Note: This translation is for reference purposes only. Should any discrepancies arise between the English and Japanese versions, the Japanese version is the authoritative version, thus the Japanese version will be deemed valid.

Nara Institute of Science and Technology X-ray Hazards Prevention Regulations

April 1, 2004 Regulations No. 40

Article 1 (Purpose)

These Regulations specify the requirements for prevention of x-ray hazards due to the use or other handling of x-ray equipment at the Nara Institute of Science and Technology (hereinafter referred to as "NAIST"), in addition to the requirements specified by the Industrial Safety and Health Act (Act No. 57, 1972) and other applicable laws and regulations, and the Nara Institute of Science and Technology Safety and Health Management Regulations (Regulations No. 1, 2004).

Article 2 (Definitions)

As used in these Regulations, the terms below shall be defined as follows:

- (1) "X-ray" refers to an x-ray with energy of less than 1 mega-electron volt
- (2) "X-ray equipment" refers to mean x-ray generators and devices that generate x-rays
- (3) "X-ray work" refers to experiments conducted using x-ray equipment

Article 3 (Scope of application)

These Regulations apply to all persons including employees and students (hereinafter referred to as "Employees, et al.") who use x-ray equipment.

Article 4 (Designation of controlled area)

- The President must designate a controlled area where the effective dose from x-rays may exceed 1.3 millisieverts (mSv) / 3-month period and identify the area by a visible sign; provided, however, that an area shielded so that the effective dose does not exceed 1.3 mSv / 3-month period and equipped with x-ray equipment including a controlled area shall also be identified by a visible sign.
- 2. The President shall not allow any persons other than Employees, et al., who are required to do so, to enter the controlled area.
- 3. The President must post requirements for of x-ray worker health impairment prevention, such as wearing a radiation meter, precautions for handling radioactive substances, and emergency measures in case of accident, in a visible location in the controlled area.

Article 5 (Measurement of dose in the controlled area)

1. The President must measure the 1-centimeter dose equivalent rate or 1-centimeter dose equivalent inside and outside the controlled area at least once at intervals less than six months.

2. Measurement under the preceding paragraph shall be made with a radiation meter; provided, however, that if radiation meter measurement is extremely difficult, such values may be obtained by calculation

Article 6 (Labeling)

The President must label x-ray equipment stating the rated output, model, manufacturer's name and date of manufacture.

Article 7 (Prohibition of access)

- 1. When industrial or other x-ray equipment is used in a location other than the x-ray equipment room, the President shall not allow Employees, et al., to access areas (excluding areas where the effective dose from external radiation is not more than 1 mSv per week) located within 5 meters from the focus of the x-ray tube or irradiated body.
- 2. The President must identify the prohibited areas for Employees, et al., by a visible sign.

Article 8 (X-ray equipment room)

- 1. When x-ray equipment is installed, the President must provide a dedicated room (hereinafter referred to as the "X-ray Equipment Room"), in which the relevant x-ray equipment shall be installed; provided, however, that this provision shall not apply when the x-ray equipment to be installed is constructed with a shield so that the 1-centimeter dose equivalent rate does not exceed 20 microsieverts per hour outside the shield, or x-ray equipment needs to be constantly moved while in use, or otherwise the installation of x-ray equipment in the X-ray Equipment Room significantly interferes with the intended use or is difficult because of the nature of use.
- 2. If x-ray equipment is used in a location other than the X-ray Equipment Room under the provision of the preceding paragraph, the President shall not allow Employees, et al., to access areas (excluding areas where the effective dose from external radiation is less than 1 mSv per week) located within 5 meters from the focus of the x-ray tube, radiation source, or irradiated body.
- 3. The President must put a sign displaying the following information at the entrance of the X-ray Equipment Room according to the provisions of the preceding paragraphs.
- (1) Designation as a X-ray Equipment Room, and
- (2) Type of x-ray equipment installed in the X-ray Equipment Room.
- 4. The President shall not allow any persons other than Employees, et al., who are required to do so, to enter the X-ray Equipment Room.

Article 9 (Warning system, etc.)

The President must take measures to warn all x-ray workers and other concerned parties if any of the events described below occur; provided, however, that x-ray equipment except those with tube voltages of 150 kV or less must be equipped with an automated warning system.

- (1) Power is supplied to x-ray equipment, or
- (2) Power is supplied to apparatus for degassing or inspecting an x-ray tube or kenotron involving the generation of x-rays.

Article 10 (X-ray Operations Chief and work manager)

- 1. The President must appoint an x-ray operations chief (hereinafter referred to as the "Operations Chief") for each controlled area specified in Article 4.1 hereof, from among Employees, et al., who use x-ray equipment in the relevant controlled area and have an x-ray operations chief license.
- 2. The President must appoint an x-ray work manager (hereinafter referred to as the "Work Manager") for each piece of x-ray equipment other than those described in the preceding paragraph, from among Employees, et al., who use the relevant x-ray equipment.

