### STATUTORY INSTRUMENTS

# 2021 No. 792

# The Space Industry Regulations 2021

# PART 9

Cosmic radiation requirements: crew of a launch vehicle and crew of a carrier aircraft CHAPTER 1

# Interpretation

### Interpretation

**134.**—(1) In this Part—

"approved doctor" means a registered medical practitioner who—

- (a) is an appointed doctor for the purposes of the Ionising Radiation Regulations 2017(1) (see regulation 2 of those Regulations),
- (b) has completed a course of training in providing medical surveillance for crew who have been exposed to ionising radiation, and
- (c) has been approved by the regulator for the purposes of carrying out a medical assessment or a health review for the purposes of this Part;

"approved medical assessor" means an individual employed by the regulator who—

- (a) is qualified and holds a valid licence to practise medicine from the General Medical Council,
- (b) has qualifications in aviation or space medicine, and
- (c) has been authorised by the regulator for the purposes of regulations 73(5) and 74(5);
- "carrier aircraft cabin crew" means those individuals carried in a carrier aircraft for the purpose of performing duties in the interests of safety of the passengers but who do not act as members of the carrier aircraft flight crew;
- "carrier aircraft flight crew" means individuals working on a carrier aircraft who undertake to act as pilot, flight navigator, flight engineer or flight radiotelephony operator of the aircraft;
- "carrier aircraft task specialist" means an individual who performs specialised tasks on board the carrier aircraft;
- "classified crew member" has the meaning given in regulation 143(1);
- "crew" means-
- (a) in relation to a carrier aircraft, individuals carried in the aircraft who are—
  - (i) members of the carrier aircraft flight crew,
  - (ii) members of the carrier aircraft cabin crew, or
  - (iii) carrier aircraft task specialists, and

- (b) in relation to a launch vehicle, individuals carried in the launch vehicle who are—
  - (i) members of the flight crew, or
  - (ii) members of the cabin crew, and

"the Directive" means Council Directive 2013/59/Euratom(2) as it was on IP completion day(3), laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation;

"effective dose" has the meaning given in Article 4(25) of the Directive;

"health review" has the meaning given in regulation 144;

"launch vehicle task specialist" means a spaceflight participant who performs specialised tasks on board the launch vehicle;

"mSv" means one thousandth of a sievert;

- "overexposure" means in relation to a crew member performing duties for a spaceflight operator—
- (a) in relation to a classified crew member, that the crew member has received an effective dose of cosmic radiation that exceeds 20 mSv in a calendar year;
- (b) in relation to any other crew member, that the crew member has received an effective dose of cosmic radiation that exceeds 6 mSv in a calendar year.
- (2) For the purposes of this Part a launch vehicle task specialist is treated as a crew member.
- (3) References in this Part to a crew member in relation to a spaceflight operator are to a crew member of a carrier aircraft or launch vehicle which takes part in the operator's spaceflight activities.
- (4) References in this Part to cosmic radiation do not include cosmic radiation prevailing at ground level.

## **CHAPTER 2**

# Generally applicable provisions

# Authorisation and prohibition on exposure

- 135.—(1) No spaceflight operator may employ or otherwise engage an individual to perform duties as a crew member on a launch vehicle or carrier aircraft that would render the individual liable to receive an effective dose of cosmic radiation that exceeds 6 mSv in a calendar year unless the individual is a classified crew member (see regulation 142).
- (2) No spaceflight operator may employ or otherwise engage an individual to perform duties as a classified crew member on a launch vehicle or carrier aircraft that would render the individual liable to receive an effective dose of cosmic radiation that exceeds 20 mSv in a calendar year (see regulation 142).

### Risk of exposure of crew members to cosmic radiation

**136.**—(1) Subject to paragraph (2), a spaceflight operator must ensure that a suitable and sufficient assessment of the magnitude of the risk to crew members from exposure to cosmic radiation in the course of performing their duties on board a launch vehicle or a carrier aircraft (an "exposure assessment") is conducted before carrying out the operator's spaceflight activities.

<sup>&</sup>quot;crew member" is to be read accordingly;

<sup>(2)</sup> O.J. No. L 13/1, 17.1.2014, p.1.

