

# DEPARTMENT OF HEALTH DIRECTORATE: RADIATION CONTROL

# CODE OF PRACTICE FOR USERS OF MEDICAL X-RAY EQUIPMENT

**Code: Diagnostic Use** 

**WEB ADDRESS:** 

https://sites.google.com/site/radiationcontroldoh/

**Compiled by Radiation Control** 

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#### 1. INTRODUCTION

This Code sets out requirements and recommendations for radiation safety associated with the use of medical diagnostic x-ray equipment.

The Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973) govern the safe use of medical x-ray equipment in South Africa.

Requirements from the Act and Regulations are incorporated in this Code. Further requirements are taken from source material listed in the section of References.

Whenever compliance with a requirement in this Code is mandated the word **must / shall** is used. The word **should** indicate a practice that is recommended but not mandatory at this stage.

Where a given technology or practice is not specifically covered by this Code, guidance in matters of radiation protection should be sought from the Department of Health: Radiation Control.

The Licensee shall be responsible for ensuring that corrective action takes place on items of non-compliance with this Code.

The Act does not allow any person to use radiation equipment unless he/she holds a licence under the Act for that purpose.

This Code does not cover the use of x-rays for dental and veterinary diagnosis.

This Code must be read in conjunction with DOH: Radiation Control Guideline documents as listed in Annexure A of this Code.

All forms and guidelines are available at: <a href="https://sites.google.com/site/radiationcontroldoh/">https://sites.google.com/site/radiationcontroldoh/</a>

<sup>\*</sup> DOH Guideline documents: https://sites.google.com/site/radiationcontroldoh/

#### 2. ABBREVIATIONS

ACT Hazardous Substances Act, 1973 (Act 15 of 1973)

**DOH** Department of Health

**HPCSA** Health Professions Council of South Africa

IER Individual Equipment Record

mSv milliSievert

**TLD** Thermo Luminescent Dosimeter

NTP Nuclear Technology Products

**PRMD** Personal Radiation Monitoring Device

SABS South African Bureau of Standards

SANAS South African National Accreditation System

**SDR** Supplementary Diagnostic Radiographer

**QA** Quality Assurance

QC Quality Control

#### **DEFINITIONS**

**Actinic marking** Permanent transfer of patient data / identification on to

the film prior to processing

ALARA As Low As Reasonably Achievable

**Controlled area** A controlled area is a limited access area in which the

occupational exposure of personnel to radiation is under the supervision of an individual in charge of radiation protection. This implies that access, occupancy and working conditions are controlled for radiation protection

purposes

**Department** Department of Health

**Diagnostic QC** Requirements for licence holders with respect to Quality

Control Test for diagnostic x-ray imaging systems

**Inspection Bodies** An organisation approved by the Department of Health:

Directorate Radiation Control and accredited by SANAS

to perform acceptance and QC tests on diagnostic x-ray equipment

Radiation worker Any person who is potentially exposed to radiation as a

result of his/her occupation to more than three tenths of

the occupational dose limit (20mSv per annum)

**Regulations** Regulations relating to the Control of Electronic Products

(No R1332 of 3 August 1973)

**Supervision** The supervisor accepts and shares with the supervisee

responsibility for ensuring that the supervisee's work is professional and ethical, operating within whatever legal

requirements and organisational norms apply

**Supervision (direct)** The supervisor provides on-site and in-view observation

and guidance of a supervisee who performs an assigned activity. The proximity of this supervision is such that

immediate intervention is possible if problems occur

**X-ray unit** An electronic product that is designed, manufactured or

assembled with the primary purpose of producing x-rays

#### 3. LICENSING

- 3.1 The Regulations concerning to the Control of Electronic Products require that a joint product and premises licence be obtained for x-ray equipment **before** it may be installed and commissioned.
  - (a) Licences are not transferable and are issued:
    - To a specific person or institution;
    - For specific equipment and its application, and
    - For a specific premises.
  - (b) Licences are issued subject to the Regulations concerning the Control of Electronic Products and the application of specific conditions.
  - (c) Licence holders must verify the accuracy of the information displayed on the licence issued and communicate any inaccuracies to DOH: Radiation Control.

#### Application for licences

3.2 It is the responsibility of the prospective user of an x-ray unit to be in possession of a licence from Radiation Control **prior to installation** of the unit.

