

## 6.7.5 DETG Convenors User Guide

As a DETG Convenor you have three main roles within the system.

### 1. Reallocating Terms to another DETG

If upon entering the system and reviewing "Original Terms by Primary Interest Group" you find a term that should not be assigned to yourself you can reassign it. You do this by double-clicking on the term to open the GMDN Entry form and go into EDIT mode by clicking "Edit Document". Use the "Set Interest Groups" action button. This will open the dialog box in Figure 1. Simply click the relevant and select which Interest group you want.

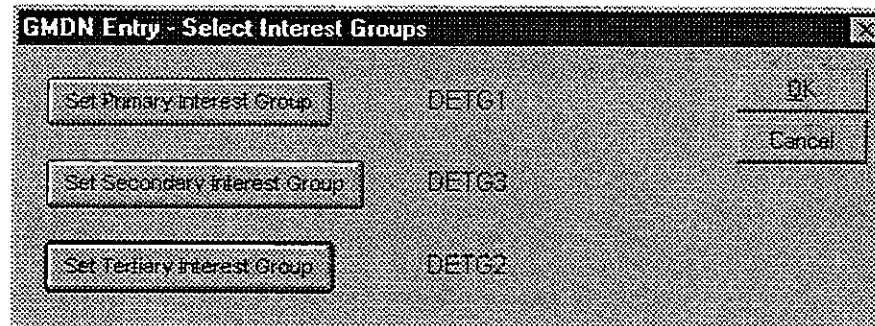


Figure 1 - Reallocating to Another DETG

### 2. Approving the Generic Terms

When a DETG member has finished working on a set of terms and they have produced their Generic Term suggestion, it will be reallocated back to the Main Group. Anything that is sitting under this category is waiting for your approval. To approve a set of terms go into the Preferred Term and have a look at each of the suggestions given by the DETG members. These will be found in the DETG Working Area section. After you have reviewed them you need to accept one of them as the chosen term and approve it. To do this open the "Convenor Only" section by clicking on its title and hit the "Select Term" button. A dialog box will come up and you will be asked to select a term number from 1 to 7. These numbers relate to the working area boxes. Once you have clicked OK the chosen term will be copied into the Proposed Term Details table.

Now click the "Approve" button to pass the terms over to the Language Experts. This will save and close the current term and then select and move the related terms.

### 3. Move Terms into "To Be Resolved"

If a particular set of terms has been disapproved a number of times by the EAT it may be prudent to stop concentrating on them until you have reduced the outstanding workload. In which case the terms need to be moved out of the Main Group workload into another "bucket". This is done by selecting all the terms that you want to move and using the "Move To Be Resolved" action button.

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## 6.7.7 EAT Members User Guide

EAT Members need to assess the Language Experts comments and then make a decision whether or not the recorded term and definition meet the standard.

As an EAT team member you can either approve or disapprove the term. This approving and disapproving must be conducted from the Preferred Term and not any of the equivalents or synonyms.

Once you have opened the Preferred Term it is simply a case of reviewing the data and then opening the EAT section and either hitting Approve or Disapprove. If you choose to Disapprove it you will be asked for your comments why? otherwise it will move all the terms on to the Project Council for approval.

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## 6.7.9 Management Reporting

Within the system there are various Management Reports. The reports are accessed through the Management Reporting option from the Main Navigator.

The reports are :

- Number of New Terms Recommended - total number of new terms created using the application rather than importing from an existing nomenclature.
- Number of Terms Recommended without Change - The total number of terms put forward to the EAT without changing either the Term or Definition from the original nomenclature.
- Number of Terms Recommended with Change - The total number of terms put forward to the EAT with changing either the Term or Definition from the original nomenclature.
- Number of Terms Approved by EAT - The total number of terms approved by the EAT.
- Number of Terms Referred back to DETG by EAT - Total number of Terms currently disapproved by the EAT.
- Number of Terms Referred back to DETG by EAT 2+ Times - Total number of Terms currently disapproved by the EAT 2 or more times.

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## 6.7.11 System Administrators Guide

Below are the considerations and requirements for installation and maintenance of the GMDN System.

### Installation Instructions

#### Security Groups

The following security groups need to be created in the Public Name & Address book.

GMDN\_EAT\_TEAM - The members of the EAT

GMDN\_PROJECT\_COUNCIL - The members of the Project Council

GMDN\_LANGUAGE\_EXPERTS - The language experts.

DETGx - The members of the particular DETG

There are no roles used within the system.

As the system only conducts look ups into itself the database does not need to be located on any particular server or within any particular directory.

#### System Maintenance

The only system maintenance needed will be the DETG Directory listings. These lists can be found by following DETG Directory Maintenance from the main navigator. This will display all existing DETGs and you can either Edit or create a new one by using the action buttons.