<sup>(3)</sup> Schedule 1 to the Interpretation Act 1978 (c. 30) provides that "IP completion day" has the same meaning as in the European Union (Withdrawal Agreement) Act 2020 (c. 1) (see section 39(1) to (5) of that Act).

- (2) Where a spaceflight operator has completed an exposure assessment (the "previous exposure assessment") in relation to the operator's spaceflight activities involving the launch vehicle or carrier aircraft, no further exposure assessment needs to be conducted in relation to those activities, but a further assessment must be conducted if—
  - (a) the spaceflight operator has reason to suspect that the previous exposure assessment is no longer valid,
  - (b) there has been a material change to the matters to which the previous exposure assessment relates, or
  - (c) the spaceflight operator has reasonable cause to believe that a crew member has received an overexposure while performing duties for the spaceflight operator on board the launch vehicle or the carrier aircraft.
- (3) The spaceflight operator must take into account the results of the most recent exposure assessments it has conducted in relation to the operator's spaceflight activities when managing the operation of the launch vehicle or carrier aircraft, with a view to minimising as far as reasonably possible the exposure of crew members to cosmic radiation.
- (4) In carrying out an exposure assessment the spaceflight operator must take into account any existing legal requirements relating to safety.

### Requirements to assess and inform

- 137.—(1) A spaceflight operator must—
  - (a) take appropriate measures to assess the exposure to cosmic radiation of each crew member,
  - (b) take into account the assessed exposure when organising working schedules, with a view to reducing the doses of highly exposed crew, and
  - (c) inform each crew member of their dose as assessed under sub-paragraph (a).
- (2) "Assess" and "highly exposed" have the same meaning as in Article 35 of the Directive.

# Protection of pregnant crew

- 138.—(1) A spaceflight operator must inform all crew members of the importance of giving early notification of pregnancy to the spaceflight operator in view of the risks of exposure to the unborn child.
- (2) If the suspension of a pregnant crew member's medical certificate is lifted in accordance with regulation 76(5)(a), a spaceflight operator must ensure that—
  - (a) the conditions of exposure to cosmic radiation for the crew member in the context of her duties are such that the equivalent dose to the unborn child is as low as reasonably achievable, and
  - (b) it is unlikely that that dose will exceed 1 mSv during the remainder of the pregnancy.
  - (3) In this regulation, "equivalent dose" has the meaning given in Article 4(33) of the Directive.

### Monitoring of exposure to cosmic radiation: crew other than classified crew

- 139.—(1) A spaceflight operator must ensure that the exposure to cosmic radiation of crew members who are not classified crew members is monitored to such an extent as is sufficient to identify any crew members who should be classified under regulation 143.
- (2) Monitoring of the crew of a carrier aircraft or a launch vehicle under this regulation may be undertaken by proper use of any of the following computer programs, which calculate the effective dose of cosmic radiation received by an individual on board a carrier aircraft or a launch vehicle, or of a computer program that performs an equivalent function—

- (a) CARI-7;
- (b) EPCARD;
- (c) SIEVERT PN;
- (d) PCAire.
- (3) In this regulation—
  - (a) "CARI-7" means the computer programme of the same name, developed by the Federal Aviation Administration's Civil Aerospace Medical Institute;
  - (b) "EPCARD" means the European Program Package for the Calculation of Aviation Route Doses, developed by the Institute of Radiation Protection at Helmholtz Zentrum Munich, German Research Centre for Environmental Health;
  - (c) "SIEVERT PN" means the computer programme of the same name, developed by the Institut De Radioprotection et de Surete Nucleaire;
  - (d) "PCAire" means the computer programme of the same name, developed by PCAire Inc.

### Provision of information and training to crew

- **140.**—(1) A spaceflight operator must ensure that each crew member is given appropriate information and training about—
  - (a) the health risks arising from exposure to cosmic radiation while performing the crew member's duties on board the carrier aircraft or the launch vehicle,
  - (b) the spaceflight operator's procedures for conducting an exposure assessment mentioned in regulation 136(1), and
  - (c) the spaceflight operator's procedures for assessing and monitoring crew exposure to cosmic radiation.
- (2) The spaceflight operator must ensure that training under paragraph (1) is given before the crew member performs any duties on board the carrier aircraft or launch vehicle.

