LICENSING OF A TYPE B(U) PACKAGE DESIGN FOR THE TRANSPORT AND TRANSFER OF MEDICAL ^{60}Co SEALED SOURCES IN ARGENTINA

J.R. López Vietri, A.J. Bianchi and C.A. Menossi

Nuclear Regulatory Authority, Avda. del Libertador 8250, 1429 Buenos Aires, Argentina

SUMMARY

This paper points out the relevant regulatory issues related to the licensing process of a Type B(U) package design (hereinafter called CONTRAS), approved for the transport by all modes and the transfer of ^{60}Co sealed sources of up to 555 TBq, as a special form radioactive material, for medical use in a circular section drawer of a cobalt-therapy equipment, as carried-out by the Nuclear Regulatory Authority (hereinafter called ARN) of Argentina, the former Nuclear Regulatory Entity (ENREN), of Argentina.

A description is made of both, the decisions taken during the different stages of the main technical development areas for the licensing process and the requirements and conditions that must be fulfilled by applicants prior a CONTRAS licensing be issued, in accordance with the 1985 Edition (As Amended 1990) of the IAEA Regulations for the Safe Transport of Radioactive Material (hereinafter called IAEA Regulations).

Further on, the paper describes the most relevant activities performed by the ARN during the licensing process, among others: packaging manufacturing inspections; handling performance test; shielding behaviour and tests prior first shipment.

Finally, brief comments are made on the experience gained from previous Type B(U) package design developments. And, finally, some ARN aspects of the applicants documentation revision and assessment, as well as main conclusions after the above mentioned licensing process.

INTRODUCTION

Since 1984, and as a result of a CANDU nuclear power reactor operation, Argentina become an important exporter of ^{60}Co, and has had to develop both, the industrial and medical sealed sources as well as package designs for their containment, handling and transport. The CONTRAS package was designed and manufactured by INVAP SE, Applied Research State Company (hereinafter called INVAP), a company partially owned by the National Commission of Atomic Energy, of Argentina and the Government of the Province of Río Negro, Argentina, with a large experience and training in the field that accredited for the task.

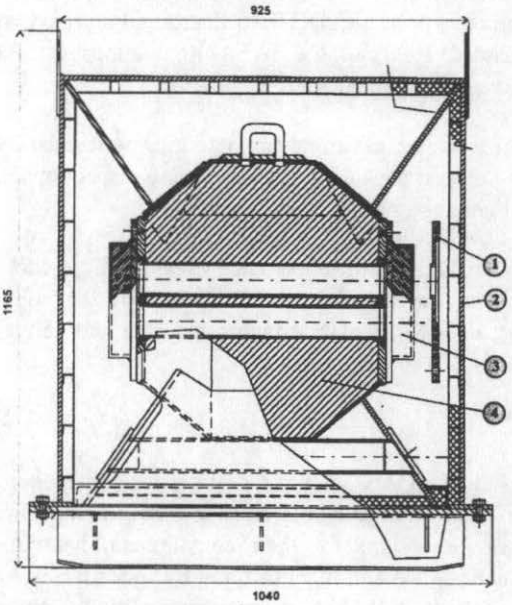
The paper analyses the ARN requirements that must be fulfilled by the applicant to certify that Type B(U) CONTRAS package design, complies with the IAEA Regulations under both normal and accident conditions of transport including: (i) experimental mechanical tests planning; calculation methods; tests prior first package shipment, and manufacturing procedures; (ii) mechanical evaluation, involving scale laws, model specifications, deceleration and strain-stress measuring methods, and number, sequence and drops attitude; (iii) thermal analysis, including selection of codes and analytical models, and conservative hypothesis assessment; (iv) shielding analysis by computational codes; and (v) analysis and validation results.

The whole licensing process took approximately three years. Thereafter, the documentation submitted to the ARN by the applicant, such as: safety analysis report; manufacturing programme; operation, inspection and maintenance, and emergency procedures; and quality assurance programme, was fully studied and assessed.

THE CONTRAS PACKAGE DESIGN DESCRIPTION

The CONTRAS package is a 2,300 kg transfer case consisting of a main body and a fireshield. The main body has lead-filled stainless steel AISI 304 encased, as a primary containment and shielding, which has two circular section channels with steel and lead lid, where the drawer and dummy goes into. The main body is, in turn, inserted in a cubic fireshield (1 m edges), made of 25.4 mm Fiberfrax insulated and covered by 6.3 mm AISI 304 steel, to prevent heat transfer in case of external fire. The approximated overall external dimensions are: 1.040 m width by 1.040 m deep and 1.167 m high, see Figure 1.