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## Exercise 1 - Finding Information

### Purpose

In this exercise, you will navigate through Notes views to find the answers to some simple questions.

### Instructions

1. Start Lotus Notes
2. Locate the "GMDN Project Discussions" database and open it.
3. How many people have contributed to this database?  
(Hint:       Select the "View by Author"  
              Collapse the view)
4. What is John Carroll's mobile phone number?  
(Hint:       Select the "View by Category"  
              Go to the "Participants" category  
              Look in the document called "UIT Participants")

## Exercise 2 - Electronic Mail

### Purpose

In this exercise, you will learn how to:-

- Read electronic mail that has been sent to you
- Reply to mail messages
- Create new mail messages
- Categorise mail items

### A comment on Notes IDs

When you are working with Lotus Notes "in real life", your Notes ID will be the same as your name. So if your name is "John Smith", then your Notes mail database will also be called "John Smith", and people will address mail to you as "John Smith".

People who send you mail from another Notes system have to specify which Notes system you are using - so they will address mail to "John Smith @ BSI". If you want to send mail to John Carroll, who uses the "Unipart" Notes system, you have to address it to "John Carroll @ Unipart".

For this training exercise, you are not using your own Notes ID - you will have an ID in the form "GMDNUKnn", where "nn" is a number.

### Instructions

1. Open your mail database. It will be called "GMDNUKnn on Local".
2. Read any new mail that you have received. New mail is displayed in red.
3. Reply to one of the mail messages.
4. Create a new mail message, and send it to GMDNUK01, with a copy to John Carroll @ Unipart.
5. Send this message, and file it in a folder called "General".

### Discussion Point

Where has the mail that you sent gone? Has anyone received it?

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## Exercise 3 - Discussion Databases

### Purpose

In this exercise, you will be using a discussion database to find a piece of information and add your response to it.

### Instructions

1. Open the "GMDN Project Discussions" database
2. Find the document listing the members of your DETG  
(Hint: Use the "View by Category")
3. Create a response document containing your name, address, and telephone number.
4. Save it.

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# Exercise 4 - Replication

## Purpose

So far, none of the work that you have done has been communicated to anyone else - all the information you have entered is still sitting inside your own PC. "Replication" is the process that you use to transfer information to and from the Notes "server". All information between you and other people travels via the server.

Replication is a complex process but very simple to use. When you tell Notes to replicate, it starts up a telephone call to the server, exchanges any mail that is waiting, and transfers changes to the databases from your "local" replica to the "server" replica.

## Instructions

1. Select the "replicator page"
2. Click on the "start" button
3. Watch what happens. In particular, watch the messages at the bottom of the screen.
4. When replication has finished:-
  - Look at your mail. Have you received any new messages?
  - Look at the discussion database. Are there any new items?



## Section 7

### GMDN IT TRAINING MANUAL

John Carroll

#### Installation Instructions

- 7.1 GMDN PC Installation - Overview
- 7.2 Modems
- 7.3 Installing Trumpet Winsock
- 7.4 Windows 95 Dial-Up Networking
- 7.5 Installing Lotus Notes
- 7.6 Copying Notes Databases from CD
- 7.7 Infonet Access telephone Numbers
- 7.8 Infonet - US Access Numbers
- 7.9 Installation HelpLine
- 7.10 Sample - GMDN Installation Data Sheet for John Carroll
- 7.11 Problem Avoidance and Resolution

## 7.1 GMDN PC Installation - Overview

Every participant in the GMDN project must be equipped with an IBM-compatible personal computer running a Microsoft Windows operating system (Windows 3.x or Windows 95) and Lotus Notes Version 4.5 software. The PC must also be equipped with a modem and a CD-ROM drive.

Each PC will be used for the following:-

- To work with the GMDN database
- To replicate the GMDN database with the "master" copy on a server at Unipart in the UK
- To send and receive electronic mail
- To participate in discussions through dedicated "discussion databases"

It is the users' responsibility to set up their own PCs.

Each user must provide:-

- A personal computer to the required specification
- A suitable modem
- A suitable CD-ROM drive
- The Windows software