# Overexposure

- **141.**—(1) Where a spaceflight operator has reasonable cause to believe that a crew member has received an overexposure while performing duties for that operator on board a launch vehicle or a carrier aircraft, the spaceflight operator must immediately conduct an investigation in order to conclude beyond reasonable doubt that no overexposure has occurred (a "negative conclusion").
- (2) If the spaceflight operator is not able to reach a negative conclusion within fourteen days beginning with the date on which the investigation commenced (the "fourteen day period"), an overexposure is deemed to have occurred and the spaceflight operator must—
  - (a) immediately—
    - (i) notify the regulator of the overexposure,
    - (ii) where the crew member is a classified crew member, notify the approved doctor who undertook the crew member's most recent medical examination or health review of the overexposure, and
    - (iii) take appropriate steps to notify the crew member affected of the overexposure,
  - (b) where requested by the crew member, immediately arrange for an approved doctor to undertake a medical examination of the crew member in relation to the overexposure, and
  - (c) as soon as is reasonably practicable after the fourteen day period, conduct such investigation as is necessary to determine—

- (i) the dose of cosmic radiation received by the crew member, so far as is reasonably practicable, and
- (ii) the necessary measures, if any, to be taken to prevent a recurrence of the overexposure.
- (3) Where an investigation is conducted under paragraph (2)(c), the spaceflight operator must immediately upon the conclusion of the investigation—
  - (a) notify the regulator, and
  - (b) take appropriate steps to notify the crew member affected,

of the results of the investigation and any determination as to the necessary measures to be taken to prevent a recurrence of the overexposure.

- (4) A spaceflight operator who determines that there are measures necessary to be taken to prevent a recurrence of the overexposure must implement those measures as soon as practicable after such a determination is reached.
- (5) A spaceflight operator who conducts an investigation pursuant to paragraph (1) must ensure that a report of the investigation is retained until the second anniversary of the date on which the investigation was commenced.
- (6) A spaceflight operator who conducts an investigation pursuant to paragraph (2)(c) must ensure that a report of the investigation is retained until the later of—
  - (a) the 75th anniversary of the birth of the crew member affected, whether or not the crew member survives until that date, and
  - (b) the 30th anniversary of the date on which the investigation was commenced.

# Continued working of overexposed crew

- **142.**—(1) No spaceflight operator may employ or engage a crew member who has received an overexposure to perform duties on board a launch vehicle or a carrier aircraft that would render the crew member liable to receive an effective dose of cosmic radiation that exceeds X mSv for the remainder of the calendar year.
  - (2) In paragraph (1), "X" is the lower of—
    - (a) the dose limit applicable to the crew member divided by 365 and multiplied by the number of days in the remainder of the calendar year, and
    - (b) the dose limit applicable to the crew member minus the effective dose of radiation received by the crew member for the calendar year to the date on which the crew member received the overexposure, excluding the dose resulting in the overexposure.
- (3) A spaceflight operator employing or engaging a crew member who has received an overexposure to perform duties on board a launch vehicle or a carrier aircraft must inform the crew member of the dose limit applicable to the crew member.
- (4) Where an overexposure received by a crew member was caused by exceptional circumstances beyond the control of the spaceflight operator, the dose resulting in the overexposure is not to be included in any assessment of the crew member's effective dose for the purposes of regulation 135.
  - (5) In this regulation—
    - (a) the "dose limit applicable to the crew member" is
      - (i) for classified crew members, 20 mSv;
      - (ii) for all other crew members, 6 mSv;
    - (b) the "remainder of the calendar year" begins with the day after the date on which the crew member received the overexposure and ends with the last day of the calendar year.

