DIN EN ISO 19238:2023-12 (E)

Radiological protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics - Dicentric assay (ISO 19238:2023)

Contents			Page	
Euro	opean fo	oreword	4	
Fore	eword		5	
Introduction				
1	Scop	e	8	
2	-	native references		
3	Terms and definitions			
4		eviated terms		
5		ntric assay		
6		•		
7	Responsibility of the requestor			
	7.1	onsibility of the service laboratory		
	7.2	Responsibility during service		
8	Confidentiality of personal information			
	8.1	Overview		
	8.2	Applications of the principle of confidentiality		
		8.2.1 Delegation of responsibilities within the laboratory		
		8.2.2 Requests for analysis		
		8.2.3 Transmission of confidential information		
		8.2.4 Anonymity of samples 8.2.5 Reporting of results		
		8.2.6 Storage		
		8.2.7 Data security plan		
9	Laboratory safety requirements			
	9.1	Overview		
	9.2	Microbiological safety requirements		
	9.3	Chemical safety		
	9.4	Optical safety requirements		
10		ple processing		
	10.1	Culturing		
	10.2	Scoring	17 17	
		10.2.2 Scoring techniques		
		10.2.3 Procedure for scoring first-division metaphases		
		10.2.4 Laboratory scoring expertise	18	
11	Calibration curves			
	11.1	Calibration source(s)		
	11.2	Establishment of calibration curve(s)	18	
12	Criteria for converting a measured aberration frequency into an estimate of			
		rbed dose	20	
	12.1 12.2	General Testing the distribution of aberrations per cell	20 20	
	14.4	TEACHTE CHE UIACHTUUCIUH VI AUCHTACIUHA DEL CEIL	4· U	

	12.3	Comparison with the background level: Characterisation of the minimum	24	
	12.4	detectable dose		
	12.4	Calculation of absorbed dose for whole-body exposures		
	12.5	Calculation of uncertainty on absorbed dose		
	12.7	Acute and non-acute exposure cases		
	12.8	Partial body and prior exposure cases		
	12.9	Other exposure scenarios		
13	Repo	rting of results		
	13.1	General		
	13.2	Content of the report (see Annex C for a standard form)		
	13.3	Interpretation of the results		
14	Quali	ty assurance and quality control		
	14.1	Overview		
	14.2	Specific requirements		
		14.2.1 General		
		14.2.2 Performance checks by laboratory inter-comparisons		
		14.2.3 Periodical performance check of scorer qualification	29	
		14.2.4 Performance checks of sample transport integrity	29	
		14.2.5 Performance checks of sample integrity by service laboratory		
		14.2.7 Performance checks of sample protocol		
		14.2.8 Performance checks of sample scoring		
		14.2.9 Performance checks of dose and confidence limits estimation		
		14.2.10 Performance checks for result report generation		
Anne	x A (inf	ormative) Sample instructions for requestor		
	-	formative) Sample questionnaire		
		ormative) Sample of report	35	
Anne		nformative) Fitting of the low-LET dose-response curve by the method of mum likelihood and calculating the error of dose estimate	37	
Anne	x E (inf	ormative) Odds ratio method for cases of suspected exposure to a low dose	40	
Anne	x F (inf	ormative) Decision threshold and detection limit	42	
Anne	x G (inf	ormative) Sample data sheet for recording aberrations	45	
Biblio	Bibliography			