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JUN 07 1984

Dow Chemical U.S.A.
ATTN: L. W. Rampy, Chairman
Radiation Safety Committee
Industrial Hygiene Laboratory
1803 Building
Midland, MI 48640

Re: Application and letter dated September 27, 1983 for renewal of NRC Byproduct Materials License No. 21-00265-06

Gentlemen:

As discussed with your Radiation Safety Officers and members of your Radiation Safety Committee during my site visit of May 15, 16 and 17, 1984, in order to complete our review and issued your renewal, we need additional information on the following:

1. Radiation Safety Committee

   A. Describe in greater detail the functions of the radiation safety committees in administering Dow's radioactive material program. Paragraph 33.13(c)(1) of 10 CFR Part 33 requires that a Radiation Safety Committee be established and be vested with the responsibility for establishing administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations. Your description should include, but not be necessarily limited to, a brief discussion of the following:

      i. Procedures and criteria established for making safety evaluations of proposed uses of radioactive material. The procedures and criteria must include consideration of the adequacy of facilities and equipment; operating, handling, and emergency procedures; and the experience and training of the proposed users of greater than exempt quantities of the material.

         a. Specify the minimum intervals at which the full committee will meet to conduct its business, e.g. discuss and act upon proposals for the use of radioactive material. Typically a Type A broad scope licensee meets quarterly. Should your committee desire to meet at intervals greater than quarterly, please include a discussion which demonstrates the ability of the committee to adequately monitor and control Dow's radioactive materials program.

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b. The committee should perform a review of the entire radiation program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and the adequacy of the institution's management control system. Please confirm.

c. Specify the frequency or conditions under which permit holders, or user's applications and qualifications will be periodically reviewed by your committee, e.g. at least annually.

ii. Criteria established by the committee on who will receive training and how much training by category of worker (e.g., users of greater than exempt quantities of radionuclides, technicians, health and safety personnel, janitorial workers, etc.). Procedures for providing the training to each category of worker (refer to Section 19.12 of 10 CFR Part 19). Criteria and procedures for determining an acceptable level of knowledge. Identification of which records of training, testing, and competency determination are to be maintained.

a. In addition to formal health physics (radiation protection) course work, each applicant must have had actual hands on training and experience with the types and quantities of radioactive materials commensurate with his application.

b. Your application did not include a description of your Class I, II and III training. Your description should indicate course content, approximate time spent on each topic area and name(s) and qaulification(s) of the instructor(s).

iii. Procedures used for controlling and maintaining inventories, procurement of radioactive material, individual possession limits, total possession limit, transfer of radioactive material within the institution, and transfer of radioactive matrial to persons outisde the institution.

iv. Methods employed for maintaining records of the committee's proceedings and safety evaluations of proposed uses of radioactive material.

B. If fewer memebers can act in lieu of the full comittee, the number of members constituting a quorum, as well as their names should be specified. Committee actions should require a simple majority of the entire committee, e.g. at least 3 out of 6 voting members. We also recommend that a management representative and your radiation safety officer(s) be part of the voting quorum.

C. Describe in greater detail the reference to, "Interior certification may be granted by the Industrial Hygiene Laboratory" under Item A.5 of Functions for the Radiation Safety Committee. Paragraph 33.17(b) of 10 CFR Part 33, requires that byproduct material may be used by or under the supervision of, individuals approved by the licensee's radiation safety committee.

2. Radiation Safety Officer(s)

A. Describe how the RSO(s) derive their authority for carrying out the radiaton safety programs.

B. Please outline the Radiation Safety Officer(s) program of confirmatory radiation surveys and program audits. The intervals of their surveys and audits should be frequent enough to assure close communication with and surveillance of individual radioactive material users. Type A broad scope licensee's, typically require surveys and audits at least quarterly.

C. Describe your radiation safety groups organizational structure, e.g. number of staff, training, typical duties, administrative authority, etc.

3. Locations of Use and Licensee Name

A. Please provide a main business address for each location (Midland, Bay City and Agricultural Research Center) where byproduct materials are used, e.g. 1803 Building, Midland, Michigan.

B. Clarify the desired applicant's name. Your present license indicates "Dow Chemical U.S.A.", whereas your application indicates "The Dow Chemical Company".

4. Intended Use of Radioactive Materials

A. Your present statements concerning the intended use of licensed material does not provide sufficient information concerning the types of research and development conducted at your company. Although we only need a general description of your activities, you should provide sufficient information to enable us to have a clear understanding of each use.

