

Accordingly, a mere administrative circular which has never been officially published, which may be amended by the administration at will and contains only recommendations which have no binding force cannot be regarded as adequate implementation of a directive.

## REPORT FOR THE HEARING in Case C-95/92\*

### I — Legal framework and pre-litigation procedure

#### 1. *The legal framework*

1. Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (OJ 1984 L 265, p. 1) (hereinafter 'the Directive') was adopted in order to ensure more extensive harmonization of the rules on health protection against the dangers of ionizing radiation and thus to improve the radiation protection of patients and the general public.

2. The Directive provides, *inter alia*, that:

— all medical exposures are to be medically justified and kept as low as reasonably achievable (Article 1);

— the Member States are to take all appropriate measures to ensure that any ionizing radiation used in medical procedures is effected under the responsibility of practitioners who are entitled to perform such medical procedures in accordance with the national legislation (Article 2(1));

— the abovementioned practitioners must have adequate and appropriate training (Article 2(1) and (2));

— the competent authorities are to draw up an inventory of radiological equipment and nuclear medical installations and to ensure that they are kept under strict surveillance, after establishing criteria of acceptability (Article 3);

— a qualified expert in radiophysics is to be available to sophisticated departments of radiotherapy and nuclear medicine (Article 5).

\* Language of the case: Italian.

3. Article 7 of the Directive is worded as follows:

‘Member States shall take the measures necessary to comply with this Directive before 1 January 1986.

Member States shall inform the Commission of the provisions they have adopted to comply with this Directive.’

4. In that regard, the Italian Republic communicated to the Commission Circular No 62 of 2 August 1984, issued by the Ministry of Health, and a number of legislative measures.

2. *The pre-litigation procedure*

5. Taking the view that the measures adopted by the Italian Republic in order to implement the Directive did not have adequate legal force, the Commission, acting in accordance with Article 141 of the Euratom Treaty, asked the Italian Republic, by letter No 4564 of 18 April 1990, to submit its observations within two months of receiving that letter.

6. By telex message No 408 of 16 July 1990, the Permanent Representation of the Italian Republic informed the Commission in reply that the Italian authorities were in the process of drawing up the measures necessary to comply with the Directive.

7. On 31 July 1991 the Commission delivered a reasoned opinion in which it called on the Italian Republic to take the measures necessary to comply with the abovementioned articles of the Directive within two months of service of the opinion. The Italian Republic did not respond.

II — Written procedure and forms of order sought by the parties

8. The Commission’s application was lodged at the Court Registry on 23 March 1992.

9. Upon hearing the Judge-Rapporteur and the views of the Advocate General the Court decided to open the oral procedure without any preparatory enquiry.

10. The *Commission* claims that the Court should:

- declare that, by failing to adopt the laws, regulations and administrative provisions necessary to comply with Articles 1, 2(1) and (2), 3 and 5 of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (OJ

1984 L 265, p. 1), the Italian Republic has failed to fulfil its obligations under Community law;

— order the Italian Republic to pay the costs.

11. The *Italian Republic* claims that the Court should:

— dismiss the application;

— order the Commission to pay the costs.

### III — Submissions and arguments of the parties

12. The *Commission* observes that according to Article 161 of the Euratom Treaty directives are binding, as to the result to be achieved, on the Member States to which they are addressed and that the first paragraph of Article 192 of that Treaty requires Member States to take all appropriate measures to ensure fulfilment of their obligations. However, the Italian Republic has still not adopted the provisions necessary to comply with the directive and has thus failed to fulfil its obligations.

13. The *Italian Republic* acknowledges that the legislative provisions necessary to give

effect to the Directive have not yet been formally adopted, although powers have been delegated to the Government for that purpose (by Law No 212 of 30 July 1990 and also by Law No 142 of 19 February 1992). However, it points out that the requirements set out in the Directive already have a precise equivalent in Circular No 62 from the Ministry of Health of 2 August 1984 on 'the radiation protection of the sick during diagnostic examination and therapeutic treatment using radiology and nuclear medicine', which was sent to all the competent authorities and services.

14. The *Commission* claims that it is settled case-law that Member States are required to implement directives in a manner which fully corresponds with the requirements of clarity and certainty of the legal situations which the directives are intended to bring about. Circulars are not generally an appropriate means of ensuring the implementation of a directive.

15. After analysing Italian Circular No 62 of 2 August 1984 and the various measures referred to therein or accompanying it, the Commission considers that, taken together, they cannot be regarded as transposing the directive with sufficient legal force. The circular in question is an internal publication of a non-binding nature which cannot be regarded as an appropriate way of ensuring general publicity. It merely provides the competent services with certain information concerning the most recent developments in the sector in question. Furthermore, the

circular predates the directive and the way in which it transposes the directive into national law is incomplete, arbitrary and extremely fragmentary.

16. The *Italian Republic* disputes the Commission's arguments. It points out that the requirements of the circular are essentially directed at establishments, principally public but also private, and operators in the sector in question. The scope of the circular is much greater. The fact that the document

was distributed with meticulous care enabled all the operators concerned to be directly informed. The circular constitutes a significant reference text. It was adopted in the light of the preparatory works of the directive. The requirements of the circular correspond to the provisions of the directive which were required to be implemented.

P. J. G. Kapteyn  
Judge-Rapporteur