nuclear energy law, especially the legal definition of radioactive material, in order to avoid problems for the applicants, the competent authority, the public and the other authorities responsible for import licences, export licences, and intermodal and international transport.

S17. Recommendation: formal agreements between ministries in the areas of overlapping responsibilities should be developed.

S18. Recommendation: although in the CNEN the budget and the personnel for regulatory, licensing and inspection responsibilities are detached from the responsibility to promote the nuclear programme of Brazil, organization in accordance with IAEA GS-R-1 should be achieved by more clearly separating the organizations with these responsibilities.

S19. Recommendation: legislation in Brazil should set out arrangements for provisions of financial security in respect of any liability regarding the transport of radioactive material.

Authority, responsibilities, functions and organization of the regulatory body

S20. Recommendation: the memorandum of understanding between the CNEN and the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) should be completed, in order to clarify their specific responsibilities for the transport of radioactive material.

S21. Recommendation: a co-operation agreement between the CNEN and the Ministry of Transport (for transport by road and rail) and the Ministry of Defence (for transport by air and sea) should be considered.

S22. Recommendation: the regulatory functions should be more clearly separated from the operational and promotional functions. This separation should be evident from the organizational chart.

S23. Recommendation: in order to avoid any misunderstandings and potential legal conflicts, an amendment of the federal law that would extend the functions of the CNEN to cover the transport of all radioactive material, including nuclear material, should be considered.

S24. Suggestion: in order to make the organization more transparent, it might be considered to separate clearly the responsibilities for transport safety from those for radioactive waste safety.

S25. Suggestion: it is suggested that there be an evaluation of whether the actual number of staff is sufficient to cope with the different tasks attributed to the competent authority. The workload needs to be evaluated taking into account the foreseen evolution of the Brazilian nuclear programme. Changes to regulations need to be evaluated with respect to their impact on human resources, and additional recruitment should be made accordingly.

Authorization process

S26. Recommendation: the memorandum of understanding between the CNEN and IBAMA should be completed and should in particular address the specific roles of both organizations in the licensing processes for the transport of radioactive material.

S27. Recommendation: the existing draft revision of Regulation CNEN-NE-5.01 should be promulgated as soon as possible. In a further stage, the regulation should be carefully reviewed to verify that the 1996 edition of the Transport Regulations is implemented completely and in line with the international modal transport regulations. In this context, a translation of the 1996 edition of the Transport Regulations into Portuguese might be helpful.

S28. Recommendation: the guidance for the preparation of transport plans should be revised to bring it into line with the new national and international regulations. Similarly, guidance should be drafted for an application for approval of a package design.

S29. Recommendation: the contents of the authorizations for transport should be revised to bring them into line with the relevant provisions of the transport regulations of the CNEN.

Review and assessment

S30. Recommendation: it is recommended that compliance assurance mechanisms should be developed by the competent authority to ensure that consignors show evidence of having developed and implemented an acceptable quality assurance programme to satisfy the requirements of the 1996 edition of the Transport Regulations.

S31. Recommendation: it is recommended that compliance assurance mechanisms should be developed by the competent authority to ensure that manufacturers of packages, including Type A and industrial packages, show

evidence of having developed and implemented an acceptable quality assurance programme to satisfy the requirements of the 1996 edition of the Transport Regulations.

S32. Recommendation: it is recommended that compliance assurance mechanisms should be developed by the competent authority to ensure that packages designed to transport radioactive material, including Type A and industrial packages, satisfy the appropriate design and performance requirements.

S33. Suggestion: it is suggested that an attempt be made to verify that the drop test requirement for Type AF packages has been satisfied, and that the other requirements of the 1996 edition of the Transport Regulations for this type of package have been met and, if such evidence can be obtained, to discontinue the practice of using a special arrangement designation for the INB's shipments.

S34. Good practice: the emphasis on thoroughly prepared and thoroughly evaluated transport plans is a practice that is commendable, as it provides an important practical structure for ensuring compliance with many of the transport requirements.

Inspection and enforcement

S35. Recommendation: the requirement that the competent authority implement a programme to ensure compliance with the Brazilian transport regulations should be included in the Brazilian regulations. The wording in para. 7.1.3.4 of the draft revision of Regulation CNEN-NE-5.01 should be extended to include at least special form materials, since special form sources are at present in use in Brazil.

S36. Recommendation: in order to comply with the requirement in the 1996 edition of the Transport Regulations for a compliance assurance programme and the guidance of IAEA Safety Series No. 112 that this should include the auditing of quality assurance programmes, it is recommended that a programme for performing audits of quality assurance programmes should be developed.

S37. Suggestion: consideration might be given to finding ways to streamline the audit process. For example, it may be possible to design partial audits that are less detailed than a full audit or that review only certain parts of the user's quality assurance programme at a time. To improve the efficiency of the audit

process, it might also be possible to simplify the administrative controls for audits of quality assurance programmes.

S38. Suggestion: it is suggested that guidance on applying for approval of a transport plan by the Radioactive Waste Division of the CNEN (DOREJ) be formalized as an official document, and be made available on the CNEN's web site or in some other way made readily accessible to interested parties.

S39. Suggestion: it is suggested that guidance on the appropriate contents of an adequate quality assurance programme for ensuring the safe transport of radioactive material be formalized as an official document, and be made available on the CNEN's web site or in some other way made readily accessible to interested parties.

S40. Suggestion: it is suggested that specific requirements for the reporting to the competent authority of specified incidents, accidents and variations be established and incorporated in the regulations or in official guidance, and that these requirements be made available on the CNEN's web site or in some other way made readily accessible to interested parties. One way to approach this goal may be to extend the guidance in Regulation CNEN-NN-6.04, or to modify and extend it, to cover all activities relating to the transport of all types of radioactive material.

S41. Good practice: if an entity intends to receive radioactive material, it must first apply to the Division of Radioactive Facilities (DIRAD) for a licence to possess radioactive material. DIRAD gives the entity information on what must be done (at present it refers the applicant to the CNEN's web site). DIRAD will not issue an authorization to receive radioactive material unless the entity, or its contracted carrier, already has a transport plan approved by DOREJ. Similarly, if the entity wishes to ship radioactive material, it must obtain permission from DIRAD to relinquish possession, and DIRAD will not issue this permission unless a transport plan for the material to be shipped has been approved by DOREJ. The use of various computerized databases facilitates this close co-ordination.

Development of regulations and guides

S42. Recommendation: in order to avoid discrepancies between the implementation of the various editions of the Transport Regulations (and there are potential safety hazards), it is recommended that the same regulations

should be applied concurrently in Brazil for both the national and the international transport of radioactive material.

S43. Recommendation: to be in line with the other international agreements for the transport of dangerous goods, it is recommended that the MERCOSUR agreement should be updated. Enhanced co-operation between the CNEN and the Ministry of Transport is necessary in the area of the transport of radioactive material.

S44. Recommendation: to avoid differences between the current Brazilian regulation for the transport of radioactive material (Regulation CNEN-NE-5.01) and the international regulations, it is recommended that the draft revision of Regulation CNEN-NE-5.01 (now based on an IAEA TECDOC) should be implemented as soon as possible.

S45. Recommendation: it is recommended to incorporate in the next version of Regulation CNEN-NE-5.01 all the changes needed to reflect the 1996 edition of the Transport Regulations — not only the major changes that have been incorporated in the draft revised version. The document including all these changes could be approved in accordance with the regulatory procedures for revising standards.

Emergency preparedness for transport

S46. Good practice: the capabilities for responding to an emergency in the area of the transport of radioactive material have been incorporated into the overall emergency preparedness structure across the country.

S47. Good practice: the SINAER procedures, which were produced by the CNEN in 2000, are practical guidelines for responding to an emergency stemming from an event or accident; these guidelines also cover emergencies in the area of the transport of radioactive material.

GENERAL CONCLUSIONS

S48. The TranSAS appraisal team completed a thorough appraisal of the implementation of the transport regulations in Brazil. Co-operation from the Brazilian authorities, and all those who participated in the detailed discussions, was excellent and contributed much to the value of the appraisal. In general the appraisal concluded that, although some improvements are recommended, all areas of transport safety are well addressed in Brazil and the good practices are

valuable for consideration by other States for their safe transport of radioactive material.

S49. There is some potential for improvement by harmonizing revisions to the transport regulations of the CNEN with revisions to the regulations of the international modal organizations. In this respect it is important to implement formally the draft revision of Regulation CNEN-NE-5.01 as soon as possible and to update the MERCOSUR agreement concerning the transport of dangerous goods in line with the latest United Nations model regulations.

S50. It would also be useful to develop formal agreements between ministries in areas of overlapping responsibilities. The responsibilities for regulating, licensing and inspection should be more clearly separated from the operational and promotional functions. More formality in procedures could be used to enhance the compliance assurance aspects of regulating the transport of radioactive material.

S51. Good practices were noted in particular in the area of emergency response. The capabilities for responding to an emergency and the practical guidelines would be worth while for other competent authorities to consider. Another good practice involves the emphasis on preparing and evaluating transport plans and the practical application of these plans for ensuring compliance.

1. INTRODUCTION

BACKGROUND

1.1. In order to facilitate safety in the transport of radioactive material throughout the world, the IAEA, pursuant to its statutory authority, has established the Regulations for the Safe Transport of Radioactive Material (the Transport Regulations). The latest edition of the Transport Regulations was published in 1996 and revised in 2000 [1]. In addition to publishing the Transport Regulations, the IAEA also issues various guidance publications [2–5].

1.2. Details regarding the manner in which the Transport Regulations are incorporated into international regulatory documents are provided in Section 2 of this report. Effective implementation of the Transport Regulations at the State level is essential for ensuring a high level of safety in the transport of radioactive material. Other key documents that should be considered by a State in regulating its transport of radioactive material are discussed in Section 2.

1.3. On 25 September 1998 the General Conference of the IAEA, which meets annually, adopted resolution GC(42)/RES/13 on the Safety of Transport of Radioactive Materials. In adopting that resolution, the General Conference recognized that "*compliance with regulations that take account of the Agency's Transport Regulations is providing a high level of safety in the transport of radioactive materials...*" In addition, it requested the IAEA Secretariat to provide for the application of the Transport Regulations by, inter alia, providing a service for carrying out, at the request of any State, an appraisal of the implementation of the Transport Regulations by that State.

1.4. In response to this request the Director General offered the requested Transport Safety Appraisal Service (TranSAS) to all States in letter J1.01.Circ., dated 10 December 1998.

1.5. The first TranSAS was undertaken and completed at the request of Slovenia in 1999. Brazil was the second State to request a TranSAS.

1.6. In each of the General Conferences since 1998 resolutions focused on transport safety have commended the Secretariat for establishing the TranSAS, commended those States that have requested this service and encouraged other

States to avail themselves of this service (see GC(43)/RES/11, GC(44)/RES/17, GC(45)/RES/10 and GC(46)/RES/9).

REQUEST FROM BRAZIL

1.7. On 10 May 2000 the Head of the International Relations Office of the Brazilian National Nuclear Energy Commission (CNEN) requested the IAEA to organize and conduct a TranSAS appraisal in Brazil. Further discussions on this request were held in Vienna during the following week, and a preparatory mission to the CNEN's Head Office in Rio de Janeiro was conducted in August 2000 to organize and agree the details of the appraisal. These details were summarized in a preliminary agreement.

1.8. The preliminary agreement addressed the following:

- The scope of the appraisal;
- The tentative dates of the appraisal;
- The activities to be completed by the IAEA and by Brazil during the period leading up to the appraisal;
- A preliminary list of activities to be undertaken during the appraisal;
- The facilities required during the appraisal.

SCOPE OF THE APPRAISAL FOR BRAZIL

1.9. The general scope of any TranSAS appraisal includes:

- An appraisal of the State's transport safety regulatory practices with respect to the requirements of the Transport Regulations;
- Recommendations, as appropriate, in areas in which the State's transport safety regulatory programme might be improved.

1.10. The more specific scope for Brazil, as requested, included the following:

- An evaluation of the national transport legislation and regulations, taking into account applicable international practices. Special attention was to be given to the need to take into account the implementation of the requirements of the 1996 edition of the Transport Regulations [1], which became effective during 2001 for international air and sea transport through the applicable regulations of the International Civil Aviation

Organization (ICAO), the ICAO Technical Instructions [6], and the applicable regulations of the International Maritime Organization (IMO), the International Maritime Dangerous Goods (IMDG) Code [7].
— A review and evaluation of the efficiency of the inspection and enforcement programme related to the transport of radioactive material.
— An evaluation of the co-operation arrangements with key government organizations, with specific attention to be given to areas of overlapping responsibilities in, for example, the area of environmental protection.

ACTIVITIES COMPLETED PRIOR TO THE APPRAISAL

1.11. Preparations completed by Brazil included the following:

— The completion and transmittal to the IAEA of the detailed TranSAS questionnaire. Related relevant supporting documentation had already been provided as working papers and information papers. The translations still required for some of these papers were carried out both by the CNEN and the IAEA.
— Ensuring the availability of key personnel from the CNEN and other authorities during the appraisal.
— The arrangement of the logistics for the appraisal, which included accommodation and local transport for the team members, and some translation services during the appraisal.

1.12. Preparations completed by the IAEA included the following:

— The recruitment of the appraisal team (this included arranging for the necessary approvals for the recommended team members);
— Providing the appraisal team with relevant documentation and the TranSAS guidelines;
— Arranging for the transport of the team members to and from Brazil.

APPRAISAL REPORT

1.13. This report documents the results of the TranSAS appraisal conducted in Brazil from 15 to 26 April 2002. The appraisal team was composed of five independent experts. These experts were representatives of regulatory authorities in Belgium, Germany and the United States of America responsible for the transport of radioactive material, a legal expert from Germany with

experience in the transport of radioactive material and the team leader, a transport safety expert from the IAEA.