The following will be provided as part of the project:-

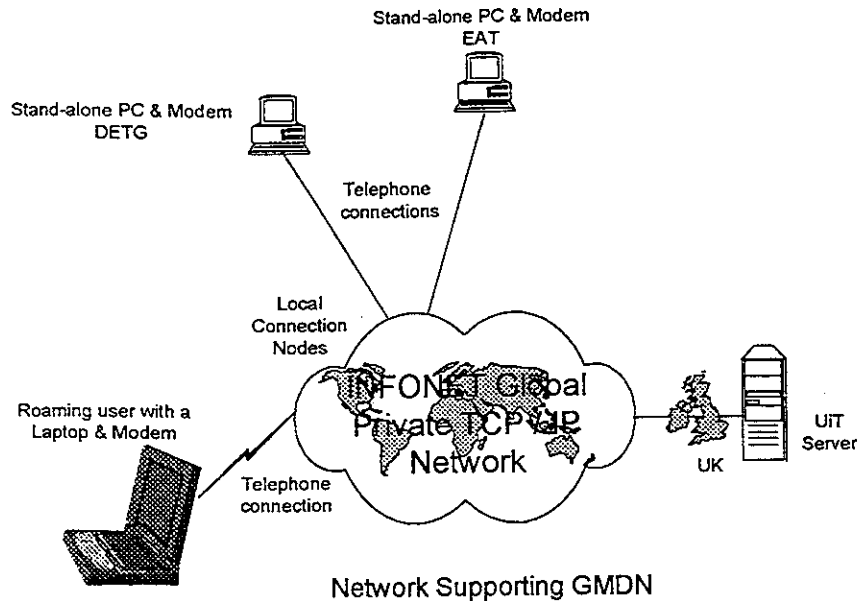
- The Lotus Notes software (on CD-ROM)
- Copies of all relevant Notes databases (on CD-ROM or by replication from the server)
- "Trumpet" dialler software (for Windows 3.x users only)
- Installation instructions (this database)
- A data sheet giving the following information for the specific user:-
  - Notes userid and password
  - Infonet network userid and password
  - Local Infonet dial-up telephone number

It is the users' responsibility to ensure that their modems are setup and working prior to the installation of the Notes software, and to set up the Notes software and databases and establish communications with the server, as per these instructions. Unipart will provide a telephone hotline for a limited period only to assist in solving installation problems.

## GMDN Communications Network

All users' PCs will communicate with the central server via the "Infonet" network. This is a public valued-added network service, which has entry points in all of the countries involved in the GMDN. Calls made by the PC to the Infonet network are standard dial-up telephone calls. Thus the end user will be responsible for telephone costs only as far as the Infonet entry point in his own country. The GMDN project will bear the costs of the use of Infonet.

This network is illustrated below.



GMDNnet.ppt - JC

### Installation Steps - Windows 3.x Users

1. Make sure that the modem is installed and working
2. Install Trumpet Winsock
3. Install and Configure Lotus Notes
4. Test Communication
5. Copy databases from CD

### Installation Steps - Windows 95 Users

1. Make sure that the modem is installed and working
2. Configure Dial-Up Networking (a component of Windows 95)
3. Install and Configure Lotus Notes
4. Test Communication
5. Copy databases from CD

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## 7.2 Modems

The correct use of the GMDN application, and Lotus Notes in general, is dependant on the availability of a working modem.

Because each user may have a different type of modem, the installation of modems is not part of the scope of these instructions and is the responsibility of the user. It must be done BEFORE Dial Up Networking is configured (Windows 95) or Trumpet Winsock is installed (Windows 3.x), and before Lotus Notes is installed.

You will need to know which communication port your modem is setup to use - COM1, COM2, COM3, or COM4.