Article 11 (Duties of the Operations Chief and the Work Manager)

The Operations Chief and the Work Manager shall perform the following duties relating to the relevant controlled area and the relevant x-ray equipment:

- (1) Checking on the proper implementation of protective measures specified by the Ordinance on Prevention of Ionizing Radiation Hazards (Ministerial Ordinance No. 41, 1972, Ministry of Labour),
- (2) Checking on the proper sign and label installation as provided for in Article 4.1, 6, 7.2, 8.3, and 19.1 hereof, and proper posting of information necessary for x-ray hazard prevention as provided for in Article 4.3 hereof,
- (3) Checking access to areas specified in Article 8.2 hereof by any Employees, et al., before starting and during irradiation, and
- (4) In addition to the duties listed in the preceding two paragraphs, controlling irradiation conditions, etc., to minimize the dose to Employees, et al., from x-ray exposure.

Article 12 (Measurement of personal radiation exposure dose)

- 1. The President must instruct Employees, et al., to wear a radiation meter appropriately and measure personal radiation exposure dose, when having Employees, et al., engage in x-ray work in controlled areas for the first time after controlled area designation, or at intervals up to one month (or six months, if x-ray equipment is used in a fixed location in the controlled area), in accordance with the items below; provided however, that if measurement with a radiation meter is extremely difficult, such values shall be obtained by calculation.
- (1) External radiation exposure doses shall be measured.
- (2) The measurement shall be made to determine the 1-centimeter dose equivalent and the 70-micrometer dose equivalent on the chest (or on the abdomen for women (excluding those who have no possibility of pregnancy).
- (3) With regard to head and neck, chest and upper arms, and abdomen and thighs measurement, if any parts other than the chest and upper arms (or the abdomen and thighs for women [excluding those not able to be pregnant]) may be subjected to the highest radiation exposure, the measurement shall also be made for such part.
- (4) If any parts other than the head and neck, chest and upper arms, and abdomen and thighs may be subjected to the highest radiation exposure, the measurement shall also be made for such part that may be subjected to the highest radiation exposure.
- (5) Measurement shall be conducted for the duration of stay of Employees, et al., in the controlled

area; provided, however, that such measurement may be omitted for those who temporarily enter the controlled area, if the President considers that the external radiation exposure effective dose for such persons is unlikely to exceed 100 microsieverts.

- (6) The personal radiation exposure dose measurement results shall be compiled and recorded for respective 3-month periods starting April 1, July 1, October 1, and January 1, for each year starting from April 1, and for each month on the 1st day of every month for women from pregnancy diagnosis until delivery (hereinafter referred to as "During Pregnancy") and for women (excluding those not able to be pregnant), whose effective dose may exceed 1.7 mSv per month.
- (7) The effective dose and equivalent dose shall be calculated from measurement results in the preceding item and recorded for respective three-month periods starting April 1, July 1, October 1, and January 1 for each year starting from April 1, and the relevant periods for each month starting the first day of every month for women During Pregnancy and women (excluding those not able to be pregnant), whose effective dose may exceed 1.7 mSv per month; provided, however, that as a result of effective dose calculation, if the effective dose exceeds 20 mSv for a one-year period starting April 1, the cumulative effective dose for the five-year period, including the relevant one-year period, divided by five years starting from April 1, 2001, shall be annually calculated and recorded for the relevant five-year period after the relevant one-year period.
- (8) When work is performed, where the 1-centimeter dose equivalent for external radiation exposure dose may exceed 1 mSv per day, Employees, et al. shall wear radiation meters to measure daily external radiation exposure dose, and measure and check the daily measurement results.
- 2. The President must, when records are made under items (6) and (7) above, promptly inform the relevant Employee of the effective dose and equivalent dose for the relevant period.

Article 13 (Registration of workers)

- 1. Employees, et al., involved in x-ray work at NAIST must apply in advance to the President for registration.
- 2. Those who apply for registration under Paragraph 1 hereof must receive education under Article 16 hereof and undergo medical examinations under Article 17 hereof.
- 3. The President shall register only those applicants under Paragraph 1 hereof, whose results of the medical examinations are evaluated to be satisfactory.
- 4. Registration under the preceding paragraph shall be made annually, and may be renewed.

Article 14 (Periodic inspections and record keeping)

The President must, at intervals not exceeding one year, conduct periodic inspections of x-ray equipment, and keep records of the results for three years.

Article 15 (Notification of x-ray equipment)

The President must, upon installation, change, or removal of x-ray equipment, promptly notify the Chief of the competent Labor Standards Office of information on the relevant x-ray equipment, in accordance with the provisions of applicable laws and regulations.

Article 16 (Implementation of Education)

The President must provide prior education for items listed below to prevent x-ray hazards, when having Employees, et al., engage in x-ray work; provided, however, that such education for the relevant items may be omitted for Employees, et al., considered to have sufficient knowledge or skills.

- (1) X-ray equipment planning and handling methods,
- (2) X-ray effects on the human body, and
- (3) Applicable laws and regulations.