2. DOCUMENTS RELEVANT FOR THE TRANSAS APPRAISAL

IAEA SAFETY STANDARDS

2.1. The Transport Regulations are key to the development of a regulatory regime for the safe transport of radioactive material. These regulations were first developed in the late 1950s at the request of the United Nations Economic and Social Council. The first edition of the Transport Regulations was published in 1961, and has been updated regularly. The latest edition of the Transport Regulations was issued in 1996 and revised in 2000 to accommodate editorial changes [1]. The previous edition, upon which some States still base their national transport regulations, was issued in 1985 and amended in 1990 [8]. There are also additional guidance publications issued by the IAEA to support the application of the Transport Regulations by regulators and users [2–5]. Explanatory material [9] and advisory material [10] related to the 1985 edition of the Transport Regulations is relevant where that edition is still being applied.

2.2. These publications provide a sound basis for competent authorities in States to regulate the transport of radioactive material. Specifically, the Transport Regulations [1], and their preceding editions (e.g. the previous 1985 edition (as amended in 1990) [8]), have provided and continue to provide a model to be followed by relevant international organizations and States in developing binding regulations for the international and national transport of radioactive material. The guidance publications [2–5] also are valuable tools for competent authorities, consignors, carriers and consignees for describing how they may apply specific requirements of the regulations. For example, the general advisory publication [2] and its predecessor publications [9, 10] provide insight into why various regulatory requirements have been established and defines 'a way', or 'ways', but not 'the way' in which specific requirements may be satisfied in practice. Guidance is also provided in specific key areas, inter alia, planning and preparing for emergencies [3][1], compliance assurance [4] and quality assurance [5].

2.3. The Transport Regulations have a foundation, from a radiation protection standpoint, in the IAEA Safety Fundamentals publication

[1] The predecessor document to Ref. [3] was Safety Series No. 87.

Radiation Protection and the Safety of Radiation Sources [11] and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the Basic Safety Standards) [12].

2.4. Finally, a key publication for the application of transport regulations in a State is the publication Legal and Governmental Infrastructure for Nuclear Radiation, Radioactive Waste and Transport Safety [13], which discusses in detail the legislative and governmental responsibilities of a State and the responsibilities, functions, organization and activities of a regulatory body.

2.5. These IAEA publications serve as a basis for appraising the regulatory activities for the transport of radioactive material. However, it must be recognized that these publications are not backed by the rule of law, that they are generally not mandatory for a State and that they are advisory in nature. For example, the Transport Regulations [1, 8] serve as models for a State's national transport regulations.

2.6. In striving to foster a consistent basis for communicating these recommended requirements to its Member States, the IAEA also issues a safety glossary [14].

INTERNATIONAL REGULATORY DOCUMENTS AND STANDARDS

2.7. The Transport Regulations serve as the model for the radioactive material portions of international dangerous goods regulatory documents, some of which are applied on a mandatory basis by Member States.

2.8. The first step in applying the Transport Regulations was the incorporation of their requirements into the United Nations Committee of Experts on the Transport of Dangerous Goods' Recommendations on the Transport of Dangerous Goods — Model Regulations [15], which provide a detailed set of 'model regulations' for all nine classes of dangerous goods. Radioactive material is Class 7 in these regulations. The United Nations model regulations serve as a basis for international regulations for the transport of dangerous goods by the different modes of transport. These international modal transport regulations for air [6] and sea [7] are mandatory upon all Member States of the ICAO and the IMO, respectively. For States in Europe, the United Nations Economic Commission for Europe's Inland Transport Committee develops dangerous goods regulations (including requirements derived from the Transport Regulations) for road (the ADR requirements) [16]

and rail (the RID requirements) [17]. States that are members of the European Union are bound by European Union directives to abide by the ADR and RID requirements. Within the MERCOSUR countries (Argentina, Brazil, Paraguay and Uruguay) the international transport of dangerous goods, including radioactive material, is subject to an agreement based on an earlier version of the United Nations Recommendations on the Transport of Dangerous Goods [18].

WORKING PAPERS AND INFORMATION PAPERS PROVIDED BY BRAZIL

2.9. A considerable number of working papers and information papers were provided by Brazil prior to the appraisal. The working papers and information papers quoted in this report are:

- WP-04: Federal Law No. 7.781.
- WP-07: Decree No. 96.044.
- WP-08: Decree No. 98.973.
- WP-10: CONAMA Resolution No. 237-1997 (Resolution of the National Environmental Council).
- WP-11: Resolution No. 271-E of the Civil Aviation Department.
- WP-12: CNEN Trial Standard 5.01.
- WP-15: Maritime Authority Rule NORMAM 01/2000 (Portaria No. 39).
- IP-06: draft regulatory guide — guidelines for the transportation plan.
- IP-09: Report SUREJ No. 013/99 (UO_2 transport operation).
- IP-18: transport authorization document.
- IP-19: checklist for transport operations.

3. APPRAISAL PROCESS IN BRAZIL

OVERVIEW OF THE APPRAISAL PROCESS

3.1. The appraisal process included the following:

- A preparatory session for the appraisal team;
- The entrance meeting, in which key representatives from the CNEN and other authorities gave presentations on their responsibilities for the safe transport of radioactive material;
- Discussions to obtain clarifications and additional or more detailed information;
- Updating the TranSAS questionnaire and preparing the draft report with findings;
- Ongoing feedback on the updated questionnaire and the draft report with findings;
- A visit to the fuel manufacturing facilities of Indústrias Nucleares do Brasil (INB);
- An exit meeting to present and discuss the findings.

PREPARATORY SESSION

3.2. The members of the team had broad experience in and expertise on the implementation of regulations for the transport of radioactive material. They represented regulatory authorities in Belgium, Germany and the United States of America responsible for the transport of radioactive material, a legal expert from Germany with experience in the transport of radioactive material and a transport safety expert from the IAEA. Further details on the team members are provided in Appendix II.

3.3. Specific experience was taken into account for the assignment of the lead responsibilities for appraising the eight areas addressed in the TranSAS questionnaire.

3.4. A preparatory session preceding the formal part of the appraisal was held in order for the team members to meet with the Brazilian counterpart, to review the programme for the appraisal and the procedures to be followed, and to review the reference material to be used and the work to be carried out.

ENTRANCE MEETING

3.5. The entrance meeting involved key representatives of the following organizations of the CNEN:

- The Nuclear Safety and Radiation Protection Directorate (DRS) and the following organizations in this directorate:
  - The General Co-ordination for Licensing and Control (CGLC);
  - The Radioactive Waste Division (DOREJ);
  - The Radioprotection and Dosimetry Institute (IRD).
- The Research and Development Directorate (DPD) and the following organizations in this directorate:
  - The Institute of Nuclear Research (IPEN);
  - The Centre for the Development of Nuclear Technology (CDTN).

3.6. The agenda of the entrance meeting covered the following:

- Welcome by the CNEN;
- Review of the scope of the appraisal;
- Introduction of the appraisal team members and the CNEN participants;
- Overview of the organization of the DRS;
- Overview of the organization of the Transport Unit in DOREJ;
- Overview of the organization of the DPD;
- Overview of the legal framework for the transport of radioactive material in Brazil;
- Overview of the process (legal and technical) for implementing changes to the regulations;
- Overview of the work carried out by the Transport Unit in DOREJ;
- Overview of transport related work carried out by IPEN (the production and shipment of radioisotopes);
- Overview of the testing of transport packages carried out by the CDTN;
- Overview of the transport related emergency response procedures of the IRD;
- Overview of the inspection procedures;
- Overview of procedures for an application for a transport authorization by the CNEN and for a transport operation licence from the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA).

INTERVIEWS, UPDATING THE QUESTIONNAIRE AND DEVELOPING THE REPORT

3.7. In addition to the discussions following the presentations, the team invited several participants to discuss in more detail the information provided in the questionnaire. Subsequently, the team members pursued further information specific to the areas for which they had the lead responsibility. The additional information was reflected in an updated version of the questionnaire. The updated questionnaire was made available to the participants by the end of the first week for their comments. At the beginning of the second week the updated questionnaire was used to start drafting the findings. Interviews, review of information and feedback on the findings were incorporated into the findings presented at the exit meeting.

VISIT TO A FUEL MANUFACTURING FACILITY

3.8. A visit to the fuel manufacturing facilities of the INB in Resende, about 200 km from Rio de Janeiro, was arranged for the Thursday morning of the second week, while the draft report with findings was being reviewed. Special attention was given to the transport containers at this facility and to their marking and labelling for transport.

EXIT MEETING

3.9. The findings of the team were presented by the team members for the areas in which they had the lead responsibility. These findings are given in the Summary, Findings and Conclusions section of this report. The findings, together with the relevant background information and the basis for the findings, are presented in detail in Section 4.

4. APPRAISAL OF THE IMPLEMENTATION OF THE TRANSPORT REGULATIONS IN BRAZIL

INTRODUCTION

4.1. This section is structured around the key topic areas covered in the TranSAS questionnaire. These key areas are:

— Legislative and governmental responsibilities;
— The authority, responsibilities and functions of the regulatory body;
— The organization of the regulatory body;
— The authorization process;
— Review and assessment;
— Inspection and enforcement;
— The development of regulations and guides;
— Emergency preparedness for transport.

This section provides, for each of these areas, an overview of the relevant information followed by the findings for that area. Each finding is preceded by a basis from appropriate international regulatory and guidance documents. The findings are presented in terms of recommendations, suggestions and good practices, as applicable.

LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

Overview

4.2. The overview for this key area is subdivided into the following:

— The legislative framework;
— The Federal Constitution of Brazil;
— Federal laws;
— Decrees and resolutions;
— The CNEN's regulations;
— Administrative rules;
— Standards;
— Government bodies responsible for transport.

Legislative framework

4.3. The CNEN was created in 1956 (Decree No. 40.110 of 10 October 1956) to oversee all nuclear activities in Brazil. Later, the CNEN was reorganized and its responsibilities were laid down in Law No. 4.118/62. According to Article 4, para. V, these responsibilities included the construction and operation of nuclear power plants. The responsibilities of the CNEN were amended by Laws No. 6.189/74 and No. 7.781/89, which established that Eletrobrás (the Brazilian electrical company) was licensed to operate nuclear power plants and that the CNEN was the regulatory body in charge of regulating, licensing and controlling nuclear energy.

4.4. In 1971 Federal Law No. 5.740 authorized the CNEN to establish the Brazilian Nuclear Technology Company (CBTN) to oversee research, the mining of nuclear minerals and the development of the nuclear industry and nuclear technology. According to Federal Law No. 6.189 of 1974, the CBTN was transformed into Empresas Nucleares Brasileiras SA (Nuclebrás). On the basis of Law No. 6.189, the CNEN became the nuclear authority in charge of promotion, supervision, inspection, control and scientific research, and Nuclebrás became the executive branch of the Brazilian national nuclear programme related to research, mining and the evaluation of nuclear mineral reserves. In 1988 Nuclebrás became the INB.

4.5. The basis in Brazil for the regulations covering the safe transport of radioactive material for all modes of transport, both for national and international transport, is Regulation CNEN-NE-5.01, which is based on the 1985 edition of the Transport Regulations [8]. The international transport of cargo by air requires compliance also with the ICAO Technical Instructions [6] and the international shipment of cargo by sea is subject to the International Maritime Dangerous Goods Code of the IMO (IMDG Code) [7]. The current ICAO Technical Instructions and the current IMDG Code have incorporated all the requirements of the 1996 edition of the Transport Regulations [1]. It is obvious that a discrepancy exists, as the Brazilian rules rely on the 1985 edition of the Transport Regulations [8]. This discrepancy may cause legal difficulties in the field of both the national and international transport of radioactive material, the import into Brazil and export by Brazil of radioactive material, and also the transport of this material within the MERCOSUR area. Discrepancies have been addressed to a great extent at an informal level by applying a draft revision of Regulation CNEN-NE-5.01. The regulatory system works, but it is not in compliance with formal legal procedures.

4.6. Other authorities are empowered by law to intervene in matters relating to the transport of radioactive material: this in principle can complicate the licensing process. The National Environmental Council (CONAMA) and the State Environmental Foundation (FEEMA) have issued complementary requirements and guidelines for the transport of dangerous goods, including radioactive material. Specific standards for the transport of dangerous goods by air, land, river and sea are issued by modal transport authorities. Also applicable are the industrial standards of the Brazilian Institute of Technical Standards (ABNT), a private organization.

4.7. The transport of radioactive material is to be performed in full compliance with the applicable safety requirements. Although the CNEN, by federal law, is the competent authority for regulating the transport of radioactive material and for the licensing process, there are additional requirements of the Ministry of Transport and IBAMA.

4.8. The general legislation governing the transport of radioactive material within Brazil and the international transport of radioactive material to and from Brazil is based on the Federal Constitution of Brazil, several federal laws, and decrees and standards of the CNEN and other responsible regulatory bodies, as described below.

Federal Constitution of Brazil

4.9. The Federal Constitution of Brazil of 1988 provides that the Federal Union has exclusive competence for managing and handling all nuclear energy activities, including the operation of nuclear power plants (Article 21, Section XXIII). The Federal Union also holds exclusive rights for the prospecting for and the mining, milling, enrichment and reprocessing of nuclear minerals, and in activities relating to industrial processing and the trade in nuclear minerals and material (Article 177). All these activities must be carried out solely for peaceful uses and always with the approval of the National Congress (Article 21, Section XXIII(a)). The Federal Constitution of Brazil (Article 21, Section XXIII(b)) also provides that the use of radioisotopes for research, medicine, agriculture and industry is subject to a licensing system. Civil liability for nuclear damages is defined in the legislation (Article 21, Section XXIII(c)). The competence to enact legislation on transit and transport as well as on all nuclear activities is exclusive to the Federal Union (Article 22, Sections XI and XXVI). The Federal Union, the states, the counties and the municipalities are equally responsible for the protection of the environment; to preserve the forests, the fauna and flora (Article 23, Section VI). The Federal Union, the

states and the counties are equally competent to enact legislation on forests, hunting, fishing, fauna, nature preservation, the protection of the soil, natural resources and the environment and on pollution control (Article 24, Section VI). Public corporations and entities and private corporations that render public services are liable for the damages caused by their agents to third parties or persons; the right of action against a responsible party is ensured for fraud (dolus) or fault (Article 37, Section 6). Except for information that is to be kept confidential for State security or other State reasons, all persons have the right to receive information, whether of a private or of a collective and general nature, from public entities, within the terms established by law, under penalty of law (Article 5, Section XXXIII).