FIGURE 1. Drawing of CONTRAS Type B(U) package transfer case design



1. Adapting flange (stainless steel).
2. Fireshield (lead sandwiched in stainless steel).
3. Cover plates (thermal insulator sandwiched in stainless steel).
4. Main body (lead sandwiched in stainless steel).

CONTRAS is a package designed to content no more than 555 TBq of ^{60}Co within any sealed sources in circular section drawer which meets the IAEA Regulations for special form radioactive material. The containment system consists of ^{60}Co welded capsules and 247 mm thick steel-encased, lead-shielded inner container.

DEVELOPMENT OF THE LICENSING PROCESS

At the beginning of the licensing process, discussions were held between the ARN and INVAP on the conditions to fulfil the basic requirements established in the IAEA Regulations. At that moment, the general characteristics of the package design were analysed and definitions were made on whether the package structure, thermal and shielding performance would be evaluated through calculation or by means of experimental methods.

Further on, discussions were held concerning experimental mechanical testing programmes, calculation methods, testing prior first package shipment and general manufacturing procedures. In that stage, clear definitions were made on the mechanical evaluation (scale laws, requirements and specifications of the scale model, number of tests proposed, sequence and drops attitude, deceleration and strain-stress calculation), thermal analysis (computational codes, analytical models, hypotheses conservatism), and shielding analysis (computational codes, technical problems were simpler, and computational tools were known and reliable). In every case, the results obtained were analysed and validated.

During the whole licensing process, the applicant was requested to perform experimental tests and calculations, whose results were continuously reviewed and assessed by the ARN and discussed with INVAP.

This whole licensing process took about three years during which minor modifications were made by INVAP to the package design. Finally, the formal application was sent to the ARN for his approval. In conformity with INVAP Quality Assurance Program, the documentation submitted included a design evaluation performed by the INVAP professional team other than those involved in the product's development. The ARN started a thorough and independent review and assessment of the overall information submitted by INVAP.

We ought to mention that during the CONTRAS licensing process the personnel involved were 17 professionals between designers and applicant (INVAP) and 7 professionals from the competent authority (ARN). Such staff of 24 technicians and professionals with proved proficiency, training and experience in different areas, such as, design, materials, structures, manufacturing, thermal and radiation shielding analysis, non-destructive assays, mechanical tests, tests prior first package shipment, quality assurance and transport regulation.

DESIGN AND TEST DEVELOPMENT

The Type B(U) package must comply with the functional performance requirements and also be fitted to maintain the containment and shielding integrity against radiation after being submitted to tests simulating both normal and accident conditions of transport.

The ARN requested that compliance assurance shall be carried-out as stated in the IAEA Regulations and in their support documents IAEA Safety Series Nos. 7, 37, 112 and 113. On the other hand, the ARN as well as INVAP had been gathering experiences from previous

Type B(U) package designs to verify compliance with the applicable regulations, see the paper "Argentine experience in licensing a Type-B(U) package design for the transport of Cobalt 60", PATRAM '95.

Mechanical test

The ARN requested to INVAP the performance of an experimental mechanical test, since validated computational models for their simulation or results from other tests with similar package models, were not available in the country, therefore, and under ARN supervision during preparation and development performance the test was satisfactorily carried out. The target used is described in paper "Test facilities for radioactive material transport packages in Argentina".

A specimen built at a 1:2 scale was prepared for testing and, consequently, their escalation, requirements and specifications had to be defined. No significant differences were found between the CONTRAS model and the tested specimen.

Through this test, INVAP and the ARN outlined and defined the total number of drops, its dropping sequence and orientation, so as to obtain the greatest specimen damage. Six drops were performed in different angles with respect to the target: 4 were free drops from 9 m height producing a general deformation effects on its structure, and 2 were punctured from 1 m height and caused localised effects on the impact area.

After the most unfavourable testing sequence and orientation, first the free drop on an edge and second puncture on a lateral side, the integrity of shielding and containment were verified, concluding that: there were no important deformations or fissures in the primary containment; the fireshield was still in its fixed position and has not lost the main body thermal protection efficiency nor suffered any damage the specimen sealed source.

Thermal analysis

The CONTRAS package was particularly designed to prevent fire heat from entering into the main body, in case of fire, considering that, if lead fusion occurs (327°C), a loss of shielding could take place due to the hydraulic steel wall breakage.

Taking into account that INVAP had proved the effectiveness of independent computational models, in previous Type B(U) package designs, TAP 6 and CATE, the thermal analysis under normal conditions of transport was modelled on the basis of aximetric calculations, assuming a 231 W as the maximum thermal power of the source in the drawer and that heat is transferred out by conduction, convection and radiation. The most significant temperature figures obtained are summarised in Table 1.