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AMPLIFIER,ULTRASONIC	NKKN
ANGIOGRAPHIC X-RAY EQUIPMENT	JFMDA
ANGIOGRAPHIC X-RAY TABLE	JFMDA
ANGIOPLASTY SYSTEMS	ECRI
ANGIOPLASTY SYSTEMS,ATHERECTOMY	ECRI
ANGIOPLASTY SYSTEMS,ATHEROTOMY	ECRI
ANGIOSCOPIES	ECRI
CAMERA,RADIOGRAPHIC PHOTOSPOT	ECRI
CARDIOVASCULAR ULTRASONIC DIAGNOSTIC IMAGING EQUIPMENT	JFMDA
CHANGGER,RADIOGRAPHIC FILM/CASSETTE	FDA
CHEST SCREENING X-RAY EQUIPMENT	JFMDA
COIL,MAGNETIC RESONANCE,SPECIALTY	FDA
COMPONENT AND RELATED DEVICE FOR MRI SYSTEM	JFMDA
COMPRESSION DEVICES,RADIOGRAPHICS	ECRI
COMPUTED RADIOGRAPHIC SYSTEMS	ECRI
COMPUTED RADIOGRAPHY	JFMDA
CT SCANNER,HEAD AND NECK	JFMDA
CT,COMPUTER UNIT	NKKN
CT,CONSOLE DIAGNOSTIC	NKKN
CT,CONSOLE OPERATOR	NKKN
CT,GANTRY	NKKN
CT,OPTIONS	NKKN
CT,TABLE EXAMINATION	NKKN
CT,<SPECIFY>	NKKN
DATA ANARYSIS SYSTEM,ULTRASOUND	ECRI
DATA ANARYSIS SYSTEM,ULTRASOUND,CARDIAC	ECRI
DATA ANALYSYS SYSTEM,ULTRASOUND,OBSTETRICAL	ECRI
DEDICATED DIAGNOSTIC X-RAY EQUIPMENT	JFMDA
DEVICE,DIGITAL IMAGE STRAGE	FDA
DEVICE,MEDICAL RADIOGRAPHIC PERSONAL MONITORING	FDA
DEVICE,SPOT-FILM	FDA
DIAGNOSTIC X-RAY HIGH VOLTAGE GENERATOR	JFMDA
DIAGNOSTIC X-RAY IMAGE PROCESSOR	JFMDA
DIAGNOSTIC X-RAY SYSTEM	JFMDA
DIGITAL ANGIOGRAPHY SYSTEMS	ECRI
DIGITAL RADIOGRAPY	JFMDA
DIGITAL RADIOGRAPY BASED ON OTHER TECHNIQUES	JFMDA
DIGITIZER,IMAGE	FDA
DIRECT RADIOGRAPHIC/FLUOROSCOPIC TABLE	JFMDA
ELECTRONICALLY RECORDED DIGITAL RADIOGRAPHY	JFMDA
FILM-RECORDED DIGITAL RADIOGRAPHY	JFMDA
FILM CHANGER	JFMDA
FILM CHANGER FOR GENERAL RADIOGRAPHY	JFMDA
FILM CHANGER FOR HIGH SPEED SERIAL RADIOGRAPY	JFMDA
FLUOROSCOPIC TELEVISION CHAINS	ECRI
FULL FIELD DIGITAL,SYSTEM,X-RAY,MAMMOGRAPHIC	FDA
GASTRI SCREENNING X-RAY EQUIPMENT	JFMDA
GENERAL ANGIOGRAPHIC X-RAY EQUIPMENT	JFMDA
GENERAL RADIOGRAPHIC X-RAY EQUIPMENT	JFMDA
GENERATOR,HIGH-VOLTAGE,X-RAY,DIAGNOSTIC	FDA
IMAGE INTENSIFIERS	ECRI
INDIRECT RADIOGRAPHIC/FLUOROSCOPIC TABLE	JFMDA
INJECTOR AND SYRINGE,ANGIOGRAPHIC	FDA
LOCAL CONTROL RADIOGRAPHIC/FLUOROSCOPIC TABLE	JFMDA
LOCAL CONTROL RADIOGRAPHIC/FLUOROSCOPIC X-RAY EQUIPMENT	JFMDA
MAGNETIC RESONANCE IMAGING (MRI) UNITS	ECRI