Federal laws

4.10. Federal Law No. 4.118 of 27 August 1962 is on Brazilian nuclear policy, the exploitation of local mines and the production, industrial processing and trade in all radioactive material; it also established the CNEN. According to Article 4, the CNEN is in charge of the production and the trade in nuclear by-products and radioisotopes, the acquisition, sale, exchange, lending, leasing, transport and storage of which require a CNEN licence issued in accordance with this law.

4.11. Federal Law No. 6.189 of 16 December 1974 (which amended Law No. 4.118): Item IX of Article 2 provides that the CNEN is authorized to "*issue regulations, licences and authorizations relating to the acquisition, use, storage and transport of nuclear material and to issue safety or security rules and regulations relating to the transport of nuclear material*". This law created Nuclebrás as a company responsible for nuclear fuel cycle facilities, equipment manufacturing, nuclear power plant construction, and research and development activities.

4.12. Federal Law No 7.781 of 27 June 1989 (which amended Law No. 6.189): Article 2 amended the main competences of the transport of radioactive material. The functions of the CNEN are to issue regulations, licences and authorizations relating to the acquisition, use, storage and transport of nuclear material and to issue safety or security rules and regulations relating to the transport of nuclear material.

4.13. Law No. 7.092 of 19 April 1983 established the national register for road transport. This law was revoked by Law No. 9.611 of 19 February 1998.

4.14. Law No. 9.537 of 11 December 1997 established rules on the safety of transport on waterways under national jurisdiction.

4.15. Law No. 9.611 of 19 February 1998 governs multimodal cargo transport.

4.16. Law No. 9.765 of 17 December 1998 established a tax on the licensing and control of radioactive material and nuclear installations. The financial resources generated by this law are used to fund the activities of the CNEN in nuclear safety, licensing, control, enforcement, the inspection of nuclear and radioactive material, the inspection of nuclear installations, research and development, operational technical support for these activities, and support for public information.

4.17. Law No. 10.308 of 20 November 2001 regulates the site selection, construction and operation of initial, intermediate and final radioactive waste repositories. It determines the licensing procedures and the conditions for the recovery of relevant costs. Articles 21 and 22 provide that the operator of such repositories is absolutely and exclusively liable for any damages that might arise during the transport of waste to the repository. The operator of a repository must cover its liability with appropriate insurance. For intermediate and final repositories, the CNEN will be the operator, and its liability is covered by Article 36, Section 6 of the Federal Constitution of Brazil.

4.18. Law No. 6.453 of 17 October 1977. This law is still in force. It applies to civil liability for nuclear damages and criminal responsibility for acts related to nuclear activities (e.g. the transport of radioactive material without the necessary licence (Section 22), the export or import of nuclear material, nuclear ores or their concentrates without the necessary licence (Section 25) and failure to observe safety or protection rules applicable to the transport of nuclear material (Section 26)). Chapter III extended the scope of this law to all "nuclear material" (namely nuclear fuel and radioactive products or waste) and states that it is an offence to transport nuclear material without the necessary licence.

4.19. Federal Law No. 7.565 of 19 December 1986 established the Brazilian Aeronautic Code. Article 21 prohibits the transport of dangerous goods by aircraft, except with the authorization of the competent public entity. Section VI of Article 25 established the system of safety for air transport within the framework of aeronautical services. Section 1 of Article 25 states that the operation of any service, within the substructure of aeronautical services, is subject to the authorization of the aeronautic authority.

Decrees and resolutions

4.20. Decree No. 40.110 of 10 October 1956 created the CNEN.

4.21. Resolution No. 237 of 1997 created CONAMA. CONAMA establishes environmental licensing requirements for the transport of dangerous goods. Article 2 provides that activities such as siting, construction, installation, extension, modification and operations involving potentially polluting activities for which natural resources are used and all activities that may, in any way, cause environmental degradation shall be licensed by the competent environmental authority. Article 4 provides that IBAMA is the competent licensing authority; Item IV of Article 4 includes the transport of radioactive material as an activity with the potential to cause an environmental impact.

4.22. Resolution No. 271-E of the Civil Aviation Department of 1 July 1998 established the requirement for an authorization by the CNEN for the transport of radioactive material. Article 3 provides that, for the transport of packages containing radioactive material, an authorization by the CNEN is needed.

4.23. Decree No. 2.210 of 22 April 1997 governs the System for the Protection of the National Nuclear Programme (SIPRON). This decree states that the two main functions of SIPRON (which was created by Decree No. 1.809) are in the areas of protection against terrorism and emergency response to a nuclear accident.

4.24. Decree No. 87.648 of 24 September 1982 implements the regulation for maritime traffic. This decree was revoked by Decree No. 2.596 of 18 May 1998.

4.25. Decree No. 2.596 of 18 May 1998 is on safe transport on waterways under national jurisdiction. This decree approves the provisions of Law No. 9.537 of 11 December 1997.

4.26. Decree No. 88.821 of 6 October 1983 approves the regulation for the execution of services for the transport of dangerous goods by road. This decree provides that the transport of radioactive material is subject to the specific regulations of the CNEN.

4.27. For licensing purposes, all military facilities are subject to the requirements of the Convention on the Physical Protection of Nuclear Material and to the civil authority of the CNEN.

4.28. Decree No. 96.044 of 18 May 1988 approves the regulation for the transport of dangerous goods on highways. This decree reiterates the terms of Decree No. 88.821 of 1983 and provides that the transport of radioactive material is subject to the specific regulations of the CNEN. This decree stipulates rules concerning vehicles and their equipment, cargo and its packaging, routes, parking, the workers involved, documents and emergency procedures. This decree describes the duties and responsibilities of the manufacturer and of the importer of equipment used for transport and of the contracting party, the forwarding agent, the consignee and the carrier.

4.29. Decree No. 98.973 of 21 February 1990 approves the regulation for the transport of dangerous goods by rail. The transport of explosives and of radioactive products is subject to the specific rules of the Secretary of the Army and of the CNEN.

4.30. Decree No. 1.797 of 25 January 1996 (the MERCOSUR Decree) regulates the execution of the agreement with Argentina, Uruguay and Paraguay to facilitate the international transport of dangerous goods within the MERCOSUR area.

CNEN's regulations

4.31. Regulation CNEN-NE-5.01 of July 1988 is on the transport of radioactive material. The regulation applies to the national and international transport of radioactive material (para. 1.2.1) by land, water or air, as well as to the packaging of these materials. The regulation is based on the 1985 edition of the Transport Regulations [8]. The CNEN may, through a resolution, replace and/or add requirements to this regulation, as it deems appropriate or necessary (para. 2.1.2). The design requirements for safe packaging are also specified, as well as the documents to be prepared by the consignor for each transport operation. The regulation describes the radiation protection and safety conditions to be complied with during the transport of radioactive material, including the requirements on the activity of the material. The regulation contains annexes that describe the packaging tests required, such as impact tests and the resistance capacity in accident conditions; label models and tables of activities for radionuclides are also specified.

4.32. Regulation CNEN-NE-3.01, the basic standard on radiation protection, is dated July 1988.

4.33. Regulation CNEN-NE-5.02, on the transport, acceptance, storage and handling of fuel assemblies of nuclear power plants, was issued in October 1986.

4.34. Regulation CNEN-NE-5.03, on the transport, acceptance, storage and handling of items for nuclear power plants, is dated 2 February 1989.

4.35. Regulation CNEN-NN-3.03 and related regulations SENOR-48, Res. 05/95, Res. 05/95, Res. 12 (98) set forth the requirements for the Certificate of Qualification for an Officer of Radiation Protection.

Administrative rules

4.36. Ministry of Transport Administrative Rule No. 204 of 1997 (based on the United Nations Recommendations on the Transport of Dangerous Goods [18]) issues complementary instructions for the regulations for the transport of dangerous goods on highways (Decree No. 96.044 of 1988) and by rail (Decree No. 98.973 of 1990).

4.37. Secretary of the Navy Administrative Rule No. 11 of 11 March 1995 generally approves the norms and procedures for inland navigation for national or foreign merchant ships during their arrival at or departure from Brazil. *This rule does not apply to the transport of radioactive material.*

4.38. Secretary of the Navy Administrative Rule No. 9 of 11 February 2000 approves a series of 16 Rules of the Maritime Authority (NORMAM). NORMAM 01/2000 covers ships during navigation on the open sea. Section 1 of Chapter 5 regulates the transport of dangerous goods. The definition of dangerous goods corresponds to the IMDG Code, which classifies radioactive material as Class 7. Comprehensive and accurate information on the material transported in all cases must be provided. Again, for the transport of radioactive material, the specific regulations of the CNEN must be applied, but the requirements of the IMDG Code are also applied. Similarly, NORMAM 02/2001 applies to navigation on inland waterways.

4.39. Ministry of Defence, Secretary of the Navy, Directorate of Ports and Coasts, Administrative Rule No. 4/DPC of 10 January 2002 revokes Article 1-B of Administrative Rule No. 09/2000 (NORMAM 02/2000) and approves NORMAM 02/2002. For ships on inland waterways, Section 1 of Chapter 5 regulates the transport of dangerous goods. For the transport of radioactive material (Class 7), the specific regulations of the CNEN must be applied. In

1996 an application was submitted for an authorization to transport a ^{60}Co source on the Amazon River, which was denied.

4.40. Ministry of Defence, Secretary of the Air Force, Administrative Rule GM5 No. 957 of 19 December 1989 approves the general clauses for transport. Article 55 of Chapter VI states that luggage must not contain certain dangerous goods, including radioactive material.

4.41. Ministry of Defence, Secretary of the Air Force, Civil Aviation Department, Administrative Rule No. 060E/SPL of 7 April 1998 approves Civil Aviation Instruction IAC-1603-0498, on the transport of dangerous goods by civilian aircraft. Item 6 establishes that the loading of packages with radioactive material must comply with the regulations of the CNEN.

4.42. Ministry of Defence, Secretary of the Air Force, Civil Aviation Department, Administrative Rule No. 271E/SPL of 1 July 1998 specifies the documents compulsory for the air transport of dangerous cargo. Article 3 repeats the terms of Item 6 of IAC-1603-0498.

4.43. Ministry of Defence, Secretary of the Air Force, Administrative Rule No. 419/GM5 of 9 June 1999 approves and establishes instructions for the procedures and conditions for safety operation plans for air cargo. Section c of Chapter XI establishes that, for the transport of dangerous cargo, the instructions for packing of Administrative Rule No. 271E/SPL of 1998 must be followed.

4.44. Ministry of Defence, Secretary of the Air Force, Civil Aviation Department, Administrative Rule No. 1577/DGAC of 13 November 2001 revokes Administrative Rule No. 060E/SPL of 7 April 1998 and IAC-1603-0498. It enacts IAC-1603A, on the transport of dangerous products by civilian aircraft.

Standards

4.45. ABNT Standard 10.854, on the transport of dangerous goods by air.

4.46. ABNT Standard 7503, on emergency instructions for dangerous goods (1982).

4.47. ABNT Standard 7504, on the transport of dangerous goods (1983). Regarding the interdependence between this ABNT standard and Regulation CNEN-NE-5.01, it was stressed that there are links and commitments between the recommendations of the ABNT and the regulations promulgated by the

CNEN. The ABNT is the (private) Brazilian standards organization that generally issues non-binding recommendations for technical standards directed at the industrial sector. These recommendations may acquire the force of law as they are referenced in decrees or regulations. The CNEN has made such references. New standards, Coletânea de Normas de Transporte Produtos Perigosos, 2000 (collection of standards for the transport of dangerous goods), have been published since the promulgation of Regulation CNEN-NE-5.01 in 1988. For an overview of the basic legal aspects of the transport of radioactive material, additional information is needed on the applicability of the standards published after 1988. The ABNT standards are not of a regulatory nature, they are voluntary. Nonetheless, they are often referred to in the regulatory guide for transport. Regulatory guides are documents issued by the competent authority in order to provide applicants a model on how to apply for permissions or authorizations. An applicant may or may not follow the provided guidance. Nevertheless, applicants are aware that such guidance will be used in the assessment of documentation submitted to the competent authority.

4.48. In accordance with Regulation CNEN-NE-5.01 (para. 1.2.3), the transport of radioactive material through the mail system is prohibited in Brazil.

Government bodies responsible for transport

4.49. The following governmental organizations are responsible for the transport of radioactive material:

— The Ministry of Science and Technology (MST), through the CNEN;
— The Ministry of the Environment, through IBAMA;
— The Ministry of Defence, through the Secretary of the Army, the Secretary of the Navy and the Secretary of the Air Force;
— The Ministry of Justice, through the Federal Road Police;
— CONAMA;
— The National Agency for Land Transport (ANTT).

4.50. Other authorities that are competent, independent and guaranteed by the Federal Constitution of Brazil exist for every state and county in Brazil. These authorities are also responsible for general aspects of transport, which may affect the transport of radioactive material.

4.51. The CNEN is the national authority that establishes regulations for the safe transport of radioactive material, including packaging certification, inspections and emergency response; the CNEN is also responsible for the

licensing process in this area. IBAMA, which is the executive body of the National System of the Environment (SISNAMA), which itself is composed of CONAMA and other executive organizations at the federal, state and municipal levels, is responsible for the environmental licensing process and hence for the transport of radioactive material, but only for activities that may pose a significant environmental hazard.

Findings

4.52. Basis: Ref. [13] states in para. 2.4, inter alia, that "*This legislation:… (15) shall implement any obligations under international treaties, conventions or agreements;…*" In actuality, Regulation CNEN-NE-5.01 is based on the 1985 edition of the Transport Regulations [8]. De jure, the 1996 edition of the Transport Regulations [1] has not been adopted at the time of writing, according to the Brazilian Legal Gazette, which is published in Portuguese. To avoid conflicts with the requirements of the ICAO Technical Instructions [6] and the IMDG Code [7], which came into effect in 2001 for international air and sea transport, the CNEN decided to publish a draft revision of Regulation CNEN-NE-5.01 and to recommend its use until the formal legal procedures for adopting the draft have been completed.