B. Identify each sealed source used for research and development with an activity greater than 100 millicuries by manufacturer's name, model number, and total activity. A general description of the intended use(s) should also be included. These sources will be listed individually on your license.

C. Identify each sealed source used for purposes other than R & D. The description should include, manufacturer name(s), model numbers, activity per source and a description of use.

D. Describe in greater detail your desire to modify and/or fabricate custom made source(s) or device(s).

i. identify the individual(s) or device(s) who will be involved in fabricating custom-made source(s). Please include a description of previous training and experience which would have involved fabrication of sources or devices with the type and quantities of radioactive materials similar to your request.

ii. describe the radioactive materials to be used;

iii. indicate anticipated activities per custom-made source(s) or device(s);

iv. classify the source(s) or device(s) to be made, e.g. capsules, foil sources, sealed sources, x-ray fluorescence analyzers, thickness guages, etc.

v. describe the tests performed to ensure integrity of the sources during use (such as those outlined in National Bureau of Standards, Handbook No. 126, ANSI-542-1977).

vi. identify the location within your facility where custom-made source(s) or device(s) will be modified or fabricated.

vii. custom-made or NRC approved source(s) or device(s) used outside the scope of your R & D program, i.e. for routine non-research processes, will need to be added to the license. The amendment request should be prepared following instructions contained in NRC, Guide for Standard Format and Content of Application for Health and Safety Reviews of Custom Made Sealed Sources and Devices Containing Licensed Radioactive Material. We have enclosed a copy of the guide for your use.

E. Provide additional information with regard to the use of licensed materials in the performance of animal studies. The information should address the following:

i. A general description of the animal housing facilities.

ii. An example of the instructions provided to animal caretakers for handling animals, animal waste carcasses, and cleaning and decontamination of animal cages.

iii. Procedures for insuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

F. Describe in greater detail the proposed field studies utilizing carbon-14 at Dow's Midland Agricultural Research Center. The information should include, but not be limited to, the following:

i. an estimate of the number of studies per year, and an approximate number of application(s) of carbon-14 per study.

ii. specify the maximum area to be treated with pesticide(s) and/or herbicides labeled with carbon-14. Indicate anticipated concentration(s) per unit area of test plot, e.g., 1 millicurie per square yard, etc.

iii. describe how access is controlled to the field test plots, i.e. height and type of fence, etc.

iv. indicate the expected radiation dose to worker(s) and to human(s) in unrestricted area(s) as a results of the studies.

In addition to the above, should Dow desire to perform field studies on property other than Dow's, it will be necessary to amend your license on a case to case basis. We have attached an outline of the information necessary for submission in order to be authorized for field studies outside Dow property.

5. Personnel Monitoring

A. Describe the criteria used to determine when whole body and/or extremity monitoring devices will be provided to user(s) of licensed materials. If personnel monitoring will not be provided, describe the calculations and/or documentation which will be maintained to support the safety group(s) descision not to provide personnel monitoring.

B. Please describe your bioassay program for personnel utilizing radioactive material, e.g. hydrogen-3, iodine-125 or iodine-131, etc. in greater detail. You should include the type of bioassay (thyroid count, or urinalysis, etc.) the criteria and frequency for performing bioassays and the type of action taken when positive results are obtained. For your assistance we are enclosing bioassay guides that you may reference.

6. Calibration of Radiation Survey Instruments

A. Describe the criteria used to assign instrument calibration frequencies.

B. Clarify the points used at which instruments will be considered properly calibrated. Typically the NRC considers a survey instrument properly calibrated when the instrument readings are within ±10 percent of the calculated or known values for each point checked. However, readings within ±20 percent are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

C. Indicate the individual(s) who will perform instrument calibration and the training necessary in order to perform calibrations.

D. Clarify your statement which indicates that instruments for other groups will be calibrated. Should you desire to perform instrument calibrations as a service to other NRC Licensees, it will be necessary to contact our Fee's Management Branch located in Washington, D.C. to determine whether additional fees are necessary. You may contact them by phone by dialing (301) 492-4650.

7. Waste Disposal

A. We have attached an outline titled, Information Required For Commission approval of Treatment or Disposal by Incineration, and request that you provide information on items 1, 3, 4, 5 (with specific information regarding measurement techniques), 7, 8a and 8b.

B. Describe the procedures and mechanisms used by the RSOs to monitor, control and inventory waste prior to incineration. Also indicate who picks up radioactive wastes and means of transport.

