

ISO 14470:2011-12 (E)

Food irradiation - Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Controlling the food irradiation process	6
4.1	Responsibility and authority	6
4.2	Product realization	6
4.3	Monitoring, measurement and analysis	6
4.4	Technical agreement	6
4.5	Documentation	7
5	Irradiation facilities	7
5.1	Design	7
5.2	Radiation sources	7
5.3	Equipment	7
5.4	Personnel	8
6	Product	8
6.1	Product definition	8
6.2	Product specification	9
7	Process	9
7.1	Process definition -- Dose range	9
7.2	Process specification	9
8	Dosimetry	10
9	Validation	10
9.1	Installation qualification (IQ)	10
9.2	Operational qualification (OQ)	10
9.3	Performance qualification (PQ)	11
9.4	Review and approval of validation	13
10	Routine monitoring and control	13
10.1	Process parameters	13
10.2	Product-loading configuration	14
10.3	Routine dosimetry	14
10.4	Processing inventory control	14
10.5	Labelling	14
10.6	Process interruptions	15
10.7	Irradiation process records	15
11	Product release from irradiation process	15
12	Maintaining process effectiveness	15

12.1	Demonstration of continued effectiveness	15
12.2	Equipment calibration	15
12.3	Recalibration	16
12.4	Maintenance of equipment	16
12.5	Requalification of the irradiation process	16
12.6	Assessment of change	16
Annex A (informative) Guidelines		17
Bibliography		19