4.53. In practice IPEN, as the consignor, follows the draft revision of Regulation CNEN-NE-5.01, which includes most requirements of the 1996 edition of the Transport Regulations [1], for all shipments. The observance of Regulation CNEN-NE-5.01 by the CNEN has led to fines being levied on the CNEN by the Federal Road Police for inconsistencies in the use of placards, as the Federal Road Police were enforcing the criteria of the 1985 edition of the Transport Regulations — there are currently appeals against these fines. To date, some five or six fines have been received for some 22 000 packages shipped since 1 July 2001. Discussions were held with the Federal Road Police in November 2001 to explain the reasons for the apparent inconsistencies, and no further fines have been levied since then. IPEN, an institute of the CNEN, is using the non-mandatory guidelines in the draft revision of Regulation CNEN-NE-5.01 to allow this placarding to continue until new regulations are in force. Road and rail regulations in accordance with the 1996 edition of the Transport Regulations will be in force for trade in the MERCOSUR countries when the MERCOSUR agreement is updated.

4.54. The draft revision of Regulation CNEN-NE-5.01 establishes safety standards to provide an accepted level of control of the radiation, criticality and thermal hazards to people, property and the environment associated with the

transport of radioactive material. The draft revised Regulation CNEN-NE-5.01 is based on the 1996 edition of the Transport Regulations. Detailed background information on the 1996 edition of the Transport Regulations is given in Ref. [2].

4.55. IPEN contracts provide that the responsibility of the consignor ends on the arrival of the radioactive material packages at the airport in the country of destination. There are other laws relating to the transport of radioactive material, but they refer to Regulation CNEN-NE-5.01, where appropriate. Law No. 9.611 of 1988 relates to multimodal transport.

Recommendation: harmonization of the requirements of the various national and international regulations should be pursued so as to eliminate legal discrepancies.

4.56. Basis: Ref. [13] states in para. 2.4, inter alia, that "*This legislation… (2) shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation;…*" It is one of the fundamental principles of nuclear law that there is a need for creating clear and consistent definitions or keywords in legislation. Clarity and consistency allow clear authorization, inspection and adherence to the internationally approved rules governing international transport, the ICAO Technical Instructions and the IMDG Code, which are in harmony with the 1996 edition of the Transport Regulations [1]. In Brazil the requirements of the 1996 edition of the Transport Regulations are applicable on the basis of an informal procedure. The requirement of a licensing procedure depends on the scope and the legal definition of the material for which an authorization is to be granted. As an example, the keywords 'radioactive material' could illustrate the disparate situation: in Act No. 6453 of 17 October 1977, which applies to liability and criminal liability, the legal definition of 'nuclear material' means nuclear fuel and radioactive products or waste. In Law No. 4.118 of 27 August 1962 the definition in Chapter I of nuclear material for the CNEN has a completely different meaning. On page 10, Section 4.1 of Regulation CNEN-NE-5.01, the definition of radioactive material is "*any material having a specific activity greater than 70 kBq*". In the 1996 edition of the Transport Regulations, in para. 236, the definition of radioactive material is "*Radioactive material shall mean any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in paras 401–406*." Even the definition of radioactive material in the Convention on the Physical Protection of Nuclear Material differs from that of the aforementioned rules and regulations.

Recommendation: the legislation should, to the extent possible, harmonize the keywords in the field of nuclear energy law, especially the legal definition of radioactive material, in order to avoid problems for the applicants, the competent authority, the public and the other authorities responsible for import licences, export licences, and intermodal and international transport.

4.57. Basis: Ref. [13] states in para. 2.2, inter alia, that "…*(3) Responsibility shall be assigned to the regulatory body for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulations and guides.*" Responsibilities at the federal level have been identified for both the CNEN and IBAMA. IBAMA is responsible for the environmental aspects related to the transport of dangerous goods (including radioactive material). According to CONAMA Resolution No. 237 (1997), IBAMA is responsible for environmental licensing for the transport of radioactive material that may cause a relevant environmental impact (Article 4, Section IV). A legal definition for the key term 'radioactive material' was not given by CONAMA. Work is under way to develop a memorandum of understanding between the CNEN and IBAMA in order to address responsibilities in overlapping areas.

4.58. In addition to the competent authorities at the federal level, there exist Brazilian state and county authorities that, in accordance with public law, may apply requirements or restrictions in addition to those specified by the CNEN. This authority has on occasion been used.

4.59. There are overlapping responsibilities in several ministries in the field of the transport of radioactive material. The Secretary of the Air Force of the Ministry of Defence, for example, has adopted the ICAO Technical Instructions and revisions to these instructions for the international air transport of dangerous goods (including radioactive material). Similarly, the Secretary of the Navy of the Ministry of Defence has adopted the IMDG Code as amended, which is applicable to the international maritime transport of dangerous goods. It seems that on a governmental level there is a need for a formal agreement to address the responsibilities in the overlapping areas in order to ensure an overall harmonized legal basis for the safe transport of radioactive material.

Recommendation: formal agreements between ministries in the areas of overlapping responsibilities should be developed.

4.60. Basis: Ref. [13] states in para. 2.2, inter alia, that "…*(2) A regulatory body shall be established and maintained which shall be effectively independent of*

organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made, and enforcement actions taken, without pressure from interests that may conflict with safety."

4.61. Law No. 7.781 of 27 June 1989 provides that, in addition to the duties assigned by Federal Law No. 6.189 of 16 December 1974, the CNEN will promote and carry out the production of and trade in nuclear material and equipment, including nuclear technology transfers to the national industry, through the setting up of trade associations or agreements. The CNEN is formally linked to the INB, a State company under the MST. The CNEN owns 51% of the stock of the INB. Since the INB must comply with the Transport Regulations, this may create a conflict of interest in the CNEN's regulatory function.

4.62. There also appears to be some potential for conflict in the relationship between the CNEN as the competent authority and other CNEN departments with operational responsibilities (IPEN and the CDTN). Special care is being taken by the CNEN to act diligently in these areas of potential conflict. However, a clear separation of the responsibilities provides the best independence.

4.63. Reference [13] states in para. 2.2, inter alia, that "…(5) *No other responsibility shall be assigned to the regulatory body which may jeopardize, or conflict with, its responsibility for regulating safety.*" It was stressed that regulatory deliberation and decisions on safety issues in areas where the CNEN has other responsibilities (e.g. IPEN) are subject to special attention in order to ensure that the regulatory responsibility would not be compromised.

4.64. The Second National Report of Brazil for the Nuclear Safety Convention of September 2001 states that:

> "*…with respect to other facilities not covered by this convention, such as the CNEN's research reactors and some of its pilot fuel cycle facilities, Brazil considers that the existing arrangements, through which the DRS licenses and controls the DPD installations, provide the necessary effective separation required to ensure an independent review of design and operation. With respect to the fuel cycle facilities of the INB, the CNEN has proposed a reorganization of the MST through which the INB will formally be removed from the CNEN's control, as already occurs "de facto", since the INB President reports directly to the MST.*"

This document shows that the CNEN is taking actions to achieve a clearer separation of responsibilities.

Recommendation: although in the CNEN the budget and the personnel for regulatory, licensing and inspection responsibilities are detached from the responsibility to promote the nuclear programme of Brazil, organization in accordance with IAEA GS-R-1 should be achieved by more clearly separating the organizations with these responsibilities.

4.65. Basis: Ref. [13] states, inter alia, in para. 2.4 that "*This legislation… (11) shall define liabilities in respect of nuclear damage; (12) shall set out the arrangements for provision of financial security in respect of any liabilities;…*" The Brazilian legislation has defined the liabilities in respect of nuclear damage, but not set out the arrangements for the provision of financial security in respect of any liabilities.

Recommendation: legislation in Brazil should set out arrangements for provisions of financial security in respect of any liability regarding the transport of radioactive material.

AUTHORITY, RESPONSIBILITIES, FUNCTIONS AND ORGANIZATION OF THE REGULATORY BODY

Overview

4.66. The statutory functions of the CNEN are set by Law No. 6189 of 16 December 1974, as amended by Law No. 7781 of 27 June 1989 (working paper WP-4). They are as follows:

- To collaborate in the formulation of the national nuclear energy policy.
- To establish specific guidelines for nuclear safety and radiological protection for activities with nuclear applications in technological, scientific, industrial and other areas.
- To elaborate and make proposals concerning the national nuclear energy programme to the Superior Nuclear Policy Council (CSPN).
- To promote and support:
  - The peaceful use of nuclear energy in areas of national development;
  - Training to develop scientists, technicians and specialists in areas related to nuclear energy;
  - Scientific and technological research in the field of nuclear energy;

- The prospecting for and mining of nuclear ores;
- The processing of nuclear ores;
- The production of and trade in nuclear material and other equipment and material related to nuclear energy;
- The transfer of nuclear technology and industrial enterprises of national investment through commercial agreements.

— To trade in nuclear related goods and services in internal and external markets.
— To receive and dispose of radioactive waste.
— To offer services in the peaceful uses of nuclear energy.
— To establish regulations and to issue licences and authorizations for the transfer of nuclear technology.
— To establish regulations and to issue licences and authorizations for the internal and external trade in:
- Minerals, ores, material, equipment and projects;
- Uranium for which the percentage of ^{235}U is less than for natural uranium.

— To issue regulations, licences and authorizations relating to:
- Nuclear installations;
- The possession, use, storage and transport of nuclear material[2];
- Trade in nuclear material, nuclear ores and concentrates containing nuclear elements.

— To issue safety regulations and standards related to:
- The use of nuclear material and installations;
- The transport of nuclear material;
- The handling of nuclear material;
- The treatment and disposal of radioactive waste;
- The construction and operation of buildings for the production of nuclear material and for the use of nuclear energy.

— To render opinions on the granting of patents and licences related to the use of nuclear energy.
— To promote the organization and the installation of laboratories and research institutes technically and administratively subordinated to them as well as to co-operate with the existing institutions in the country having the same purposes.
— To specify:
- Which elements, besides uranium, thorium and plutonium, are considered to be nuclear;

[2] Nuclear material is defined as material that contains uranium and transuranic elements.

- Which elements are considered to be fertile material and special fissile material or of relevance to nuclear energy;
- Which ores are considered to be nuclear ores;
- Which installations are considered to be nuclear installations.

— To oversee:
- Geological surveys and mapping;
- The prospecting for and the mining and processing of nuclear ores;
- The production of and trade in nuclear material;
- The industries that produce material and equipment for nuclear development.

— To render opinions on treaties, agreements, conventions or any type of international agreement related to nuclear energy.
— To produce radioisotopes, radioactive substances and nuclear subproducts, and to trade in these products.
— To authorize the use of radioisotopes for research, medicine, agriculture and industry and for similar activities.
— To authorize and survey the construction and operation of radioactive installations related to the trade in radioisotopes.

4.67. The CNEN is a commission in the MST. Its organization is illustrated in Fig. 1. The statutory functions of the CNEN are given essentially to three directorates and several divisions. These attributions are approved by the Minister of Science and Technology. The function of the competent authority for the transport of radioactive material has been assigned to DOREJ, which is a division of the CGLC in the DRS of the CNEN. Four DOREJ staff members work in the area of the transport of radioactive material. Additionally, a team at the CDTN research institute in the DPD is responsible for the testing of packages. These tests are performed at the request of users (who may be another research institute of the CNEN) or of DOREJ.

4.68. The role of the CNEN as the competent authority for the transport of radioactive material appears to be clear and accepted by other authorities. Nonetheless, there are inevitably several overlaps in responsibility with other authorities. For example, CONAMA has identified IBAMA as the competent licensing authority for, among other matters, the transport of radioactive and nuclear material (see working paper WP-10). In practice there appears to be good co-operation between the CNEN and IBAMA. However, it is important that the specific responsibilities be formally agreed and clarified. A memorandum of understanding between the CNEN and IBAMA is in preparation to clarify the responsibilities of both organizations, in order to manage interfaces and to conclude arrangements for co-operation.

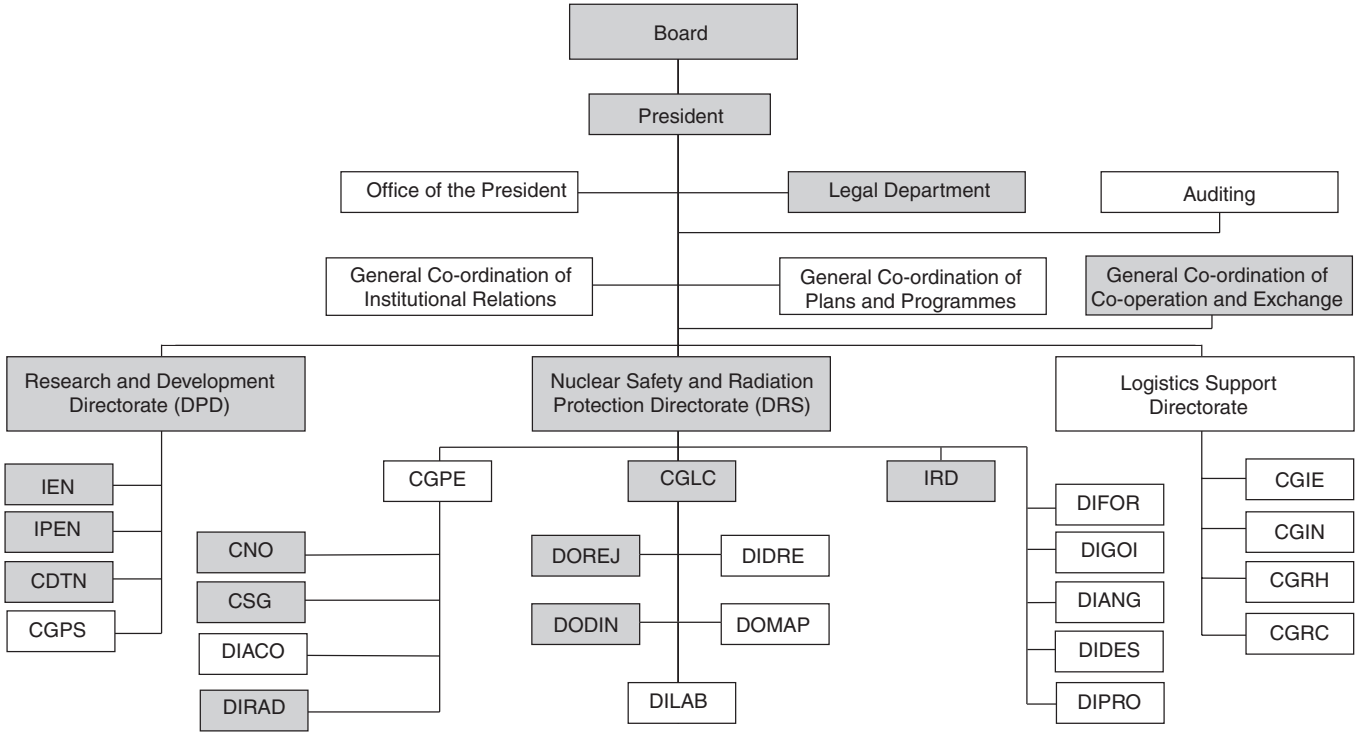

FIG. 1. Organization of the CNEN. CGIE = General Co-ordination of Infrastructure; CGIN = General Co-ordination of Information; CGLC = General Co-ordination of Licence Control; CGPE = General Co-ordination of Special Projects; CGPS = General Co-ordination of Research; CGRC = General Co-ordination of Corporate Resources; CGRH = General Co-ordination of Human Resources; CSG = Safeguards Co-ordination; DIACO = Inspection Follow-up Division; DIANG = Angra Reis District; DIDES = Development Division; DIFOR = Fortaleza District; DIGOI = Goiânia District; DILAB = Poços de Caldas Laboratory Division; DIPRO = Process Division; DODIN = Division of Nuclear Facilities and Materials; DOMAP = Raw Material and Minerals Division; IEN = Nuclear Energy Institute.