8. Surveys

A. Describe the criteria utilized to establish the frequencies at which surveys for airborne, removable surface and fixed radioactive contamination will be performed by the individual users and by your radiation safety group in greater detail. In addition, please clarify the action levels that will initiate decontamination procedures. We have enclosed Regulatory Guides 8.21 and 8.23 for review. In addition to the above, particular areas of concern were noted with regard to the following:

i. who applies the modifying factor(s), the Radiation Safety Committee/ RSO(s) at the time of the individual researcher(s) permits are reviewed or by the individual researchers?

ii. Modify basic survey commitments to read as a prerequisite and not as a recommendation, in order for an individual to be approved to use licensed materials, e.g. radiation surveys and wipes shall be performed at intervals specified by the Radiation Safety Committee.

B. Please describe your ventilation survey program in greater detail. We direct your attention to Section 1.14 of Regulatory Guide 8.21, for an example of the information to be submitted.

Include with the above information, precautions to be followed by radiation safety personnel when changing filter(s) and/or charcoal traps saturated with radioactive materials.

C. Please describe your air sampling program in greater detail. Your description should include the areas where samples will be collected, the frequency of sampling, location of the samples with respect to workers' breathing zones, assays performed to evaluate air samples and the methods used to relate results to actual personnel exposures, etc. We have enclosed Regulatory Guide 8.21 and direct your attention to Section 1.3, "Measurement of Radioactive Material Concentratons in Air". Please review and respond to the areas outlined under Section 1.3 of the guide.

9. Radiation Protection Instructions

Submit a copy of the criteria used by the Committee to establish basic instructions to be followed by laboratory personnel while working with radioactive materials. In most cases these instructions should be concise enough for posting in area(s) of use. We have enclosed Guide For Drafting Radiation Safety Instructions For Laboratory Use of Radioisotopes, for your consideration.

10. Facilities

A. Describe in greater detail the basic criteria established by the radiation safety committee for each category of use. For example, for facility requirements, please state requirements for (1) low-level tracer laboratories, (2) facilities for use of alpha-emitters, (3) high-level (100 millicuries or more) beta-gamma laboratories, and (4) area(s) where volatile radioisotopes are used, e.g. radioiodine, tritium, etc. Indicate for each category of use the minimum physical plant requirements, such as fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containmant systems, and effluent filter systems.

B. Justify the differences noted after review of Dow's, "Information For Classifying Laboratories", and International Commission on Radiological Protection's, Publication 5, e.g. number of radiotoxicity groups and levels of activity per laboratory type. Furthermore, International Atomic Energy Agencies publication Safe Handling of Radionuclides, (upon which the ICRP based the laboratory activities), was revised in 1973 creating further differences.

11. Installation and Servicing of Gauges

A. Outline the training provided to individuals who will install or service devices containing licensed materials.

B. Submit an example of the instructions provided to users of radioactive devices with regard to lock-out procedures, access control and emergency procedures.

C. Describe your procedures and frequency for leak testing sealed sources and devices.

The area(s) addressed above generalize those discussed at the time of my site visit. As indicated prior to my departure, it is expected that you will utilize your notes as additional guidance when preparing your response.

We will continue the review of your application upon receipt of the above information. Please reply in duplicate within 60 days and reference Control No. 15934. Should you have any questions or require clarification on any of the information stated above, you may contact me at (312) 790-5625.

Sincerely,

George M. McCann
Materials Licensing Section

Enclosures: Guide for Drafting Radiation Safety Instructions for Laboratory Use of Radioisotopes

Information Required For Commission Approval of Treatment or Disposal By Incineration

Guidelines for Bioassay Requirements For Tritium

Information Required to License Field Use of Byproduct Material

Guide for Standard Format and Content of Applications for Health and Safety Reviews of Custom Made Sealed Sources and Devices Containing Licensed Material

Regulatory Guides 8.20, 8.21, 8.23, 10.5

RIII 06/07/84

McCann/bm
06/04/84

ENTRY AGREEMENT

The undersigned, an employee of the U.S. Nuclear Regulatory Commission (NRC), in consideration of being admitted to Dow premises agrees that, except as indicated below, he (or she) will not release or divulge any information concerning Dow, its processes, business or employees, obtained during the course of the licensing review visit or inspection and identified to him as business confidential, proprietary or trade secret, or which could reasonably by presumed to be such. If there is a need to consider the public disclosure of Dow's information that is identified and claimed to be, or reasonably presumed to be, confidential, proprietary, or trade secret, then the NRC will notify Dow prior to making a disclosure determination. All such determinations will be made in accordance with the procedures and conditions of 10 CFR 2.790 of the Commission's regulations.

George M. McCann
(Signature)

17 May 1984
(Date)

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