MAGNETIC RESONANCE IMAGING (MRI) UNITS,EXTREMITY	ECRI
MAGNETIC RESONANCE IMAGING (MRI) UNITS,FULL-BODY	ECRI
MAGNETIC RESONANCE IMAGING (MRI) UNITS,MAMMOGRAPHIC	ECRI
MAMMOGRAPHIC X-RAY EQUIPMENT	JFMDA
MEDICAL IMAGER	JFMDA
MOBILE SURGICAL X-RAY EQUIPMENT	JFMDA
MOBILE X-RAY EQUIPMENT	JFMDA
MONOTANK X-RAY EQUIPMENT	JFMDA
MRI(MAGNETIC RESONANCE IMAGING)SYSTEM	JFMDA
MR,COIL BODY	NKKN
MR,COIL EXTREMITY	NKKN
MR,COIL SKULL	NKKN
MR,COIL SPECIAL	NKKN
MR,COIL <SPECIFY>	NKKN
MR,COMPUTER	NKKN
MR,CONSOLE DIAGNOSTIC	NKKN
MR,CONSOLE OPERATOR	NKKN
MR,GANTRY CLOSED	NKKN
MR,GANTRY OPEN	NKKN
MR,GRADIENT UNIT	NKKN
MR,RF SYSTEM	NKKN
MR,<SPECIFY>	NKKN
MULTIDIRECTIONAL RADIOGRAPHIC/FLUOROSCOPIC X-RAY EQUIPMENT	JFMDA
MULTITRACK TOMOGRAPH	JFMDA
NON-STATIONARY X-RAY EQUIPMENT	JFMDA
PEDIATRIC X-RAY EQUIPMENT	JFMDA
PERMANENT MRI SYSTEM	JFMDA
PROBES,ULTRASONIC	ECRI
RADIOGRAPHIC SUPPLY	JFMDA
RADIOGRAPHIC TABLE SYSTEMS,GENERAL-PURPOSE	ECRI
RADIOGRAPHIC UNITS	ECRI
RADIOGRAPHIC UNITS,CHEST	ECRI
RADIOGRAPHIC UNITS,CHEST,MULTIBEAM EQUALIZATION	ECRI
RADIOGRAPHIC UNITS,CYSTOSCOPY	ECRI
RADIOGRAPHIC UNITS,GENERAL-PURPOSE	ECRI
RADIOGRAPHIC UNITS,HEAD	ECRI
RADIOGRAPHIC UNITS,MAMMOGRAPHIC	ECRI
RADIOGRAPHIC UNITS,MOBILE	ECRI
RADIOGRAPHIC UNITS,PNEUMOENCEPHALOGRAPHIC	ECRI
RADIOGRAPHIC UNITS,PEDIATRIC	ECRI
RADIOGRAPHIC UNITS,POLYTOMOGRAPHIC	ECRI
RADIOGRAPHIC UNITS,SKELETAL	ECRI
RADIOGRAPHIC UNITS,SPECIMEN	ECRI
RADIOGRAPHIC UNITS,TOMOGRAPHIC	ECRI
RADIOGRAPHIC/FLUOROSCOPIC TABLE AND STAND	JFMDA
RADIOGRAPHIC/FLUOROSCOPIC TABLE SYSTEMS	ECRI
RADIOGRAPHIC/FLUOROSCOPIC TABLE SYSTEMS,UROLOGICAL	ECRI
RADIOGRAPHIC/FLUOROSCOPIC UNITS	ECRI
RADIOGRAPHIC/FLUOROSCOPIC UNITS, ANGIOGRAPHIC	ECRI
RADIOGRAPHIC/FLUOROSCOPIC UNITS,CARDIAC CATHETERIZATION	ECRI
RADIOGRAPHIC/FLUOROSCOPIC UNITS,GENERAL-PURPOSE	ECRI
RADIOGRAPHIC/FLUOROSCOPIC UNITS,MOBILE	ECRI
RADIOGRAPHIC/FLUOROSCOPIC X-RAY EQUIPMENT	ECRI
RADIOGRAPHIC/FLUOROSCOPIC UNITS,SPECIAL PROCEDURE	ECRI
RADIOGRAPHIC/TOMOGRAPHIC TABLE SYSTEMS	ECRI
REMOTE CONTROL RADIOGRAPHIC/FLUOROSCOPIC TABLE	ECRI
REMOTE CONTROL RADIOGRAPHIC/FLUOROSCOPIC X-RAY EQUIPMENT	JFMDA