4.69. The CNEN has issued regulations for the transport of radioactive material (working paper WP-12). The CNEN is empowered in these regulations to grant approval certificates, as required in the Transport Regulations. The CNEN's regulations are referred to in decrees and administrative rules dealing with the transport of dangerous goods, including radioactive material: the Ministry of Transport is responsible for road (working paper WP-7) and rail (working paper WP-8) transport; the Ministry of Defence is responsible for air (working paper WP-11) and sea (working paper WP-15) transport. It is stated in these decrees and administrative rules that the transport of radioactive material needs to comply with the specific regulations issued by the CNEN.

4.70. It should be noted that the Transport Regulations are reviewed every two years in order to keep them up to date with scientific and technological developments. Revised editions of the international modal transport regulations [6, 7] are also expected to be published every two years. It is a good practice that national competent authorities are involved in the development and the revision of regulations. This two year revision cycle implies a regular update of the national regulations.

Findings

4.71. Basis: when two organizations have overlapping or complementary responsibilities it is of the utmost importance that an agreement be reached on the specific responsibilities and on the management of the interfaces. Consideration should be given to the fact that the CNEN has personnel qualified in the field of nuclear safety and radiological protection. A memorandum of understanding between the different parties involved (the CNEN and IBAMA) could help to clarify the overlaps.

Recommendation: the memorandum of understanding between the CNEN and IBAMA should be completed, in order to clarify their specific responsibilities for the transport of radioactive material.

4.72. Basis: several ministries (the Ministry of Transport for the land mode and the Ministry of Defence for the air and sea modes) are involved in regulating the transport of dangerous goods, including radioactive material. Regulations promulgated by these two ministries refer to the CNEN's regulations for the transport of radioactive material. A co-operation agreement between the parties involved (the CNEN, the Ministry of Transport and the Ministry of Defence) could help to harmonize the applicable national and international regulations for the transport of dangerous goods.

Recommendation: a co-operation agreement between the CNEN and the Ministry of Transport (for transport by road and rail) and the Ministry of Defence (for transport by air and sea) should be considered.

4.73. Basis: the statutory functions of the CNEN include both the regulation and the licensing of nuclear activities, but the CNEN also has responsibilities as a producer of radioisotopes and as an operator of nuclear facilities (research institutes and others). The CNEN holds 51% of the shares of the INB and the Chairman of the INB reports to the Minister of Science and Technology, who is also responsible for the CNEN. Despite the practical arrangements, and the fact that the INB and the CNEN's research institutes are treated as any other applicant, there may be a potential for conflicts of interest and the independence of the competent authority may be questioned. This situation is dealt with as follows in Section 7.7 of the Second National Report of Brazil for the Nuclear Safety Convention (September 2001):

> "*With respect to other facilities not covered by this convention, such as the research reactors of the institutes belonging to the CNEN and some of their pilot fuel cycle facilities, Brazil considers that the existing arrangements, through which the DRS licenses and controls the DPD installations, provide the effective separation required to ensure an independent review of design and operation.*"

4.74. With respect to the fuel cycle facilities of the INB, the CNEN has proposed a reorganization of the MST, through which the INB will be formally removed from the control of the CNEN, which is at present a de facto arrangement, since the President of the INB reports directly to the MST. According to para. 2.2 (2) of Ref. [13], the regulatory body shall be effectively independent of the organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities.

Recommendation: the regulatory functions should be more clearly separated from the operational and promotional functions. This separation should be evident from the organizational chart.

4.75. Basis: the regulatory functions of the CNEN as spelled out in law only refer to the transport of nuclear material and not to the transport of radioactive material, while the decrees and administrative rules dealing with the transport of dangerous goods refer to the transport of radioactive material. The CNEN's regulations deal with the transport of all radioactive material, including nuclear material.

Recommendation: in order to avoid any misunderstandings and potential legal conflicts, an amendment of the federal law that would extend the functions of the CNEN to cover the transport of all radioactive material, including nuclear material, should be considered.

4.76. Basis: the CNEN is recognized as the competent authority for the transport of radioactive material. However, on the basis of the organizational chart of the CNEN, it is not clear which division is responsible for this activity.

Suggestion: in order to make the organization more transparent, it might be considered to separate clearly the responsibilities for transport safety from those for radioactive waste safety.

4.77. Basis: the CNEN is involved in the regular updating of the Transport Regulations. However, it appears to be difficult to update the national regulations and related guidance material in parallel with the updating of the IAEA's regulations. An update of the national regulations in accordance with Ref. [1] has not been made.

4.78. New requirements in the 1996 edition of the Transport Regulations [1] with respect to the 1985 edition of the Transport Regulations [8], for instance related to the transport of uranium hexafluoride, may lead to significant additional work for the competent authority. A higher workload may also result from new orientations in the Brazilian nuclear programme.

Suggestion: it is suggested that there be an evaluation of whether the actual number of staff is sufficient to cope with the different tasks attributed to the competent authority. The workload needs to be evaluated taking into account the foreseen evolution of the Brazilian nuclear programme. Changes to regulations need to be evaluated with respect to their impact on human resources, and additional recruitment should be made accordingly.

AUTHORIZATION PROCESS

Overview

4.79. Every shipment needs to comply with a transport plan, to be submitted by the carrier to the regulatory body responsible for transport, and with the terms of reference for the transport of radioactive material, to be submitted to the regulatory body responsible for environmental protection (IBAMA)

(working paper WP-10). The CNEN examines the transport plan from the radiological protection and nuclear safety points of view, while IBAMA examines the transport plan from the environmental protection point of view. The review of the transport plan by the CNEN results in a technical evaluation report, which is the basis for the transport authorization issued by the CNEN. A copy of this authorization is then forwarded to IBAMA. The transport authorization issued by IBAMA is, in practice, an endorsement of the authorization issued by the CNEN.

4.80. Transport plans can be of a general nature or can be submitted on a case by case basis. Simplified transport plans may be used for the transport of relatively small quantities of material. This system is illustrated in Fig. 2.

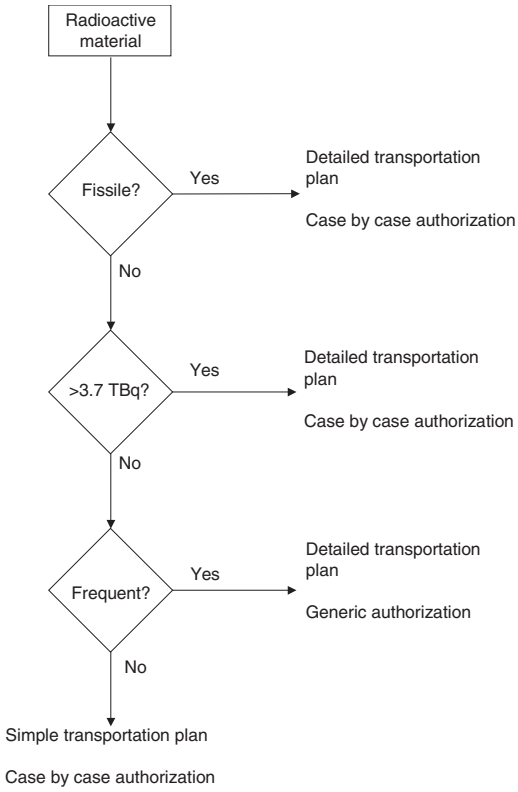

FIG. 2. The various options for transport authorizations that are reviewed by the CNEN.

4.81. The CNEN reviews the transport plan to verify compliance with the regulations issued by the CNEN (Regulation CNEN-NE-5.01). It must be noted that the current version of this regulation is still based on the 1985 edition of the Transport Regulations [8]. While the CNEN's regulation on the transport of radioactive material has been revised using Ref. [19], to conform with the 1996 edition of the Transport Regulations [1], it exists in draft form only, pending the promulgation in Brazil of amended general regulations for radiological protection, which are to be harmonized with the Basic Safety Standards [12]. In practice, however, the new regulation for transport is applied through the recommended use of the draft revision of Regulation CNEN-NE-5.01. By recommending the use of the draft revised regulations contained in Regulation CNEN-NE-5.01, the CNEN facilitates compliance by carriers with the 1996 edition of the Transport Regulations [1].

4.82. The use of a single standard (Regulation CNEN-NE-5.01) to provide regulations for all modes of the transport of radioactive material, national and international, is a good practice. However, this requires that Regulation CNEN-NE-5.01 include all the requirements from the 1996 edition of the Transport Regulations, as they have been incorporated into the international regulations for the air (ICAO Technical Instructions) and sea (IMDG Code) modes, as well as in the United Nations model regulations for the transport of dangerous goods, which are referred to in the MERCOSUR agreement. Any (necessary) deviations from international regulations should be clearly identified and brought to the attention of the international organizations involved, if appropriate.

4.83. It must be noted that the Transport Regulations do not require that all shipments be licensed. The (multilateral) approval of shipments is only required in a limited number of cases (e.g. large sources in Type B(M) packages, certain shipments of fissile material, shipment under special arrangement). In such cases the transport plans are also used as a means to apply for shipment approval.

4.84. The CNEN has drafted guidance on the preparation of transport plans. Annex A of this guidance document specifically addresses quality assurance. This guidance document formally exists only in a draft form, but it is applied in practice. No guidance is available for applications for design approvals.

4.85. Typical applications submitted every year can be divided into the following categories:

— New transport plans: 20 per year.
— Special form designs: 0 per year.
— Type B package designs: 0 per year.
— Designs of packages containing fissile material: 5 validations per year, 0 certificates per year.
— Shipment approvals: 40 per year.
— Special arrangements: 5 per year.

4.86. No time scales are set in the transport regulations of the CNEN. The average time needed for review and assessment is as follows:

— Transport plan: 1 month.
— Validation of approval certificate: 1.5 months.
— Shipment approval: 2 to 3 weeks.
— Special arrangements: 2 months.

4.87. The authorizations are valid for 6 months for the transport of fissile material and for 4 months for the transport of other radioactive material. To obtain an extension of the period of the authorization, the applicant needs to submit a justification.

4.88. The standard format of the authorizations (information paper IP-18) does not completely comply with Annex B of Regulation CNEN-NE-5.01.

Findings

4.89. Basis: both IBAMA and the CNEN issue transport authorizations. In practice, the authorization issued by IBAMA is an endorsement of the CNEN's authorization. The memorandum of understanding that is in preparation could be used to make the licensing process more transparent and to define better the role of both organizations in the authorization process.

Recommendation: the memorandum of understanding between the CNEN and IBAMA should be completed and should in particular address the specific roles of both organizations in the licensing processes for the transport of radioactive material.

4.90. Basis: only the information in Ref. [19] has been used in drafting the revision of the transport regulations of the CNEN and not the complete 1996 edition of the Transport Regulations [1]. It must be noted that Ref. [19] addresses only the major changes with respect to the previous edition. The

international modal transport regulations [6, 7], however, completely implement the 1996 edition of the Transport Regulations, and this may lead to potential conflicts. Any deviations from the international modal transport regulations should be clearly identified and brought to the attention of the international organizations, if deemed necessary.

Recommendation: the existing draft revision of Regulation CNEN-NE-5.01 should be promulgated as soon as possible. In a further stage, the regulation should be carefully reviewed to verify that the 1996 edition of the Transport Regulations is implemented completely and in line with the international modal transport regulations. In this context, a translation of the 1996 edition of the Transport Regulations into Portuguese might be helpful.

4.91. Basis: it is of great importance for a user of the transport regulations of the CNEN that these regulations be consistent with the guidance in support of the regulations. It might be useful to make a clear distinction between the transport approvals required in the Transport Regulations and the authorizations required by Brazilian law. Due account should be given to the IAEA publications published in support of the Transport Regulations, such as Refs [2–5]. According to para. 3.3 of Ref. [13], the regulatory body "…*(3) shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information;*…"

Recommendation: the guidance for the preparation of transport plans should be revised to bring it into line with the new national and international regulations. Similarly, guidance should be drafted for an application for approval of a package design.

4.92. Basis: the CNEN generally implements formally the requirements of the Transport Regulations. However, the standard format of the authorizations (information paper IP-18) does not fully comply with the relevant provisions of the Transport Regulations and of the transport regulations of the CNEN.

Recommendation: the contents of the authorizations for transport should be revised to bring them into line with the relevant provisions of the transport regulations of the CNEN.