#### 3.2.1 New units (Form RC-DEALER)

A RC-DEALER application form is a combined form to be completed by both the supplier and the end user of a new x-ray unit. The prospective user must obtain the RC-DEALER form from the supplier of the x-ray unit. The section applicable to the user must be completed and the form returned to the supplier.

The supplier is responsible to submit the completed form to Radiation Control for processing.

#### 3.2.2 Pre-owned units (Form RC001)

Form RC001 must be completed for a pre-owned x-ray unit.

It is the responsibility of the prospective user to submit the completed application form RC001 to Radiation Control.

#### Allow 30 days for processing of applications.

#### **Installations**

3.3 The installation of an x-ray unit may only commence after a licence to install the unit has been issued.

#### **Acceptance tests**

(Refer to "Diagnost QC" document on Radiation Control website – see Annexure A.1 in this Code)

3.4 Only Inspection Bodies approved by DOH: Radiation Control and accredited by SANAS may perform acceptance tests on x-ray equipment. A list of approved Inspection Bodies and scope of the licences are available on the Radiation Control website.

#### 3.5 New Units

When a new unit is installed, acceptance tests must be performed by the supplier of the x-ray unit and the results recorded on the prescribed form and filed in the IER of the unit.

#### 3.6 Pre-owned units

The prospective user must ensure that acceptance tests are performed. Granting of a licence to use a unit is subject to submission of the results of the tests to Radiation Control.

When an existing licenced unit is moved to a new premises (building) or room, prior to use, acceptance tests must be performed on the unit and the results submitted to Radiation Control.

Units that have not been previously licensed by the Directorate: Radiation Control will not be licensed for use.

## Disposal / modification of x-ray equipment (Form RC002)

- **3.7** The licence holder must apply for and obtain permission from Radiation Control by submitting a completed form RC002 **prior to** cancellation, modification, disposal and/or sale of x-ray equipment.
  - Particulars regarding the type of disposal, e.g. sale, dismantling, disappearance or storage of a unit, must be furnished to Radiation Control before the cancellation of the licence will be effected.

## New / modified premises (Form RC002)

- **3.8** The licence holder must apply for and obtain permission **prior to**:
  - (a) Modification of any licensed premises or layout of equipment on such premises, and/or
  - (b) Change of licensed premises (building) or equipment moved to other rooms within the same building.

## Responsible person

- 3.9 The licence holder must appoint a responsible person that has adequate knowledge and experience in the field of radiation protection in general. The appointed person is responsible to the licence holder for the safe use of the x-ray equipment (see also par 4).
- **3.10** The person appointed must be qualified in either of the following categories and registered with the Health Professions Council of South Africa (HPCSA):
  - Radiography;
  - Radiology;
  - Medical Physics, or
  - Chiropractics.
- **3.11** The responsible person must be appointed in writing indicating the scope of the actions delegated by the licence holder.

# Change of responsible person (Form RC005)

**3.12** The licence holder must notify Radiation Control of a change in responsible person by submitting a completed form **RC005**.

# 4. RESPONSIBILITIES OF LICENCE HOLDERS / RESPONSIBLE PERSONS

#### 4.1 The licence holder of a diagnostic x-ray facility is ultimately responsible for:

- (a) The entire scope of radiation safety, for the equipment and premises for which he/she holds a licence:
- (b) Fulfilment of all related statutory requirements, and
- (c) Compliance to the Act, Regulations and Conditions specified in the licence.

#### 4.2 The licence holder / responsible person must ensure that:

- The equipment and the facilities, in which such equipment is installed and used, meet all applicable radiation safety standards;
- The equipment is maintained and functions properly;
- The equipment is used and maintained only by competent and appropriately trained persons / personnel;
- Applicable Quality Control (QC) tests are performed at the prescribed frequencies as stipulated in "Diagnost QC" document on DOH: Radiation Control website (see Annexure A1 in this Code);
- The required QC equipment is provided;
- Ensure that radiation surveys to monitor safe performance of equipment and to monitor radiation levels in work areas are undertaken;
- Radiation workers (occupationally exposed persons) are identified and issued with personal radiation monitoring devices (PRMD's);
- The appropriate protective clothing, devices and equipment is provided to personnel and properly used;
- Radiation safety rules are communicated to and followed by all personnel;
- Operational procedures are established and maintained to ensure that the radiation exposure to workers, patients and public is kept as low as reasonable achievable (ALARA) without compromising the diagnostic efficiency of the result, and
- Workers are educated in the hazards and risks of ionising radiation.