RESISTIVE MRI SYSTEM	JFMDA
ROTOR CONTROLLER,X-RAY TUBE	ECRI
SKULL RADIOGRAPHIC EQUIPMENT	JFMDA
SKULL RADIOGRAPHIC STAND	JFMDA
SOLID STATE X-RAY IMAGER(FLAT PANEL/DIGITAL IMAGER)	FDA
STATIONARY X-RAY EQUIPMENT FOR OPERATING THEATER	JFMDA
STEREOTACTIC BIOPSY SYSTEMS,MAMMOGRAPHIC	ECRI
STEREOTACTIC HEADFLAMES	ECRI
STEREOTACTIC RADIOSURGICAL SYSTEMS	ECRI
SUPERCONDUCTING MRI SYSTEM	JFMDA
SURFACE,COILS,MAGNETIC RESONANCE IMAGING(MRI)	ECRI
SYSTEM,TOMOGRAPY,COMPUTED,EMISSION	FDA
SYSTEM,X-RAY,ANGIOGRAPHIC	FDA
SYSTEM,X-RAY,FLUOROSCOPIC,IMAGE-INTENSIFIED	FDA
SYSTEM,X-RAY,FLUOROSCOPIC,NON-IMAGE-INTENSIFIED	FDA
SYSTEM,X-RAY,MAMMOGRAPHIC	FDA
SYSTEM,X-RAY,MOBILE	FDA
SYSTEM,X-RAY,PHOTOFLUOROGRAPHIC	FDA
SYSTEM,X-RAY,STATIONARY	FDA
SYSTEM,X-RAY,TOMOGRAPHIC	FDA
SYSTEM,X-RAY,TOMOGRAPHY,COMPUTED	FDA
SYSTEM,X-RAY,EXTRAORAL SOURCE,DIGITAL	FDA
TABLES,RADIOGRAPHIC	FDA
TABLES,RADIOGRAPHIC/FLUOROSCOPIC	FDA
TABLES,RADIOGRAPHIC,NON-TILTING,POWERD	FDA
TIMERS,RADIOGRAPHIC/FLUOROSCOPIC	ECRI
TOMOGRAPHIC STAND/TABLE	JFMDA
TOMOGRAPHIC X-RAY EQUIPMENT	JFMDA
TRANSPORTERS,MAMMOGRAPHY UNIT	ECRI
ULTRASONIC DIAGNOSTIC IMAGING EQUIPMENT	JFMDA
ULTRASONIC DIAGNOSTIC IMAGING EQUIPMENT FOR GENERAL USE	JFMDA
ULTRASONIC DIAGNOSTIC IMAGING EQUIPMENT FOR SPECIFIC USE	JFMDA
ULTRASONIC PROBE	JFMDA
ULTRASONIC,DOPPLER	NKKN
ULTRASONIC,IMAGING UNIT	NKKN
ULTRASONIC,PROBE DOPPLER	NKKN
ULTRASONIC,PROBE ELECTRONIC CONVEX	NKKN
ULTRASONIC,PROBE ELECTRONIC LINEAR	NKKN
ULTRASONIC,PROBE ELECTRONIC SECTOR	NKKN
ULTRASONIC,PROBE ELECTRONIC<SPECIFY>	NKKN
ULTRASONIC,PROBE M-MODE	NKKN
ULTRASONIC,PROBE MECHANICAL	NKKN
ULTRASONIC,PROBE MULTI-FREQUENCY	NKKN
ULTRASONIC,PROBE PHYSIOTHERAPY	NKKN
ULTRASONIC,PROBE POSITIONING UNIT	NKKN
ULTRASONIC,<SPECIFY>	NKKN
ULTRASONIC,PROBE<SPECIFY>	NKKN
UNIT,X-RAY,INTRAORAL	FDA
UNIT,X-RAY,EXTRAORAL WITH TIMER	FDA
UROLOGICAL AND GYNECOLOGICAL X-RAY TABLE	JFMDA
UROLOGICAL X-RAY EQUIPMENT	JFMDA
WHOLE BODY X-RAY CT SCANNER	JFMDA
X-RAY AUTOMATIC EXPOSURE CONTROL	JFMDA
X-RAY CT SCANNER FOR MEDICAL USE	JFMDA
X-RAY EQUIPMENT FOR BONE MINERAL ANALYZER	JFMDA
X-RAY EQUIPMENT FOR NEUROLOGICAL ANGIOGRAPHY	JFMDA
X-RAY EXPOSURE REDUCTION DEVICE	JFMDA

X-RAY GENERATORS	ECRI
X-RAY GRID	JFMDA
X-RAY IMAGE INTENSIFIER	JFMDA
X-RAY IRRADIATION EQUIPMENT	JFMDA
X-RAY TUBE ASSEMBLIES	ECRI
X-RAY TUBE ASSEMBLY	JFMDA
X-RAY MONITORS	ECRI
X-RAY TUBES	ECRI
TUBE/IMAGE INTENSIFIER SUPPORT	JFMDA
X-RAY,ANATOMIC PROGRAMING	NKKN
X-RAY,CONSOLE OPERATOR	NKKN
X-RAY,CONTRAST MEDIUM,INJECTOR	JFMDA
X-RAY,DSA-SYSTEM	NKKN
X-RAY,DSA-SYSTEM OPTIONS	NKKN
X-RAY,DSI-SYSTEM	NKKN
X-RAY,EXPOSURE CONTROL AUTOMATIC	NKKN
X-RAY,EXPOSURE DIGITALISER	NKKN
X-RAY,FLUOROSCOPIC CONTROL UNIT	NKKN
X-RAY,GENERATOR	NKKN
X-RAY,GENERATOR OPTIONS	NKKN
X-RAY,GRID<SPECIFY>	NKKN
X-RAY,HIGH VOLTAGE SWITCH	NKKN
X-RAY,IMAGE INTENSIFIER POWER SUPPLY	NKKN
X-RAY,MAMMOGRAPHIC CASSETTE HOLDER	NKKN
X-RAY,MAMMOGRAPHIC CONE	NKKN
X-RAY,MAMMOGRAPHIC GRID	NKKN
X-RAY,MAMMOGRAPHIC MAGNIFICATION PLATE	NKKN
X-RAY,MAMMOGRAPHIC MOUNT	NKKN
X-RAY,MAMMOGRAPHIC STEREOTACTIC UNIT	NKKN
X-RAY,MAMMOGRAPHIC TABLE	NKKN
X-RAY,MAMMOGRAPHIC <SPECIFY>	NKKN
X-RAY,PULSED FLUOROSCOPY	NKKN