REVIEW AND ASSESSMENT

Overview

4.93. For the area of review and assessment, this overview addresses in particular the approval of package designs and the approval of shipments.

Approval of package designs

4.94. IPEN produces radiopharmaceuticals and is the consignor of most of the shipments of radioactive material in Brazil. Most of this radioactive material is shipped in packages defined in the Transport Regulations as Type A packages. IPEN designs its Type A packages, contracts their manufacture and sends them to the CDTN, where they are tested against the requirements for Type A packages set forth in the 1996 edition of the Transport Regulations [1]. A test report certifying the tests performed and the test results is sent to IPEN, and IPEN sends a copy of this report to DOREJ.

4.95. In accordance with the Transport Regulations, competent authority approvals are required for Type B(U), Type B(M) and Type C packages, packages containing 0.1 kg or more of uranium hexafluoride and for all packages containing fissile material. Brazil uses fissile, Type B(U) and uranium hexafluoride packages. It does not manufacture Type B(U), uranium hexafluoride or Type B(U)F packages; however, it does manufacture a Type AF package used for the transport of fresh fuel from the INB's facilities in Resende to the two Brazilian nuclear power reactors. This package is constructed in accordance with a German design from the early 1980s. Since facilities are not available in Brazil to perform the Type AF drop test, the CNEN has authorized use of this package under a special arrangement.

4.96. From the information provided, it appears that up to now Brazil has not used Type B(M) or Type C packages. Brazilian Certificates of Competent Authority for package design (validations) are issued by DOREJ. In principle such certificates are issued in accordance with Regulation CNEN-NE-5.01, approved in July 1988 in accordance with the 1985 edition of the Transport Regulations [8]. In practice, a 2001 draft revision of Regulation CNEN-NE-5.01, which incorporates some of the main changes in the 1996 edition of the Transport Regulations [1], is used.

4.97. The issuance of a validation certificate is based on information in the original certificate, and in any previous validations.

4.98. Sources have been transported to Brazil using Type B(U) certificates that have since expired. Since DOREJ also regulates the use of Type B packages within Brazil, it has indicated that it may consider allowing the continued transport of these packages within the country, based on the maintenance history of the package.

Approval of shipments

4.99. Although this requirement is not written in the transport regulations of the CNEN, DOREJ requires that any entity desiring to transport radioactive material submit a transport plan to DOREJ for approval, whether it be for transport within the country or for import–export shipments. Most applications are made by licensed facilities, but for the routine transport of radiopharmaceuticals there are also approved transport plans for about six carriers. Approximately 400 transport plans have been approved, the majority for fixed facilities transporting radiopharmaceuticals and small industrial sources.

4.100. Since any fixed facility is operating under a licence granted by the Division of Radioactive Facilities (DIRAD), the facility will apply to DIRAD for approval to acquire or relinquish possession of the radioactive material that it wishes to ship, as well as submit a transport plan to DOREJ for its approval, or submit evidence that an approved transport plan already exists. DIRAD will not approve the change in the licence provisions until it has obtained confirmation that there exists a corresponding transport plan approved by DOREJ. For imports, this information is entered into an external import database named SISCOMEX; after the approval of both DIRAD and DOREJ is obtained, an import licence is issued electronically, and DOREJ issues a transport authorization. DIRAD makes use of a database called SINRAD (system of radioactivity information) that lists the radioactive material registered with each licensee. Similar co-ordination takes place between DIRAD and DOREJ for a transfer of radioactive material between two licensees, or for the export of radioactive material. Co-ordination is controlled in all cases by use of the computerized CNEN document control system SISDOC.

4.101. As for the issuance of package design certificates, a transport plan approval is carried out in accordance with the draft revision of Regulation CNEN-NE-5.01, which incorporates the principal changes contained in the 1996 edition of the Transport Regulations [1]. An applicant seeking approval for a transport plan is sent a draft of the regulatory guide for the preparation

of transport plans (information paper IP-06) and a summary list of items that should be included in the transport plan, which may be 'simple' or 'complete'. If the plan is to be 'simple' a summary list of items that should be addressed in the transport plan is sent to the applicant with the draft regulatory guide; if the plan is to be 'complete' a more extensive list, which contains suggested quality assurance items, is sent to the applicant with the regulatory guide, along with Annex A of the draft regulatory guide. Annex A describes the principal components of a good quality assurance programme for the transport of radioactive material.

4.102. DOREJ staff evaluate the data provided with an application for the approval of a transport plan and describe their findings in a technical evaluation report, which is expanded upon in accordance with an internal procedure, IN-SLC-0001, Revision 0 (1994). If the findings are positive, a letter is sent to the applicant indicating that the transport plan submitted has been found adequate.

4.103. In principle, IBAMA should evaluate the transport plan on the basis of the possible environmental impact and issue a separate authorization. In practice, however, since IBAMA has no personnel with the required expertise in radioactive material, it generally issues its authorization without additional evaluation once the CNEN has done so.

4.104. Approved transport plans for shipping fissile material are valid for 6 months, those for non-fissile radioactive material are valid for 4 months; approved transport plans for the routine shipment of radiopharmaceuticals have no expiry date. The transport of radioactive material through the mail system is not permitted in Brazil (Regulation CNEN-NE-5.01).

4.105. After receiving approval from DOREJ for its transport plan, the carrier must also apply for and receive a transport authorization (information paper IP-18). A transport authorization may be granted for an individual shipment or may allow repeated shipments.

4.106. The guidelines used by DOREJ are:

— If the shipment is of fissile material, or of non-fissile material with an activity greater than 3.7 TBq, a complete transport plan, a quality assurance plan and an individual transport authorization are required.
— If the shipment is of non-fissile material with an activity not greater than 3.7 TBq and frequent shipments are envisaged, a complete transport

plan and a quality assurance plan are required, but a generic, multiple shipment transport authorization will be issued.
— If the shipment is of non-fissile material with an activity not greater than 3.7 TBq and the shipment is isolated or infrequent, a simple transport plan is required, but no authorization is issued for the individual shipment.

4.107. IPEN is the largest shipper of radioactive material in Brazil, as its radiopharmaceutical production facilities ship some 30 000 packages per year. However, for routine shipments of radiopharmaceuticals IPEN depends on carriers that have approved transport plans; these are generic plans with no expiry date, issued for the carriage of a range of radionuclides and activities. Radionuclides transported under these plans are primarily $^{99}Mo/^{99m}Tc$, ^{131}I and ^{67}Ga, of which about 40% are shipped by road and 60% by air, with part of the latter transport conducted by road. IPEN also ships about 190 packages per year of ^{192}Ir and ^{60}Co and a small number of other packages. Since the medical facilities using these materials often have to ship them, the majority of the approximately 400 transport plans that the CNEN has approved have been for shipments of radiopharmaceuticals.

4.108. The other important shipper of radioactive material is the INB, the company that oversees fuel cycle activities in Brazil; its shipments are primarily of yellow cake (export), uranium hexafluoride (import) and domestic shipments of fresh fuel to the two Brazilian nuclear power reactors.

4.109. Table I shows the routine validations for the transport of radioactive material completed by DOREJ in 1999, 2000 and 2001. These figures were provided by DOREJ.

Findings

4.110. Basis: DOREJ carries out an extensive programme for the evaluation and approval of transport plans as part of the procedures that it follows to ensure compliance with the radioactive material transport regulations, in accordance with para. 311 of the 1996 edition of the Transport Regulations [1]. For fissile material, and for non-fissile material with activity greater than 3.7 TBq or for which frequent routine shipments are expected, the transport plan is required to include some quality assurance aspects. These quality assurance aspects are selected aspects from Standard CNEN-NN-1.16, on quality assurance for the safety of nuclear power plants and other installations.

TABLE I. ROUTINE ACTIVITIES COMPLETED BY DOREJ IN 1999, 2000 AND 2001

Activity of DOREJ	Completed in 1999	Completed in 2000	Completed in 2001
Permissions granted for the re-export of radioactive material	62	97	97
Transport authorizations	40	40	34
Technical evaluation reports	123	158	19
Special arrangement certificates	2	8	5

4.111. However, while para. 311 of the 1996 edition of the Transport Regulations [1] refers to "…*the establishment and execution of a programme for monitoring… the preparation, documentation, handling and stowage of packages by consignors…*", transport plans concentrate on the satisfaction of the transport requirements during the physical transport of the packages: actions by the consignor are not emphasized. In this regard, para. 310 of the 1996 edition of the Transport Regulations, on quality assurance, requires that consignors satisfy certain of these requirements, and that competent authority approvals take into account and be contingent upon the adequacy of the (consignors') quality assurance programme. Clearly, the quality assurance programme requirements also apply to the manufacturers and users of transport packages for radioactive material.

Recommendation: it is recommended that compliance assurance mechanisms should be developed by the competent authority to ensure that consignors show evidence of having developed and implemented an acceptable quality assurance programme to satisfy the requirements of the 1996 edition of the Transport Regulations.

Recommendation: it is recommended that compliance assurance mechanisms should be developed by the competent authority to ensure that manufacturers of packages, including Type A and industrial packages, show evidence of having developed and implemented an acceptable quality assurance programme to satisfy the requirements of the 1996 edition of the Transport Regulations.

Recommendation: it is recommended that compliance assurance mechanisms should be developed by the competent authority to ensure that packages designed to transport radioactive material, including Type A and industrial packages, satisfy the appropriate design and performance requirements.

4.112. Basis: the CNEN has issued competent authority approval to the INB to transport fresh fuel assemblies within Brazil under special arrangement, using Type AF packages constructed in Brazil in accordance with an older German design. The reason given for the use of a special arrangement designation is that the Brazilian manufacturers and users have not been able to find a facility within the country able to perform the Type AF drop test.

4.113. In accordance with para. 825 of the 1996 edition of the Transport Regulations [1], a special arrangement designation may be authorized for a consignment that does not satisfy all the applicable requirements of the Transport Regulations if the competent authority is satisfied that special administrative or operational controls will be followed to ensure that the overall level of safety in transport is at least equivalent to that which would be provided if all the requirements of the Transport Regulations had been met.

4.114. It is generally advisable to limit the use of special arrangements as much as possible, since their continued use implies a continued inability to comply with the transport regulations in a specific area. It is likely that the Type AF package manufactured in Brazil now being used was shown to satisfy the Type AF drop test requirements when it was originally introduced in Germany. If access to such documentation can be obtained, if it can be shown that the Brazilian manufacturer faithfully followed the original packaging design and if it can be shown that the package with its contents satisfy the criticality requirements, it should be possible to show that this package, as used, satisfies completely the requirements of the 1996 edition of the Transport Regulations [1].

Suggestion: it is suggested that an attempt be made to verify that the drop test requirement for Type AF packages has been satisfied, and that the other requirements of the 1996 edition of the Transport Regulations for this type of package have been met and, if such evidence can be obtained, to discontinue the practice of using a special arrangement designation for the INB's shipments.

4.115. Basis: the Brazilian authorities have chosen to place emphasis on the development and approval of transport plans as a means to ensure compliance with the transport regulations in Regulation CNEN-NE-5.01 and in the 1996 edition of the Transport Regulations [1].

Good practice: the emphasis on thoroughly prepared and thoroughly evaluated transport plans is a practice that is commendable, as it provides an important practical structure for ensuring compliance with many of the transport requirements.

INSPECTION AND ENFORCEMENT

Overview

4.116. DOREJ has established a system of periodic and occasional inspections of transport operations. This inspection programme is based on various national and international standards for fixed nuclear facilities; these are:

- CNEN Standard 1.04 (1984), on the licensing of nuclear facilities;
- CNEN Standard 1.16 (1999), on quality assurance for the safety of nuclear power plants and other installations;
- IAEA Safety Series No. 50-SG-G4 (Rev. 1) [20];
- IAEA Technical Reports Series No. 296 [21];
- The CNEN Inspector's Manual (1986).

4.117. Regulatory inspections are planned, prepared and conducted in accordance with the following documents:

- IN-DRS-001 (1994), the general surveillance plan;
- IN-DRS-002 (1994), on the qualification and certification of inspectors;
- IN-DRS-003 (1996), on the administrative control of regulatory inspections;
- P-DRS-001 (1994), on the conduct of regulatory inspections.

Also used is a checklist for the inspection of transport operations (information paper IP-19).

4.118. DOREJ follows the qualification scheme of IN-DRS-002: for an inspector to become qualified at Level I, he or she must have a university level education and have two years of experience in activities involving the application of the transport regulations of the CNEN; to become qualified at Level II, he or she must have an additional three years of experience, which includes previous experience as an inspector.

4.119. Mechanisms for enforcement, aside from dialogue with the offending party, are limited to the non-approval of transport plans, refusal to issue other approvals required of the competent authority, the withdrawal of approvals or the issuance of a 'stop work' order. Establishment of a more comprehensive system of enforcement penalties is currently being pursued.

4.120. At present DOREJ inspects all shipments of fissile material and of non-fissile material with an activity greater than 3.7 TBq. Other types of shipment are inspected on a random basis. Inspections may be routine, follow-up or reactive. A plan for routine inspections is presented to the DRS each year. DOREJ generally plans five or six such inspections each year. The entities to be inspected are selected according to specific criteria.

4.121. Inspectors prepare by planning which items or operations are to be observed, following the guidance listed above. The requirements of any pertinent transport plan are taken into account in this planning process.

4.122. Resident nuclear power plant inspectors are authorized to inspect shipments of fresh or spent fuel. External inspectors are also designated to witness shipments (spot checks). An example of a report of such witnessing performed by DOREJ staff is found in information paper IP-09, which describes the inspection, and escort by DOREJ staff, of the transport of uranium dioxide powder from Rio de Janeiro International Airport to the INB fuel fabrication facilities in Resende. Certain emergency response personnel in Rio de Janeiro, São Paulo, Minas Gerais, Brasilia and the northeastern area of the country are also trained to review shipments whenever CNEN staff are not available. The checklist used for such inspections is found in information paper IP-19.

4.123. At present it appears that quality assurance programmes, specifically with respect to the transport regulations of the CNEN, are not being audited. In the DRS, the Reactor Division (DIDRE) performs audits of quality assurance programmes for nuclear reactors.