# **Keeping of patient records**

- **4.3** Records must be kept and available for inspection purposes by Radiation Control.
- **4.4** A record / register must be kept of all patients undergoing x-ray examinations. The record / register must be preserved for 5 years and contain the following information:
  - surname, name, date of birth or ID number / age and gender;
  - date of examination;
  - brief clinical indication of the examination;
  - type of examination;
  - number of exposures (repeat exposures included) and
  - fluoroscopy time, dose results (if available) and the name of the person performing the fluoroscopy procedure
  - total dose read-out or Dose Area Product (DAP) reading (if applicable)
  - brief statement of the diagnostic information obtained from the examination.

# Keeping of equipment records

- **4.5** IER must be kept and contain all required information as stipulated in "Diagnost QC" document on Radiation Control website see Annexure A.1 in this Code
- **4.6** Radiation worker record (see par 6.3)

## **Submission of acceptance tests results to Radiation Control**

**4.7** Acceptance test results of pre-owned x-ray units must be submitted to Radiation Control following installation (see par 3.6).

# Appointment of Medical Physicist for Interventional Radiology Procudures (Form RC006-1)

4.8 A medical physicist must be appointed in writing to establish and implement an optimisation program for interventional Radiology procedures as stipulated in "Diagnost QC" document on Radiation Control website - see Annexure A.1 in this Code

#### 5. OPERATORS

- 5.1 Only the following persons who are appropriately trained and registered with the HPCSA in Radiography and/or Radiology, may operate x-ray equipment and perform examinations within their appropriate scope of practice:
  - Radiographer
  - Supplementary Diagnostic Radiographer (SDR):
    - May only work in a Government hospital or an institution operated or subsidised by government or provincial authority or by the South African Chamber of Mines
      - (Refer to Medical, Dental and Supplementary Health Services Professions Act, 1974 (Act no 56 of 1974) Annexure 7)
    - Supplementary diagnostic radiographers must be supervised, at least once a week, by a qualified registered radiographer
    - The supervisor is not required to be present at all times. However, the supervisor shall meet with the supervisee on a continuous and regular basis and review the assigned duties as appropriate to the tasks to be performed.
  - Chiropractor
  - Radiologist

## Operators of mammography units

- 5.2 With effect from 1 July 2009 mammography examinations shall only be performed by qualified radiographers in possession of a recognised additional qualification (post graduate) in mammography.
  - Details of accredited courses can be obtained from the Professional Board for Radiography and Clinical Technology at the HPCSA.

# **Operators of C-arm units**

**5.3** The operator **MUST BE** a Radiographer or Radiologist.

#### 6. RADIATION WORKERS

#### 6.1 Dose limits for radiation workers and public

Application	Occupational	Public	
Effective dose	20 mSv per annum, not more than 100 mSv over a period of 5 years (not more than 50 mSv in any one year)	1 mSv per annum	
Annual equivalent dose to the			
lens of the eye	20 mSv	1 mSv	
skin	500 mSv	50 mSv	
hands and feet	500 mSv		

- 6.2 A radiation worker must be older than 18 years. However, if a radiation worker in training is younger than 18, but older than 16, such worker must work under direct supervision.
- 6.3 The holder of the licence must keep record of the following for a period of 10 years for each radiation worker:
  - (a) The monthly dose reports furnished by the monitoring service provider (SABS) and
  - (b) results of medical examinations.

# **Pregnant radiation workers**

- When pregnancy has been diagnosed the women shall not be allowed to work under working conditions where the maximum equivalent dose limit of 2 mSv to the women's abdomen (lower trunk) for the remainder of the pregnancy could be exceeded. Pregnant radiographers shall continue to be monitored in the prescribed manner. Taking into account the specific working conditions, pregnant radiographers must be issued with a direct reading pocket alarm dosimeter, and in so doing prevent that such women are unwittingly exposed to radiation.
  - The employer should provide continuous education as to the risks to the foetus and actual dose levels in the various working environments.
  - Radiation workers, especially young females, must always and not only when pregnant, be well versed in the uses of ionisation radiation.