Article 17 (Medical examinations)

- 1. The President must conduct periodic x-ray worker medical examinations as follows:
- (1) When having new workers engage in x-ray work,
- (2) At intervals not exceeding six months after being engaged in x-ray work.
- 2. Medical examinations under the preceding paragraph shall include the following test items:
- (1) Examination and evaluation on whether workers have a radiation exposure history (if workers have a radiation exposure history, their workplace, work description and duration, the presence of radiation hazards, the presence of subjective symptoms, and other radiation exposure situations,
- (2) Tests for white blood cell count and differential white blood cell count in peripheral blood,
- (3) Tests for red blood cell count and Hemoglobin contents or hematocrit values in peripheral blood,
- (4) Eye examinations for cataracts, and
- (5) Skin examination.
- 3. When medical examinations under Article 17.1(1) are conducted, examinations under item (4) above may be omitted.
- 4. Medical examinations under Paragraph 1, item (2) hereof shall be conducted as follows:
- (1) The items for examinations under Article 17.2(2) through (5) shall not be required for workers, whose effective dose in the previous year is less than 5 mSv and the effective dose in the current year is unlikely to exceed 5 mSv, unless a doctor considers it necessary.
- (2) For workers other than those under the preceding paragraph, all or part of the examination items under Article 17.2(2) through (5) may be omitted, when a doctor considers it unnecessary.
- 5. The President must prepare individual ionizing radiation medical examination cards based on the results of medical examinations under Article 17.1 and keep them for 30 years. The President must also, without delay, prepare and submit a report on the ionizing radiation medical examination results to the Chief of the competent Labor Standards Office.

Article 18 (Measures for those who are subjected to x-ray hazards)

If x-ray workers or persons who enter the controlled area are or may be subjected to x-ray hazards, the President must take the necessary precautions to maintain their health, such as shortening time in the controlled area, prohibiting access, and work content changes until such hazards and the doubt or possibility thereof are completely eliminated, medical diagnosis and provision of necessary health guidance without delay.

Article 19 (Emergency evacuation and prohibition of access)

- 1. The President must immediately evacuate Employees, et al., from an area significantly exposed, or likely to be exposed, to x-rays, if any of the events described below occur. In such a case, the President must immediately identify the area by a visible sign.
- (1) Damage to a shielding wall provided to shield external x-ray radiation, a protective screen, or other shielding item in the X-ray Equipment Room during x-ray irradiation that cannot easily be stopped immediately, or
- (2) In addition to the event described in the preceding paragraph, any other unforeseen event that may cause significant x-ray exposure.
- 2. The President shall not allow any Employees, et al., other than those Employees, et al., who are engaged in emergency work, to enter the area described in the preceding paragraph.
- 3. In the case described in the preceding paragraph, the dose received during emergency work must be specified as follows: the effective dose shall not exceed 100 mSv; the equivalent dose received by eye lens shall not exceed 300 mSv; and the equivalent dose received by skin shall not exceed 1 sievert.

Article 20 (Report of emergency, etc.)

The President must promptly report to the Minister of Education, Culture, Sports, Science and Technology and the Chief of the competent Labor Standards Office, if any of the following occurs:

- (1) Radiation exposure of Employees, et al., exceeding the limit of the effective dose or the equivalent dose specified in the schedule, or
- (2) Any of the events described in items of Paragraph 1 of the preceding article.

Article 21 (Medical care)

The President must promptly provide medical care or treatment by a doctor for any of the persons listed in the following items:

- Persons who are in the relevant area, when damage occurs to a shielding item during handling x-ray equipment or during x-ray irradiation that cannot easily be stopped immediately, or
- (2) Any of the persons described in Paragraph 1, item (1), of the preceding article.

Article 22 (Radiation safety committee)

Requirements for the prevention of x-ray hazards at NAIST shall be discussed at the radiation safety committee provided for in Article 7.1 of the Nara Institute of Science and Technology Radiation Hazards Prevention Regulations (Regulations No. 42, 2004).

Article 23 (Miscellaneous provisions)

In addition to the provisions of these Regulations, requirements concerning the prevention of x-ray hazards shall be separately specified by the President.

Supplementary provisions

These Regulations shall come into effect on April 1, 2004.

| Category | Limits |
|-----------------|--|
| Effective dose | (1) 5-year period (each 5 year period starting from April 1, 2001) |
| | 100 mSv |
| | (2) 1-year period (starting from April 1 of each year to March 31 of |
| | the following year; hereinafter the same shall apply.) |
| | 50 mSv |
| | (3) 3-month period starting from April 1, July 1, October 1, and |
| | January 1 for women (excluding those not able to be pregnant), |
| | 5 mSv |
| | (4) Women during pregnancy (from pregnancy diagnosis until |
| | delivery) |
| | 1 mSv |
| Equivalent dose | (1) Eye lens |
| | 150 mSv (per year) |
| | (2) Skin |
| | 500 mSv (per year) |
| | (3) Surface of the abdomen of women during pregnancy (from |
| | pregnancy diagnosis until delivery) |
| | 2 mSv |