# 別添 3-2

平成 10 年度厚生科学研究(分担)報告書

## 医療用具関係の国際ハーモナイゼーションに関する研究

分担研究者：(社)日本アイソトープ協会・甲賀研究所 越川 富比古

菌の放射線抵抗性の測定法として ISO で採用されている S C D B 培地懸濁系及びリン酸緩衝液懸濁系を用いて、バイオバーデン由来の芽胞形成菌(4 菌種の芽胞)の D 値の季節的な変動について検討した。その結果、S C D B 培地懸濁系を用いて D 値を測定した場合、11 月から 3 月の期間の D 値は 4 月から 10 月の期間の D 値に比べ、平均して約 1.73 倍(1.62 から 1.85 倍)高い値が得られた。

同様にリン酸緩衝液懸濁系を用いた測定法でも、冬場(11 月から 3 月)の期間に測定した D 値は、4 月から 10 月の期間に測定した D 値に比べ、平均して 1.18 倍(1.16 から 1.19 倍)高い値が得られた。以上の実験結果から、D 値は季節的な変動をすることが判明した。

D 値の季節的な変動は S C D B 培地懸濁系に比較し、リン酸緩衝液懸濁系で測定した方が少なかった。

冬場に D 値が上昇する要因を明らかにするため、アルミラミネート袋と通常使用するポリエチレン袋包装の試料を S C D B 培地懸濁系で測定し、D 値を比較した。その結果、ポリエチレン袋包装の試料の D 値の方が高い値を示した。このことから季節的な D 値の変動は、試料の包装にポリエチレン袋を用いたため、通気性のあるポリエチレン包装の場合、照射するまでの保管時に湿度の影響を受け、試料の乾燥状態が季節により異なるものと推察された。即ち、冬場(11 月から 3 月)の期間の方が 4 月から 10 月の期間よりも試料がより乾燥されていたために D 値が上昇したと考えられる。

リン酸緩衝液懸濁系での D 値変動を基に菌の抵抗性を評価した場合、S C D B 培地懸濁系で測定された ISO の標準放射線抵抗性分布は、かなり安全サイドに評価されているものと考えられ、日本の医療用具のバイオバーデンの抵抗性分布調査結果も ISO の標準放射線抵抗性分布に類似した結果が得られているので、滅菌線量設定や監査時の検定試験で不合格になる確率は少ないものと思われる。

### A. 研究目的

ISO11137 においてバイオバーデンの標準抵抗性分布を測定するのに用いられた方法は、分離した菌を培地 (Soybean Casein Digest Broth : SCDB、以下 SCDB と略記) に懸濁して乾燥後、ガンマ線を等間隔で段階的に照射して、照射後、無菌試験を

行い、抵抗性値を評価している。日本においてもこの測定方法を使用して医療用具より検出されたバイオバーデンの抵抗性分布調査が実施された。その結果、日本での抵抗性分布は ISO11137 の標準抵抗性分布に類似していることが判明したが、詳細に解

析すると日本の抵抗性分布では高い抵抗性を示す菌の検出頻度が多いような傾向が認められた。抵抗性の強い菌の検出頻度が高かった要因の一つとして、抵抗性値の季節的な変動が考えられるので、バイオバーデン由来の4種の芽胞形成菌(芽胞)を用いて、

## B. 研究方法

### 1) 使用菌株

医療用具より検出されたバイオバーデン由来の芽胞形成菌4菌株を使用した。生残曲線が指数関数型を示す *Bacillus subtilis* 及び *B.pumilus* とシグモイド型を示す *B.cereus* 及び *B.megaterium* を用いた。

### 2) 無菌試験法を用いたD値測定

#### ① 芽胞の調製

4種の芽胞形成菌を芽胞形成培地(TYEA)にそれぞれ植菌し、30~35°Cで、3~14日間培養した。

#### ② D値測定試料の調製

培養後、芽胞が形成されていることを位相差顕微鏡で確認し、菌を取り、滅菌水に懸濁し、80±1°Cで、10分間熱処理を行い、処理後、氷水中で冷却した。次にこの芽胞液を2分間超音波処理(BRANSONIC 2210型, 47KHz)した。超音波処理した芽胞液を2倍濃度のSCDB、あるいは2/15Mリン酸緩衝液(pH 7)と1:1に混ぜた。この懸濁液を滅菌した試験管(φ=12.5mm, 長さ=75mm)に20μlずつ分注した。分注後、デシケーターで20分間吸引して乾燥した。試料3本ずつを滅菌したポリエチレン袋に入れ、シールした。

1ヶ月毎に抵抗性値を測定し、1年間の抵抗性値の変動について、菌の懸濁液としてリン酸緩衝液及び培地(SCDB)を用い、その乾燥状態での抵抗性値を測定することを目的とした。また、規格化した抵抗性測定法についても考察した。

照射する日まで室内で保管した。

#### ③ 芽胞数の測定

培地(SCDB)、あるいはリン酸緩衝液と混和した芽胞液を0.1% Tween 80溶液で10倍の段階希釈を行い、希釈液をSCDAで混釈し、30~35°Cで、1~2日間培養後、コロニー数を計測し、芽胞数を算出した。