(Refer to Guideline document on Radiation Control website – see Annexure A.2 in this Code)

#### 6.5 Appointment of radiation workers

**Note:** Licence holders are no longer required to submit form RC008 or inform Radiation Control of any change in the register as stipulated in Regulation III.4 (b) & (c).

#### 6.6 Medical examinations of radiation workers

- (a) Before any person is appointed / classified as a radiation worker, he/she must undergo a medical examination.
- (b) Medical examinations for radiation workers should follow general preemployment occupational medical practice for determining fitness for work.
- (c) In addition to the pre-employment medical examination a radiation worker may be required to undergo a medical examination in the event of the following:
  - When a radiation occurrence / incident resulting in an abnormally high dose is suspected to have taken place or has been confirmed;
  - When a medical practitioner deems it necessary;
  - When such an examination is considered necessary either by the regulatory authority or the holder of the licence and
  - When the radiation worker suspects that his/her health has been, or will be adversely affected by occupational factors.

Note: Annual medical examinations and those pertaining to de-registration are no longer required by DOH: Radiation Control but it remains the prerogative of the licence holder should he/she deems it necessary.

#### 6.7 Monitoring of radiation workers

- (a) The licence holder must ensure that all radiation workers, which include permanently allocated nursing staff involved with radiation procedures in the x-ray department, are issued with a personal radiation monitoring device (PRMD)
  - For correct positioning of the PRMD refer to guideline document on Radiation Control website see Annexure A.3 in this Code
- (b) Application forms for a PRMD can be obtained directly from the following current monitoring service provider:

SABS Holdings (Pty) Ltd
Radiation Protection Services
012-4286493 (22)
012-4286685 (fax)
rps@sabs.co.za

- (c) The service provider will forward the radiation dose records to the licence holder on a monthly basis or after a radiation occurrence. The dose records must be kept for 10 years.
- (d) The licence holder must ensure that the service provider replaces PRMD's at regular intervals not exceeding 32 days.

#### 6.8 Termination of employment as a radiation worker

(a) When a radiation worker ceases to be employed by the licence holder, the holder must provide that worker with a copy of his/her complete dose record. Such complete records can be obtained from the SABS on request.

**Note:** Licence holders are no longer required to inform Radiation Control of any change in the register as stipulated in Regulation III.4 (c).

#### 6.9 Appointment of radiation workers by a new employer

(a) The licence holder must obtain from the SABS the previous dose records of the newly appointed radiation worker.

#### 6.10 Radiation occurrences (Form RC010)

(a) Details of any radiation occurrence or suspected radiation occurrence must immediately be reported to the Director: Radiation Control on form RC010.

#### 7. RADIATION PROTECTION

#### Basic radiation protection principles are based on:

- The justification of the practice
   No radiation examination shall be adopted unless the benefit outweighs the associated risk.
- The optimisation of protection
   Radiation doses from medical exposures and those received by the public and occupationally exposed persons must be kept as low as reasonable achievable (ALARA), economic and social factors taken into account.
- Limitation of individual dose and risk

  All medical applications of ionising radiation must be managed in such a way that radiation doses to occupationally exposed person and members of the public do not exceed the specified dose limits (see par 6.1).

#### 7.1 Protection of patients

- (a) All medical exposures shall be subject to the principles of justification and optimisation.
- (b) X-ray examinations shall not be performed unless there are valid clinical indications.
- (c) Examinations on children shall require a higher justification since such patients may be more sensitive to radiation.
- (d) Obtain previous x-ray images to minimise the taking of repeat films.
- (e) CT Screening programmes of asymptomatic persons shall not be instituted unless approved by DOH. Screening programmes prescribed by other Governmental Acts are acceptable.
- (f) Licence holders shall be aware of the approximate patient radiation doses. Reference dose levels should be introduced for applications in diagnostic x-ray examinations as performed in their facilities.
  - Diagnostic reference levels (DRLs) refer to dose levels in medical diagnostic practices for typical x-ray examinations for groups of standard size patients or standard phantoms for broadly defined types of equipment. These levels are expected not be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.
  - The objective of a DRL is to help avoid unnecessary radiation dose to the patient that does not contribute to useful diagnostic information and does not produce the expected medical benefit to the patient.