Findings

4.124. Basis: para. 310 of the 1996 edition of the Transport Regulations [1] and para. 7.1.3.1 of Regulation CNEN-NE-5.01 require quality assurance programmes for the various aspects of the transport of radioactive material. Paragraph 311 of the 1996 edition of the Transport Regulations [1] establishes the responsibility of the competent authority for ensuring compliance with the regulations, and para. 7.1.3.4 of the draft revision of Regulation CNEN-NE-

5.01 requires that the CNEN implement a compliance assurance programme for packages.

4.125. Paragraph 457 Ref. [4] states that "*The competent authority should have an auditing programme to determine that the quality assurance programmes are implemented and followed correctly.*" Paragraph 4101 of Ref. [4] states that the "*Preparation and issuance of information and guidance by the competent authority are needed for the implementation and functioning of a compliance assurance programme.*"

Recommendation: the requirement that the competent authority implement a programme to ensure compliance with the Brazilian transport regulations should be included in the Brazilian regulations. The wording in para. 7.1.3.4 of the draft revision of Regulation CNEN-NE-5.01 should be extended to include at least special form materials, since special form sources are at present in use in Brazil.

Recommendation: in order to comply with the requirement in the 1996 edition of the Transport Regulations for a compliance assurance programme and the guidance of IAEA Safety Series No. 112 that this should include the auditing of quality assurance programmes, it is recommended that a programme for performing audits of quality assurance programmes should be developed.

4.126. Mechanisms that could be used include, for example, periodic audits for which the frequency could depend on criteria selected to reflect the impact and importance of certain transport plans, a history of acceptable or unacceptable performance by particular users of transport plans, simplified audits for these transport plans for infrequent carriers or small organizations, or other criteria selected by the competent authority.

Suggestion: consideration might be given to finding ways to streamline the audit process. For example, it may be possible to design partial audits that are less detailed than a full audit or that review only certain parts of the user's quality assurance programme at a time. To improve the efficiency of the audit process, it might also be possible to simplify the administrative controls for audits of quality assurance programmes.

Suggestion: it is suggested that guidance on applying for approval of a transport plan by DOREJ be formalized as an official document, and be made available on the CNEN's web site or in some other way made readily accessible to interested parties.

Suggestion: it is suggested that guidance on the appropriate contents of an adequate quality assurance programme for ensuring the safe transport of radioactive material be formalized as an official document, and be made available on the CNEN's web site or in some other way made readily accessible to interested parties.

4.127. Basis: para. 311 of the 1996 edition of the Transport Regulations [1] establishes the responsibility of the competent authority for ensuring compliance with the regulations. Paragraph 4117 of Ref. [4] states, inter alia, that "*A system of reporting of all significant incidents, accidents or deviations should be developed, and the competent authority or its agents should investigate these reported occurrences.*" Informally, DOREJ staff consider that certain types of incidents and accidents occurring during the transport of radioactive material should be reported to them within 24 hours, and that other incidents and accidents should be reported to them within 30 days, in accordance with the requirements of Regulation CNEN-NE-1.14. However, the requirements listed in Regulation CNEN-NE-1.14 are specific to reactor accidents and not explicitly applicable to transport accidents — which types of transport accident require reporting in a given period of time and which details should be reported are not clear. Obviously, these requirements are not widely known by transport plan users and at present the fact that such reporting is considered a requirement for transporters of radioactive material is not explicitly stated in any regulatory document. Transport plans sometimes contain general instructions to carriers to notify the CNEN immediately in the event of an incident that threatens to cause doses to members of the public that exceed regulatory limits, or to send the CNEN a detailed report — without specifying to which level of detail — on any abnormal occurrence during transport.

4.128. It should be noted that there exists an official regulation, Regulation CNEN-NN-6.04 on the functioning of industrial radiography services, that requires immediate notification to the CNEN of any accident or emergency situation relating to industrial radiography activities, followed by a more complete report within 24 hours or five days, depending on whether the incident meets designated criteria, and a final report as soon as possible indicating the final resolution of the incident. There is also a list of the information requested in such reports in Annex C of Regulation CNEN-NN-6.04.

Suggestion: it is suggested that specific requirements for the reporting to the competent authority of specified incidents, accidents and variations be established and incorporated in the regulations or in official guidance, and that these requirements be made available on the CNEN's web site or in some other

way made readily accessible to interested parties. One way to approach this goal may be to extend the guidance in Regulation CNEN-NN-6.04, or to modify and extend it, to cover all activities relating to the transport of all types of radioactive material.

4.129. Basis: DOREJ and DIRAD have developed a procedure involving close co-ordination and co-operation in the processing of applications by facilities to receive or ship radioactive material. This close co-ordination ensures that a licensed facility cannot take possession of or release radioactive material without complying with the requirements of DOREJ for the safe transport of radioactive material.

Good practice: if an entity intends to receive radioactive material, it must first apply to DIRAD for a licence to possess radioactive material. DIRAD gives the entity information on what must be done (at present it refers the applicant to the CNEN's web site). DIRAD will not issue an authorization to receive radioactive material unless the entity, or its contracted carrier, already has a transport plan approved by DOREJ. Similarly, if the entity wishes to ship radioactive material, it must obtain permission from DIRAD to relinquish possession, and DIRAD will not issue this permission unless a transport plan for the material to be shipped has been approved by DOREJ. The use of various computerized databases facilitates this close co-ordination.

DEVELOPMENT OF REGULATIONS AND GUIDES

Overview

4.130. In Brazil the revision and development of regulations for the transport of radioactive material are the responsibility of the CNO (Standards Commission), the CNEN's Department of Standards. A proposal for drawing up new standards and for the revision of current standards must be submitted to the CNO, which designates a working group to accomplish this task.

4.131. The CNO obtains information on the revised versions of the Transport Regulations from the Ministry of Foreign Affairs (through the Permanent Mission of Brazil in Vienna). The Mission in Vienna notifies the General Co-ordination of Co-operation and Exchange (CGCI) of the Ministry of Foreign Affairs. The CGCI contacts the DRS, which notifies the CNO, which then passes on the information to DOREJ. The CNO was informed in this way about the revisions to the Basic Safety Standards [12].

4.132. According to federal law, the application of the standards of the CNEN is mandatory. The hierarchy of the regulatory documents can be described as follows:

— Resolutions: these are often used to enact standards or to modify them.
— Draft standards: this term is officially applicable to the licensing process; a standard remains a 'draft' standard until the definitive version of the standard can be released. A draft standard can be in force for several years.
— Nuclear standards: these are final and supersede draft standards.
— Regulatory position documents: these are issued when a specific item of a standard has been found to be unclear.
— Guides: these are issued to help applicants in fulfilling the regulatory requirements. Guides are not mandatory, but applicants are aware that these guides are used by the CNEN's staff to evaluate applications (e.g. transport plans).

All documentation issued under this hierarchy needs to be endorsed by the CNO. The regulations and guides now in force for the transport of radioactive material are described in the first part of Section 4 of this report.

4.133. As mentioned, the CNO is responsible for the development of new standards and guides. When a request is made for a new standard, the CNO invites all potentially affected organizations (operators, non-operators, research institutes, related competent authorities) to form a working group to draw up a draft standard.

4.134. All organizations are free to present proposals on the subject under discussion. A completely new regulation or the revision of a current standard can be proposed by any person who represents an organization that has been invited to join the working group.

4.135. The CNO has the right to designate the secretary of the working group, to decide which proposals among those submitted are of interest and also to consider amendments to existing proposals. In developing regulations and guides, the regulatory body (the CNEN) takes into account the experience of the staff, enforcement results, the findings of investigations and internationally recognized standards.

Findings

4.136. Basis: with regard to changes to the ICAO Technical Instructions, the Ministry of Defence and its Department of Civil Aviation of the Secretary of the Air Force are competent. These two bodies issue the ICAO Technical Instructions to be applied in Brazil. For transport by sea, the Ministry of Defence and its Port Authority of the Secretary of the Navy are responsible for the implementation of the IMDG Code in Brazil. For regulations on transport by road and rail, the Brazilian Ministry of Transport has the lead responsibility (MERCOSUR Decree).

4.137. The CNEN, as the competent authority, is responsible for the implementation of the regulations for the safe transport of radioactive material for all modes of transport. For road and rail, the regulations are provided in the decrees of the Ministry of Transport. For the transport of dangerous goods by air and sea, the present regulations of the Ministry of Transport and of the Ministry of Defence refer to CNEN standards but also to the IMDG Code and the ICAO Technical Instructions. At present these are contradictory for radioactive material, because the CNEN standards are based on the 1985 edition of the Transport Regulations [8] and the IMDG Code and the ICAO Technical Instructions are based on the 1996 edition of the Transport Regulations [1].

Recommendation: in order to avoid discrepancies between the implementation of the various editions of the Transport Regulations (and there are potential safety hazards), it is strongly recommended that the same regulations should be applied concurrently in Brazil for both the national and the international transport of radioactive material.

4.138. Basis: the agreement to facilitate transport within the MERCOSUR region (Decree No. 1.797 of 1996) is based on the United Nations Recommendations on the Transport of Dangerous Goods (the Orange Book) [18], which for radioactive material is based on the 1985 edition of the Transport Regulations [8]. These recommendations are drawn up by the United Nations Committee of Experts on the Transport of Dangerous Goods and are updated every two years. Since 1996 the United Nations has reissued the Orange Book as Recommendations on the Transport of Dangerous Goods — Model Regulations, the current version of which was published in 2001 [15]. The new structure of these United Nations model regulations has been taken into account by various international and national organizations responsible for the transport of dangerous goods by different modes of transport.

4.139. The current Orange Book is the 12th (2001) edition [15], and it includes all the requirements of the 1996 edition of the Transport Regulations [1]. The MERCOSUR agreement, based on the 1991 edition of the Orange Book, is therefore not up to date.

Recommendation: to be in line with the other international agreements for the transport of dangerous goods, it is recommended that the MERCOSUR agreement should be updated. Enhanced co-operation between the CNEN and the Ministry of Transport is necessary in the area of the transport of radioactive material.

4.140. Basis: it is a common practice that the CNEN forms a study group that includes representatives from a wide range of organizations (ministries and industry) to review formally changes to the regulations. For transport matters there is also a working group with representatives from the CNEN, the Ministry of Transport, IPEN, the CDTN and industry preparing the revised version of Regulation CNEN-NE-5.01. The aim of this procedure is to reach consensus for the transport regulations of the CNEN.

4.141. For the revision of Regulation CNEN-NE-5.01 (on the basis of the 1996 edition of the Transport Regulations [1]), a potential conflict with CNEN Regulation 3.01, the basic standard on radiation protection, of July 1988, has been recognized and is being addressed. A revision of Regulation 3.01 is ongoing and may take a year to complete. However, there is a possibility of proceeding with the approval of the current draft revision of Regulation CNEN-NE-5.01 (based on IAEA-TECDOC-1194 [19]) through a resolution (para. 2.1.2 of CNEN-NE-5.01). It is recognized that additional resources may be required.

Recommendation: to avoid differences between the current Brazilian regulation for the transport of radioactive material (Regulation CNEN-NE-5.01) and the international regulations, it is recommended that the draft revision of Regulation CNEN-NE-5.01 (now based on an IAEA TECDOC) should be implemented as soon as possible.

Recommendation: it is recommended to incorporate in the next version of Regulation CNEN-NE-5.01 all the changes needed to reflect the 1996 edition of the Transport Regulations — not only the major changes that have been incorporated in the draft revised version. The document including all these changes could be approved in accordance with the regulatory procedures for revising standards.

EMERGENCY PREPAREDNESS FOR TRANSPORT

Overview

4.142. In Brazil SIPRON is responsible for emergency preparedness for nuclear activities; SIPRON brings together several organizations at the federal, state and local levels. The CNEN is a participant in SIPRON and the CNEN is the regulatory body responsible for the licensing of all aspects of nuclear safety. Licensees are obliged to prepare and submit an emergency plan to the CNEN. The CNEN has its own emergency plan, the Plan for Emergency Situations (PSE), to be activated in the event of a nuclear or radiological emergency in the country (with real or potential off-site consequences). The PSE itself is composed of five categories of emergency plans aimed at the following sectors: (1) nuclear power reactors; (2) research reactors; (3) industrial, medical, teaching and research installations; (4) nuclear fuel cycle installations (except reactors); and (5) special operations. Category (5) deals with transport emergencies. This plan is intended for any accident in the local, national and international transport of radioactive material.

4.143. SIPRON covers any type of nuclear installation and is activated in the event of a nuclear accident. Two general norms (NGs) define the duties of the organizations that participate in SIPRON: (a) NG-02, the general norm for the planning of the response to emergency situations, and (b) NG-04, the general norm for emergency situations in transport units. According to these norms, in an emergency situation various organizations have responsibilities and participate in the decision making process. These organizations are:

— The regulatory body (the CNEN);
— The civil defence and fire brigade authorities;
— The Federal Road Police and the Military Police;
— The Ministry of Transport;
— The Bureau of Public Safety.

4.144. The PSE is activated for radiological accidents, but SIPRON will lend assistance at the request of the CNEN through the MST. For example, in the autumn of 1987 SIPRON was activated in the response to the radiological accident in Goiânia.

4.145. The PSE provides that within the CNEN the IRD is responsible for off-site emergency response for all radioactive material, including nuclear material. The IRD has four emergency teams, with about 45 people per team and all the

equipment needed for emergency response. The areas covered by the sectorial emergency plans are:

— Responsibilities and duties of the organizations involved;
— Procedures for alerting and notifying the persons and organizations involved;
— The methods for notifying the public;
— Intervention levels for exposure and contamination;
— Protective measures;
— Procedures for response actions;
— Training and exercises;
— Public information;
— Communication.

4.146. IPEN staff members are included in the IRD emergency response teams for all notifications in the state of São Paulo. In addition, IPEN is an operational unit of SIPRON and has its own emergency response plans and an emergency response team for all aspects of its areas of responsibility, including transport. There are 15 radiation protection officers and 25 technicians involved. A vehicle and equipment are available for emergency response. Training is provided twice a year by IPEN for the police and fire departments of the state (São Paulo). Training courses conclude with an exercise in which an accident is simulated.