### **CHAPTER 3**

## Provisions relating to classified crew

#### Classification of crew

- **143.**—(1) Subject to paragraph (2), a spaceflight operator may classify a crew member for the purpose of regulation 135(1) and (2) and a crew member classified under this regulation is referred to in this Part as a "classified crew member".
  - (2) A spaceflight operator must not classify a crew member unless—
    - (a) at the crew member's most recent medical examination or health review, under regulation 144, an approved doctor determined that the crew member is—
      - (i) fit to work as a classified crew member, or
      - (ii) fit, subject to certain conditions, to work as a classified crew member, and
    - (b) in a case within sub-paragraph (a)(ii), the conditions are complied with.
- (3) A spaceflight operator must, as soon as is practicable following a crew member's most recent medical examination or health review under regulation 144, review the suitability of the crew member for the crew member's classification, having regard to the results of—
  - (a) any monitoring under regulation 139 or 146 undertaken in relation to the crew member since the beginning of the year in which the medical examination or health review takes place,
  - (b) the crew member's most recent medical examination or health review under regulation 144, and
  - (c) any other medical examination the crew member has been subject to since the date of the crew member's most recent medical examination or health review under regulation 144.
  - (4) A spaceflight operator must cease to classify a crew member as a classified crew member if—
    - (a) at the crew member's most recent medical examination or health review, in accordance with regulation 144, an approved doctor determines that the crew member is—
      - (i) unfit to work as a classified crew member, or
      - (ii) fit, subject to certain conditions, to work as a classified crew member, and
    - (b) in a case within sub-paragraph (a)(ii), the conditions are not complied with.

#### Medical surveillance

- **144.**—(1) A spaceflight operator must ensure that—
  - (a) before classifying a crew member as a classified crew member, the crew member undergoes a medical examination by an approved doctor to determine the crew member's fitness to perform duties as a classified crew member, and
  - (b) each classified crew member has at least one review of their health ("health review") by an approved doctor once in every 12 months to determine whether the crew member remains fit to perform their duties.
- (2) For the purposes of paragraph (1), every crew member must submit to such a medical examination or health review when required by the spaceflight operator to do so.
- (3) A spaceflight operator must ensure that the approved doctor who performs an examination or health review in accordance with paragraph (1)—
  - (a) determines that the crew member is—
    - (i) fit to work as a classified crew member,

- (ii) fit, subject to certain conditions, to work as a classified crew member, or
- (iii) unfit to work as a classified crew member, and
- (b) in a case within sub-paragraph (a)(ii), specifies the conditions concerned.
- (4) A spaceflight operator must, as soon as reasonably practicable, notify the crew member concerned of—
  - (a) the determination made by the approved doctor of the crew member's fitness under paragraph (3)(a), and
  - (b) any conditions the approved doctor has specified in relation to the crew member under paragraph (3)(b).
- (5) A spaceflight operator must allow an approved doctor access to any information the approved doctor may reasonably require in relation to the approved doctor's functions under this regulation.

#### Health records

- **145.**—(1) A spaceflight operator must ensure that a health record is created in respect of each classified crew member.
  - (2) A "health record" is a written document containing the information specified in Schedule 6.
  - (3) A spaceflight operator must ensure that each health record is—
    - (a) maintained while the crew member to whom it relates is classified by the spaceflight operator as a classified crew member, and
    - (b) retained until the later of—
      - (i) the 75th anniversary of the birth of the crew member, whether or not the crew member survives until that date, and
      - (ii) the 30th anniversary of the date on which the crew member was last exposed to cosmic radiation in the course of performing duties for the spaceflight operator on board a carrier aircraft or launch vehicle.
  - (4) A crew member may request a copy of their health record.
- (5) An approved doctor may request a copy of the health record in respect of a crew member whom the approved doctor has examined, is due to examine, or whose health the approved doctor has reviewed, or is due to review, in accordance with regulation 144(1) in connection with the performance of the approved doctor's functions under that regulation.
- (6) A spaceflight operator must, within a reasonable time of receiving a request under paragraph (4) or (5), ensure that a copy of the health record is produced to the crew member or approved doctor.
- (7) The spaceflight operator must take measures to ensure that a health record is protected as confidential information, and not disclosed otherwise than in accordance with this regulation or to an approved medical assessor for the purposes of that assessor performing duties as a medical assessor.