• The specific purpose of the DRL is to provide a benchmark for comparison, not to define a maximum of minimum exposure limit.

(Refer to the Guideline document on Radiation Control website – see Annexure A.9 in this Code)

- (g) When appropriate, consider other modalities such as MRI or ultrasound which do not use ionising radiation.
- (h) Examinations with potential high patient doses such as CT examinations should only be carried out after a proper clinical justification by the radiologist.
- (i) For each projection select the highest kilovoltage (KV) and fastest film-screen combination compatible with the image quality requirements of the examination.
- (j) The primary beam shall be collimated at all times.
- (k) Means to permanently transfer patient identification, prior to processing of the images, must be provided.
- (I) Radiation examinations may only be requested by:
  - A medical practitioner or
  - Any appropriately trained and registered health professional.

(Refer to the Guideline document on Radiation Control website – see Annexure A.4 in this Code)

- (m) Pulsed fluoroscopy should be routinely used. During fluoroscopy, radiation time is minimised by pulsing the beam.
   At low-pulsed frequencies, major dose savings are made while ensuring diagnostic images.
- (n) A film screen speed of not less than 300 is recommended for general radiography.

#### 7.2 Protection of pregnant patients

- (a) X-ray examinations must be justified and only essential views performed.
- (b) Alternative imaging modalities, especially ultrasound for obstetric procedures, shall be used where appropriate. An x-ray examination shall not be performed to assess foetal development where ultrasound facilities are available.
- (c) X-ray pelvimetry shall not be performed on a routine basis.
- (d) For examinations where the primary beam unavoidably irradiates the foetus, the methods of minimising dose shall be used as appropriate and particular attention shall be given to:
  - Minimising the number of views;
  - Strict beam collimation:
  - Using higher kVp settings;

- Using fast image recording media;
- Where practicable, using PA projections in preference to AP projections.

#### 7.3 Protection of women of reproductive capacity

- (a) X-ray examinations involving the exposure of the abdomen of women likely to be pregnant shall be avoided unless there are strong clinical indications for the examination.
- (b) In order to minimise the possibility of unintentional exposure to the embryo / foetus, notices must be posted at several places within the radiology facility. The notices shall contain wording similar to or having the same meaning as the following:
  - "If you might be pregnant notify the radiographer before your x-ray examination."

#### 7.4 Protection of paediatric patients

The longer life expectancy of children results in greater potential for the manifestation of possible harmful effects of radiation.

In addition to the requirements in this Code for patients in general (see par 7.1), the following requirements for paediatric x-ray examinations shall be observed:

- (a) For a given procedure each view shall be examined, where practical, before deciding whether to take a further view;
- (b) Fluoroscopy shall be used only when general radiography will not provide the information required and
- (c) There shall be strong justification for x-ray procedures involving high doses such as CT (Refer to Guideline document on Radiation Control website see Annexure A.5 in this Code).

#### 7.5 Protection of non-radiation personnel and members of the public

- (a) Members of the public are not allowed to enter controlled areas unsupervised.
- (b) Non-radiation personnel or members of the public shall not remain in the x-ray room during any x-ray procedure unless they are required to be in attendance.
- (c) The occasional use of non-radiation personnel to give assistance, particularly in ward or theatre radiography, is acceptable but shall involve the full use of protective clothing, devices and techniques to minimise personnel dose. Care shall be taken to ensure that the same non-radiation personnel are not always involved. Women who are pregnant shall not be used in this role.

#### 7.6 Protection of persons holding patients or image receptors

(a) No person shall hold a patient, x-ray film cassette, or other imaging equipment or x-ray tube head in position during exposures unless it is otherwise impossible to obtain a diagnostically useful image and not merely that it is a matter of convenience.

- (b) Holding of patients or x-ray film cassettes during exposure shall be done by persons accompanying the patient in preference to non-radiation personnel; and by non-radiation personnel in preference to radiation workers. Non-radiation personnel should be chosen on the basis of a roster, i.e. it shall not be the same person who does the holding. No pregnant women or young persons (under the age of 18) shall do any holding.
- (c) Any persons holding patients or film cassettes in position during an x-ray examination shall wear a lead rubber apron and wherever practicable, lead rubber gloves. No part of the holder's body shall be in the primary beam, even if covered with protective clothing.