4.147. In addition to these programmes, the CNEN has produced guidance (SINAER) for providing emergency response across the country. This guidance contains a list of contact persons around the country; these persons must be qualified as radiation protection supervisors and must be accepted by the CNEN.

4.148. At the international level, Brazil is a State Party to the Convention on Early Notification of a Nuclear Accident.

4.149. For emergency response exercises, a committee has been established under SIPRON called COPREN (Committee for the Planning of the Response to Nuclear Emergencies), which is responsible for the preparation and evaluation of such exercises. The CNEN is a member of COPREN. The civil defence authorities (at the federal, state and local levels), Eletronuclear (the electricity utility) and the INB are permanent members of COPREN.

4.150. Exercises are conducted annually. Emergency response exercises are held on a periodic basis, mainly for power plant accidents. Fire-fighters, police

officers, doctors and other auxiliary staff undergo a one week course (45 people per course) several times per year. On the fourth day of this course a transport accident is simulated, for which the CNEN provides support.

4.151. COPREN is responsible for the preparation of the scenario, which can take into account aspects such as car accidents involving radioactive material, radioactive material that is stolen, and sabotage. COPREN is responsible for the evaluation of the exercises. All organizations participate in the exercise once a year, and all the organizations involved have the necessary budget.

4.152. Two regulations concerning providing information to the public apply: general norm 05 (NG-05), the general norm for establishing public information campaigns about emergency situations, which regulates all aspects of public information, and general norm 06 (NG-06), the general norm for the installation and operation of emergency management centres, which establishes a specific centre to deal with public information and the media. This centre is called the Nuclear Emergency Information Centre (CIEN) and is co-ordinated by the CNEN. In general the following kinds of information are foreseen to be released:

— The accident location;
— The nature of the hazard and risks;
— Warnings to keep away from the accident;
— Actions to be taken;
— The final results of actions;
— Follow-up steps to be taken.

4.153. The CIEN is in Angra, where both nuclear power reactors are located. The dissemination of public information is voluntary. According to the Federal Constitution of Brazil, any member of the public may request information from the government, which should then be provided.

Findings

4.154. Basis: Brazil has emergency preparedness regulations and capabilities that are well developed. Emergency preparedness modalities address all aspects of radioactive and nuclear material transport.

Good practice: the capabilities for responding to an emergency in the area of the transport of radioactive material have been incorporated into the overall emergency preparedness structure across the country.

Good practice: the SINAER procedures, which were produced by the CNEN in 2000, are practical guidelines for responding to an emergency stemming from an event or accident; these guidelines also cover emergencies in the area of the transport of radioactive material.

5. GENERAL CONCLUSIONS

5.1. The TranSAS appraisal team completed a thorough appraisal of the implementation of the transport regulations in Brazil. Co-operation from the Brazilian authorities, and all those who participated in the detailed discussions, was excellent and contributed much to the value of the appraisal. In general the appraisal concluded that, although some improvements are recommended, all areas of transport safety are well addressed in Brazil and their good practices are valuable for consideration by other States for their safe transport of radioactive material.

5.2. There is some potential for improvement by harmonizing revisions to the transport regulations of the CNEN with revisions to the regulations of the international modal organizations. In this respect it is important to implement formally the draft revision of Regulation CNEN-NE-5.01 as soon as possible and to update the MERCOSUR agreement on the transport of dangerous goods in line with the latest United Nations model regulations.

5.3. It would also be useful to develop formal agreements between ministries in areas of overlapping responsibilities. The responsibilities for regulating, licensing and inspection should be more clearly separated from the operational and promotional functions. More formality in procedures could be used to enhance the compliance assurance aspects of regulating the transport of radioactive material.

5.4. Good practices were noted in particular in the area of emergency response. The capabilities for responding to an emergency and the practical guidelines would be worth while for other competent authorities to consider. Another good practice involves the emphasis on preparing and evaluating transport plans and the practical application of these plans for ensuring compliance.

Appendix I

ABBREVIATIONS

The abbreviations below are for the purposes of this report only.

ABNT	Associacão Brasileira de Normas Técnicas (Brazilian Institute of Technical Standards)
ADR	European Agreement Concerning the International Carriage of Dangerous Goods by Road
ANTT	Agência Nacional de Transporte Terrestre (National Agency for Land Transport)
CBTN	Companhia Brasileira de Tecnologia Nuclear (Brazilian Nuclear Technology Company)
CDTN	Centro de Desenvolvimento da Tecnologia Nuclear (Centre for the Development of Nuclear Technology)
CGCI	Coordenação Geral de Cooperação e Intercâmbio (General Co-ordination of Co-operation and Exchange)
CGLC	Coordenação Geral de Licenciamento e Controle (General Co-ordination for Licensing and Control)
CIEN	Centro de Informações de Emergência Nuclear (Nuclear Emergency Information Centre)
CNEN	Comissão Nacional de Energia Nuclear (National Nuclear Energy Commission)
CNO	Comissão de Normas (Standards Commission)
CONAMA	Conselho Nacional do Meio Ambiente (National Environmental Council)
COPREN	Comitê de Planejamento de Resposta a Emergências Nucleares (Committee for the Planning of the Response to Nuclear Emergencies)
CSPN	Conselho Superior de Politica Nuclear (Superior Nuclear Policy Council)
DIDRE	Divisao de Reatores (Reactor Division)

DIRAD	Divisão de Instalações Radiativas (Division of Radioactive Facilities)
DOREJ	Divisão de Rejeitos Radiativos (Radioactive Waste Division)
DPD	Diretoria de Pesquisa e Desenvolvimento (Research and Development Directorate)
DRS	Diretoria de Radioproteção e Segurança Nuclear (Nuclear Safety and Radiation Protection Directorate)
FEEMA	Fundacao Estadual de Estudos do Meio Ambiente (State Environmental Foundation)
IBAMA	Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis (Brazilian Institute of Environment and Renewable Natural Resources)
ICAO	International Civil Aviation Organization
IMDG Code	International Maritime Dangerous Goods Code
IMO	International Maritime Organization
INB	Indústrias Nucleares do Brasil
IPEN	Instituto de Pesquisas Energéticas e Nucleares (Institute of Nuclear Research)
IRD	Instituto de Radioprotecão e Dosimetria (Radioprotection and Dosimetry Institute)
MST	Ministério da Ciência e Tecnologia (Ministry of Science and Technology)
NORMAM	Normas da Autoridade Marítima (Rules of the Maritime Authority)
Nuclebrás	Empresas Nucleares Brasileiras SA
PSE	Plano para Situações de Emergência (Plan for Emergency Situations)
SINAER	Sistema Nacional de Averiguação de Eventos Radiológicos (Guidance for the Provision of Emergency Response across the Country)
SIPRON	Sistema de Proteção ao Programa Nuclear Brasileiro (System for the Protection of the National Nuclear Programme)
SISNAMA	Sistema Nacional de Meio Ambiente (National System of the Environment)

RID	Regulations Concerning the International Carriage of Dangerous Goods by Rail

Appendix II

THE BRAZIL TRANSPORT SAFETY APPRAISAL SERVICE (TRANSAS) TEAM

L. BAEKELANDT — Team member

Mr. Baekelandt is a physicist and at present Head of the Regulatory and Licensing Department of the Federal Agency for Nuclear Control, Belgium. Mr. Baekelandt started his professional career as an assistant at the Institute for Theoretical Physics at the Catholic University of Leuven. From 1973 to 1988 he worked for the competent authority for radiation protection and nuclear safety at the Belgian Ministry of Public Health and the Environment. In 1988 he moved to the Belgian Agency for the Management of Radioactive Waste and Enriched Fissile Materials, where he served as an attaché to the general management in charge of radiological protection, environmental protection and safety issues. In May 1999 he was appointed Head of the Regulatory and Licensing Department of the newly established Federal Agency for Nuclear

FIG. 3. The Brazil TranSAS team in front of the headquarters of the CNEN in Rio de Janeiro. From left to right: W. Huck, C. Fasten, L. Baekelandt, G.J. Dicke and F.D. Ferate.

Control, the regulatory authority for radiation protection and nuclear safety, which is also competent in the area of the transport of radioactive material. As such, he is involved in the implementation of the Belgian and international regulations dealing with the transport of radioactive material.

He was involved in several revisions of the IAEA's Regulations for the Safe Transport of Radioactive Material and in compiling the supporting explanatory and advisory material and has lectured at several IAEA transport training courses and IAEA workshops.

He is Chairman of the IAEA Waste Safety Standards Committee (WASSC) and is now involved in the discussions on the definition of the scope of regulatory control.

G.J. DICKE — Team leader

Mr. Dicke is a Transport Safety Specialist in the IAEA Transport Safety Unit of the Division of Radiation and Waste Safety, Vienna, Austria. He is the Scientific Secretary for the annual IAEA meetings on the review and revision of the Transport Regulations. He represents the IAEA at meetings of the United Nations Committee of Experts on the Transport of Dangerous Goods and the Dangerous Goods Panel meetings of the ICAO for the incorporation of the Transport Regulations into the United Nations model regulations and the ICAO Technical Instructions. He chairs the annual interagency meeting with the ICAO, the United Nations and the IMO in support of the harmonized and integrated implementation of the Transport Regulations into the United Nations model regulations and the international modal transport regulations. Mr. Dicke had the lead role in the development of the working procedures and the questionnaire for the IAEA's TranSAS and served as Team Leader for the first TranSAS appraisal.

Prior to joining the IAEA in May 1997, Mr. Dicke worked for 26 years for the Nuclear Operations Division of Ontario Hydro in Canada. For close to 20 years he was responsible, initially as Unit Head and later as Section Head, for the operational and regulatory aspects of Ontario Hydro's transport of radioactive material. He completed his doctoral examinations in chemical engineering at Delft University in the Netherlands. He is a Professional Engineer in Ontario, a Member of the Chemical Institute of Canada and a Member of the Editorial Board of the International Journal of Transport of Radioactive Material.

C. FASTEN — Team member

Ms. Fasten is a physicist and a Scientific Co-worker at the Bundesamt für Strahlenschutz in Germany. She has been working in the radiation protection field since 1974 and has held responsibilities in the field of the safe transport of radioactive material since 1983.

At the Bundesamt für Strahlenschutz (the competent authority for the safe transport of radioactive material in Germany) she has been involved in the implementation of the 1985 edition as well as the 1996 edition of the IAEA's Regulations for the Safe Transport of Radioactive Material in Germany and the incorporation of the requirements of these regulations into international agreements for road and rail transport. She has worked as the international chairperson of the United Nations Joint Meeting on the RID Safety Committee and the Working Party on the Transport of Dangerous Goods. This Joint Meeting prepared the revisions to the RID/ADR regulations for the rail and road mode in Europe. These revisions have included the incorporation of all the requirements of the Transport Regulations into the RID/ADR regulations.

Ms. Fasten's work with the IAEA has included participation in meetings on the review and revision of the Transport Regulations and related Consultant Services Meetings since 1984. At these meetings she has often been a Group Leader or Secretary. She has also co-ordinated the IAEA's Transport Safety course in Germany and has lectured in IAEA training courses.

F.D. FERATE — Team member

Mr. Ferate serves as a Health Physicist with the Radioactive Materials Branch of the Office of Hazardous Materials Safety at the United States Department of Transportation (DOT) headquarters in Washington, D.C., United States of America. He also serves as Project Manager for the DOT rule making presently under way to adopt the 1996 edition of the IAEA's Regulations for the Safe Transport of Radioactive Material into the US hazardous goods transport regulations, and works closely with staff of the US Nuclear Regulatory Commission (NRC) to co-ordinate the DOT rule making with the parallel NRC rule making. Mr. Ferate was the leader of the US delegation at four Technical Committee Meetings at the IAEA in Vienna that dealt with radioactive material transport issues.

Mr. Ferate reviews applications for US competent authority certifications of package designs for the international transport of Type B quantities and fissile radioactive material, and for certifying special form sources. He works closely with nuclear engineers of the NRC who serve as the technical resource of the DOT for the evaluation of Type B and fissile material package designs. Mr. Ferate represents the DOT in various interagency committees in the USA involved in risk harmonization and emergency response planning for accidents involving radioactive material.

Mr. Ferate was Professor of Physics and established the undergraduate physics major programme at the Universidad de Antioquía, Medellín, Colombia, where he worked from 1969 to 1981.

W. HUCK — Team member

Mr. Huck is Dean of the Faculty of Law at the University of Applied Sciences in Braunschweig/Wolfenbüttel, Germany, where he also gives lectures on the law of transportation and the environment. Between 1991 and 1997 he was Head of the Division for Law and Strategy in the Department for the Nuclear Fuel Cycle, Transport and Storage of Radioactive Materials at the Federal Office of Radiological Protection in Salzgitter, Germany. The topic of his doctoral dissertation at the University of Bonn in 1991 was the transport of radioactive material.

Appendix III

PHOTOGRAPHS OF URANIUM HEXAFLUORIDE TRANSPORT IN BRAZIL

FIG. 4. Unloading a shipment of uranium hexafluoride at the harbour of Rio de Janeiro: a four cylinder shipping rack is lowered on to a flatbed truck.

FIG. 5. Closer view of a shipping rack with three cylinders of uranium hexafluoride. The rack is positioned above the flatbed of the first truck in a convoy of several vehicles.

FIG. 6. Closer view of a shipping rack with four cylinders of uranium hexafluoride. The rack is lowered on to the flatbed of the second truck in the convoy.

FIG. 7. A technician of the INB applying placards on a truck that carries a load of uranium hexafluoride cylinders.

FIG. 8. General view of the convoy as it is being loaded with uranium hexafluoride. The convoy that carries the shipment is bound for the facilities of the INB in Resende, state of Rio de Janeiro.

FIG. 9. Reception of uranium hexafluoride at the INB's facilities in Resende, state of Rio de Janeiro: the crane operator and handler position the pulley and hook to lift a uranium hexafluoride cylinder out of its outer packaging.

FIG. 10. Reception of uranium hexafluoride at the INB's facilities in Resende, state of Rio de Janeiro: the crane hoisting a cylinder out of its packaging.

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