Analytical models and hypothesis conservatism were assessed in order to model the thermal test. The hypotheses considered by INVAP were: undamaged package after the mechanical test, initial temperature distribution at a steady state the same as that calculated under normal conditions; ambient temperature of 800°C and emission of 0.9 were assumed during the 30 minutes heating period; while, during the 2 hour natural cooling time, ambient temperature was assumed to be 38°C. In case of fire, the thermal analysis was modelled considering that heat runs through the fireshield mainly by radiation. The most important results obtained were

those indicating that: the main body maximum surface temperature was 220°C, there was not melted lead, maximum temperature at the ^{60}Co sealed source was less than 339°C, internal pressure was the same as the atmosphere, and steel stress, due to differential and thermal expansion, was negligible. That was how the thermal test served to verify the containment and shielding integrity.

Other tests and evaluations

INVAP demonstrated the package integrity through calculations after the water immersion test, since hydrostatic pressure does not affect its external components.

Under normal and accident conditions of transport, the shielding was evaluated by the computational MERCURE IV code and submitted to an optimisation process, taking into account one ^{60}Co source of 555 TBq located in the upper channel. Tables 2 and 3 show a summary of the radiation level values and their compliance with the IAEA Regulations criteria.

In complying with the tests for normal conditions of transport required by the IAEA Regulations, INVAP had proved that: water spray test was not relevant and free drop and penetration tests can be disregarded when compared with those for accident conditions, and stacking test is not applicable because, for operational reasons, these package must not be stacked on each other. The lifting eyebolts and the tie-up systems were calculated in accordance with the IAEA Safety Series No. 37.

TABLE 1. Temperature figures calculated by design for maximum radioactive contents and required by the IAEA Regulations for normal conditions of transport

	MAXIMUM TEMPERATURES (°C)	
	Design	**Regulations**
External surface of the primary containment	110.0	Not specified
Internal cavity wall of the primary containment	----------	Not specified
Internal wall of the fireshield	79.5	Not specified
External wall of the fireshield	51.0	50 - 85 **(1)**
Lifting handles	50.0	50 - 85 **(1)**

(1) Paragraphs 544 and 555 of the IAEA Regulations require that the maximum temperature of any surface readily accessible during transport of a package shall not exceed 50°C; if this maximum temperature is between 50°C and 85°C the package shall be transported under exclusive use.

TABLE 2. Radiation levels measured during Pre-shipment Tests interpolated to the maximum radioactive contents and required by the IAEA Regulations for normal conditions of transport

	RADIATION LEVEL (mSv/h)			
	In contact with the external surface of the fireshield		At 1 m of the external surface of the fireshield	
	Tests	**Regulations**	**Tests**	**Regulations**
Maximum in the lower zone	0.10	2.0	--------	0.1
Minimum in the lower zone	0.02		--------	
Maximum in the lateral zone	0.20		0.020	
Minimum in the lateral zone	0.03		0.001	
Maximum in the upper zone	1.40		0.080	
Minimum in the upper zone	0.05		0.002	

TABLE 3. Acceptance criteria for normal and accident conditions of transport

	CALCULATED/TEST	REGULATIONS
Shielding after tests for normal conditions		
- Radiation level on external surface of the package	1.0 mSv/h (1)	2.0 mSv/h
- Radiation level at 1 m of the external surface of the package	0.08 mSv/h (1)	0.1 mSv/h
Shielding after tests for accident conditions		
- Radiation level at 1 m of the external surface of the package	8.0 mSv/h (2)	10.0 mSv/h
Containment after tests		
- Leaktight for normal conditions	$2\ 10^{-10}$ TBq/h	$4\ 10^{-7}$ TBq/h
- Leaktight for accident conditions	$3\ 10^{-3}$ TBq/week	0.4 TBq/week

(1) Figures obtained by tests.
(2) Figures calculated in points placed in the upper surface of the package.

QUALITY ASSURANCE, MANUFACTURE AND TESTS BEFORE FIRST SHIPMENT

The design, documentation, material purchasing, tests and manufacture of the CONTRAS transfer case have been carried-out in accordance with both the INVAP and the GURI 01 Quality Assurance Manuals.

The ARN carried-out inspections to verify that the manufacture of packaging Serial N° 1, 2 and 3 were performed in a controlled manner and in agreement with the design specifications. The most important procedures assessed was the lead melting, since its design requires lead-steel adherence above 40%. The non-destructive assays were performed to verify the adequacy of welding and adherence. On the other hand, control over adequate material purchasing was made, especially to verify steel ductility even at –40°C, for avoiding the possibility of brittle fracture during transport and in-transit storage operations.