#### 7.7 Protective clothing

- (a) Any person who cannot remain in the protected area during x-ray examinations shall wear a protective apron of **at least 0,25mm** lead equivalence.
- (b) Any person standing within 1 metre of the x-ray tube or patient during fluoroscopy examinations shall wear eye protection (leaded glasses), thyroid protection and a protective apron of at least 0.35mm lead equivalent.
- (c) Protective gloves shall be at least 0.35mm lead equivalence.
- (d) Gonad shields shall be at least 0.5mm lead equivalence.

(Refer to the Guideline documents on Radiation Control website – see Annexure A.3, A.8 & A.10 in this Code)

#### 7.8 Record and Report Radiation Injuries

The licence holder shall ensure that all suspected radiation occurrences are immediately reported to the Director: Radiation Control. A "radiation occurrence" means a single event or series of events occurring in the course of the use of a listed electronic product which has resulted in injurious or potentially injurious exposure of any person to ionising radiation as a direct result of the use of that product. The licence holder must investigate the circumstances of the exposure, the possible effects on a person(s) concerned and decide on the action to be taken. The outcome of this investigation must be documented.

#### 8. PREMISES REQUIREMENTS

Refer to guideline document on Radiation Control website: General Guidelines with regard to the design of x-ray rooms (see Annexure A.6 in this Code)

# 9. RADIATION WARNING SIGNS, NOTICES AND LIGHTS AT ENTRANCES TO X-RAY ROOMS

- **9.1** Appropriate radiation warning signs and notices must be displayed and required warning lights in working order:
  - (a) Fixed units:

A radiation warning sign and warning notice, "X-RAYS - NO UNAUTHORISED ENTRY" must be displayed at all entrances leading to the rooms where x-ray units are installed.

#### (b) Mobile units:

A radiation warning sign and warning notice, "X-RAYS - NO UNAUTHORISED USE" must be displayed on the control panel of the x-ray units.

#### (c) Warning lights for CT & Fluoroscopy units (excluding theatres):

A red warning light, which is only activated when the beam is on and when fluoroscopy is in progress, must be mounted in a conspicuous place outside the entrance to the x-ray rooms.

(Refer to Guideline document on Radiation Control website – see Annexure A.7 in this Code)

#### 10. ANNEXURE A

Guideline documents available on Radiation Control website: https://sites.goggle.com/site/radiationcontroldoh/

- 1. Code: Diagnostic QC Requirements for licence holders with respect to Quality Control tests for diagnostic x-ray imaging systems.
- 2. Management of pregnant radiographers and other staff members.
- 3. Personal monitoring when a lead rubber apron is worn medical and veterinary use of x-ray equipment.
- 4. Request for medical examinations.
- 5. FDA Public Health Notification: Reducing radiation risk from computed tomography for paediatric and small adult patients 2 November 2001.
- 6. General guidelines with regard to the design of x-ray rooms.
- 7. Display and format of radiation warning signs at entrances to rooms containing x-ray units.
- 8. Guidelines Protective Clothing.
- 9. Patient dose measurements in Diagnostic Radiography.
- 10. Radiation Protection of personnel in theatre

# 11. CONTACT DETAILS

Offices	Postal address	Street address	Tel & Fax
Head Office	Private Bag X62	c/o Kort & Vrede Str	021-9486162 🕿
Bellville	Bellville	2 <sup>nd</sup> Floor	021-9461589
	7535	Louwville Place	
		Bellville	
		7530	
Regional Office	PO Box 977	Rooms NP28 - 47	012-3959121 🕿
Pretoria	Pretoria	Podium Level	012-3959122 🕿
	0001	North Tower	012-3959125
		Civitas Building	
		c/o Andries &	
		Struben Street	
		Pretoria	
		0002	
Regional Office	PO Box 4301	6 <sup>th</sup> Floor, Room 604	031-3072111 🕿
Durban	Durban	85 On Field Building	031-3076099
	4000	Field Street	
		Durban	
		4001	

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#### 12. REFERENCES

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   <a href="http://www.icrp.org">http://www.icrp.org</a>
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