# Monitoring of exposure to cosmic radiation: classified crew

- **146.**—(1) A spaceflight operator must ensure that the exposure to cosmic radiation of each classified crew member is individually monitored.
- (2) Monitoring of the crew of a carrier aircraft or a launch vehicle under this regulation may be undertaken by proper use of any of the following computer programs, which calculate the effective dose of cosmic radiation received by an individual on board a carrier aircraft or a launch vehicle, or of a computer program that performs an equivalent function—
  - (a) CARI-7;

- (b) EPCARD;
- (c) SIEVERT PN;
- (d) PCAire.
- (3) In this regulation, "CARI-7", "EPCARD", "SIEVERT PN" and "PCAire" have the same meaning as in regulation 139.

# Records of exposure to cosmic radiation of classified crew

- **147.**—(1) A spaceflight operator must maintain a record of all monitoring undertaken under regulation 146.
  - (2) A record under paragraph (1) is a written document containing—
    - (a) the crew member's—
      - (i) name,
      - (ii) date of birth,
      - (iii) gender, and
      - (iv) nationality,
    - (b) the name and address of the crew member's employer, where it is not the spaceflight operator, and
    - (c) the start date of the period to which the monitoring relates and, where possible, the end date.
  - (3) An operator must ensure that a record under paragraph (1) is retained until the later of—
    - (a) the 75th anniversary of the birth of the crew member to whom the record relates, whether or not the crew member survives until that date, and
    - (b) the 30th anniversary of the date on which the crew member was last exposed to cosmic radiation in the course of performing duties for the spaceflight operator on board a launch vehicle or a carrier aircraft.
- (4) On or before 31st March of each calendar year the spaceflight operator must submit to the regulator a copy of all records under paragraph (1) relating to the previous calendar year.

# Access to records of individual exposure to cosmic radiation

- **148.**—(1) An interested person may request that a spaceflight operator cause to be produced to the interested person a copy of the record required to be maintained under regulation 147 in relation to a crew member specified in that request.
  - (2) "Interested person" means—
    - (a) the crew member to whom the record relates,
    - (b) another spaceflight operator ("O"), or a person other than O employing or otherwise engaging the crew member to perform duties for O on board a launch vehicle or a carrier aircraft, where the request is made for the purpose of complying with O's requirements in relation to the crew member under this Part,
    - (c) any approved doctor who makes the request—
      - (i) in relation to an examination or health review the approved doctor is due to perform, or has performed, in accordance with regulation 144 of the crew member to whom the record relates, and
      - (ii) in connection with making a determination as mentioned in paragraph (3) of that regulation.

- (3) The spaceflight operator must, within a reasonable time of receiving a request under paragraph (1), cause a copy of the record to be produced to the person who requested it.
- (4) The spaceflight operator must take measures to ensure that all records referred to in paragraph (1) are protected as confidential information, and not disclosed otherwise than in accordance with this regulation or to an approved medical assessor for the purposes of that assessor performing duties as a medical assessor.

### **CHAPTER 4**

# Instruction of experts

### **Instruction of experts**

- **149.**—(1) A spaceflight operator must instruct a suitably qualified person to review the processes implemented by the spaceflight operator to comply with the regulations in this Part.
- (2) The spaceflight operator must ensure that the review referred to in paragraph (1) is completed within a reasonable period of the spaceflight operator commencing the operator's spaceflight activities which involve employing or engaging a crew member to perform duties on board a launch vehicle or a carrier aircraft.
- (3) A spaceflight operator must pay due regard to the results of any review undertaken under paragraph (1).
- (4) A spaceflight operator must provide the person instructed under paragraph (1) with any information and facilities that the person reasonably requests for the purpose of performing their review.
- (5) The spaceflight operator must take measures to ensure that any information provided under paragraph (4) is protected as confidential information and not disclosed otherwise than in accordance with this regulation or to an approved medical assessor for the purposes of that assessor performing duties as a medical assessor.

# **CHAPTER 5**

Consequential amendments to Air Navigation Order

#### **Consequential amendments**

**150.** In consequence of the provisions of this Part, the amendments to the Air Navigation (Cosmic Radiation: Protection of Air Crew and Space Crew and Consequential Amendments) Order 2019(4) in Schedule 7 have effect.