The ARN made evaluations and inspections over the tests performed prior first package shipment, verifying their handling, containment and shielding behaviour evaluated in the design. A transfer test with simulated sealed source was performed to verify package operation with a cobalt-therapy equipment, and a shielding test with radioactive contents for verifying radiation level values. Tables 2 and 3 summarise the values obtained in these tests. In addition, these tests allow to verify the validation of operation and preparation for shipment procedures as stated in the CONTRAS Operation Manual.

ASSESSMENT BY THE NUCLEAR REGULATORY AUTHORITY OF ARGENTINA

The ARN personnel performed an independent analysis and, in some cases, a re-calculation of the information contained in the following documentation presented by INVAP: Final Safety Analysis Report; Operation, Inspection & Maintenance and Quality Assurance Manuals; Production and Control Programme; Tests Before the First Shipment Program; Emergency Procedures, as well as protocols and results from manufacturing controls and tests. These analyses confirmed that INVAP has developed the CONTRAS transfer case design using appropriate conservative criteria, so as to insuring a high level of compliance with the IAEA Regulations.

Tables 1, 2 and 3 show a summarised comparison between the results obtained by calculation and from the tests, and those required by IAEA Regulations. We ought to mention that both the design and the postulated hypotheses have been conservative.

CONCLUSIONS

The following conclusions were reached after the licensing process for the CONTRAS Type B(U) package, used for the transport and transfer of medical ^{60}Co sealed sources:

- During the licensing process the Nuclear Regulatory Authority of Argentina supported continually the designers, manufacturers and applicant -INVAP- with necessary informal advice without commitment, while the independence and objectivity between them were clearly understood and maintained.

- As the CONTRAS was the third important Type B(U) package design in Argentina developed by INVAP, it is noted that the experience reached in the country allows the reduction in the designing, manufacturing and licensing time, as well as in minimising the CONTRAS design changes produced during its licensing process.

- INVAP established and implemented an appropriate quality assurance programme for the design, documentation, tests, transport and in-transit storage operations for the CONTRAS package as well as for the materials purchasing, maintenance, inspection and packaging manufacture.

- The ARN was fully satisfied with the CONTRAS Type B(U) transfer package design fulfilment with the provisions of the 1985 Edition (As Amended 1990) of the IAEA Regulations by reviewing and, in some cases, re-calculating the design by using different methods.

- CONTRAS was finally approved by the ARN in July 1995 who issued the Approval Certificate RA/0074/B(U)-85 under the provisions of the mentioned edition of the IAEA Regulations.

- The package design is only used for both the transport and the transfer of ^{60}Co sealed sources of up to 555 TBq in circular-section drawers. It is very important because in Argentina from over 95 cobalt-therapy equipments in operation, only 8 are using square-section drawers.

- On-going with benefits obtained from the development and experience of the local nuclear industry, CONTRAS has resulted in a product with appropriate quality and comparable with other similar designs at international level.

REFERENCES

Regulations for the Safe Transport of Radioactive Material. 1985 Edition (As Amended 1990). Safety Series No. 6, Vienna, 1990. IAEA.

Explanatory Material for the IAEA Regulations for the Safe Transport of Radioactive Material. (1985 Edition), 2nd Edition (As Amended 1990). Safety Series No. 7, Vienna, 1990. IAEA.

Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (1985 Edition), 3rd Edition (As Amended 1990), Safety Series No. 37, Vienna, 1990. IAEA.

Compliance Assurance for the Safe Transport of Radioactive Material, Safety Series No. 112, Vienna, 1994. IAEA.

Quality Assurance for the Safe Transport of Radioactive Material, Safety Series No. 113, Vienna, 1994. IAEA.

López-Vietri, J.R., Novo R.G. and Benito G. Test Facilities for Radioactive Material Transport Packages in Argentina, Vol. 2 Nos. 4/5, England, 1991. RAMTRANS.

López Vietri, J.R., Novo, R.G. Argentine Experience in Licensing a Type-B(U) Package Design for the Transport of Cobalt 60. PATRAM '95, Las Vegas, 1995. ARN.

Operation Manual of the CONTRAS Package Design, Document No. 0756-2010-3MOMC-002-1A. Argentina, 1995. INVAP SE.

Inspection and Maintenance Manual of the CONTRAS Package Design, Document No. 0756-2010-3MOMC-003-1A. Argentina, 1995. INVAP SE.

Quality Assurance Manual of INVAP SE, Document No. 0000-0110-3MGGC-001-1A. Argentina, 1980. INVAP SE.

Quality Assurance Manual of the GURI 01 Package Design. Argentina, 1985. INVAP SE.