#### ④ ガンマ線照射

ポリエチレン袋包装した試料を段階的に等間隔で照射した。線量はアラニン線量計で測定した。照射する試料は調製後、4日から6日以内に照射した。

#### ⑤ 無菌試験

各線量照射した試料にSCDBを充填し、30~35°Cで14日間培養した。各照射線量での陽性本数と陰性本数を求めた。

#### ⑥ D値の算出

以下の式よりD値を算出した。

$$D \text{ 値(kGy)} = \frac{\text{[(陽性と陰性を示す線量)]}}{\text{[log(芽胞数) - log(3/陰性数)]}}$$

または

$$D \text{ 値(kGy)} = \frac{\text{[(3本が陰性を示す最小線量)]}}{\text{[log(芽胞数)]}}$$

C. 研究結果

1. 芽胞の放射線抵抗性値の年間変動

4種の芽胞形成菌について1ヶ月毎にD値を測定し、12ヶ月間のD値の変動について検討した。

① *B.subtilis* 芽胞のD値の変動

*B.subtilis* 芽胞のD値を1ヶ月毎に1年間測定した結果を表1及び図1に示した。SCDB 培地懸濁系(乾燥状態)では、4月から11月までのD値はほぼ同じ値(平均D値は1.61 kGy)であったが、12月から3月までのD値は上昇し、ほぼ一定した値を

示した(平均D値は2.98 kGy)。

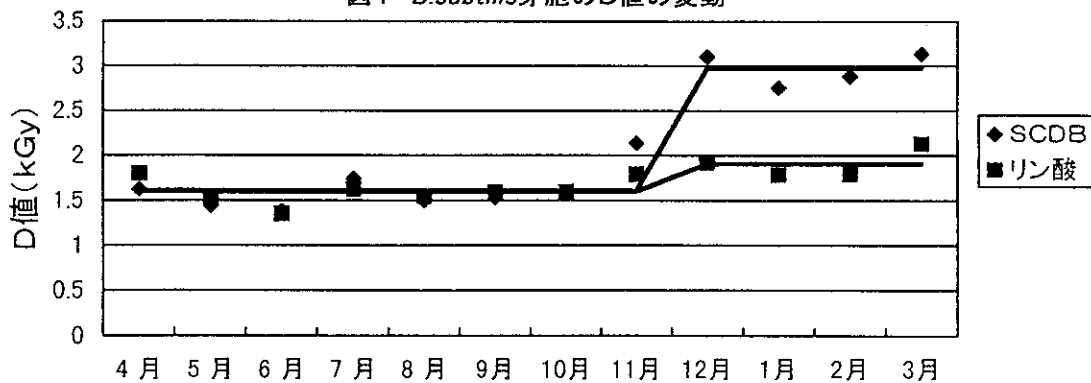
リン酸緩衝液懸濁系(乾燥状態)では、4月から11月までのD値はほぼ同じ値(平均D値は1.60 kGy)であったが、12月から3月までのD値は僅かに上昇(1.19倍)し、ほぼ一定した値を示した(平均D値は1.91 kGy)。

両懸濁系の4月から11月までのD値は、ほぼ同じであったが、12月から3月までのD値はSCDB 培地懸濁系では1.85倍、リン酸緩衝液系では1.19倍高い値を示した。

表1 *B.subtilis* 芽胞のD値の変動

測定した月	放射線抵抗性値(D値)		測定した月	放射線抵抗性値(D値)	
	SCDB (kGy)	リン酸緩衝液 (kGy)		SCDB (kGy)	リン酸緩衝液 (kGy)
4月	1.62±0.11	1.80±0.07	10月	1.57±0.07	1.59±0.07
5月	1.44±0.09	1.53±0.11	11月	2.14±0.15	1.79±0.09
6月	1.38±0.08	1.35±0.14	12月	3.10±0.07	1.92±0.16
7月	1.74±0.07	1.62±0.11	1月	2.76±0.17	1.78±0.12
8月	1.49±0.12	1.54±0.10	2月	2.88±0.02	1.79±0.07
9月	1.53±0.14	1.59±0.09	3月	3.13±0.02	2.13±0.16

図1 *B.subtilis* 芽胞のD値の変動



② *B.pumilus* 芽胞のD値の変動

*B.pumilus* 芽胞のD値を1ヶ月毎に1年間測定した結果を表2及び図2に示した。SCDB 培地懸濁系(乾燥状態)では、4月から10月までのD値はほぼ同じ値(平均D値は1.76 kGy)であったが、11月か

ら3月までのD値は上昇し、ほぼ一定した値を示した(平均D値は3.05 kGy)。

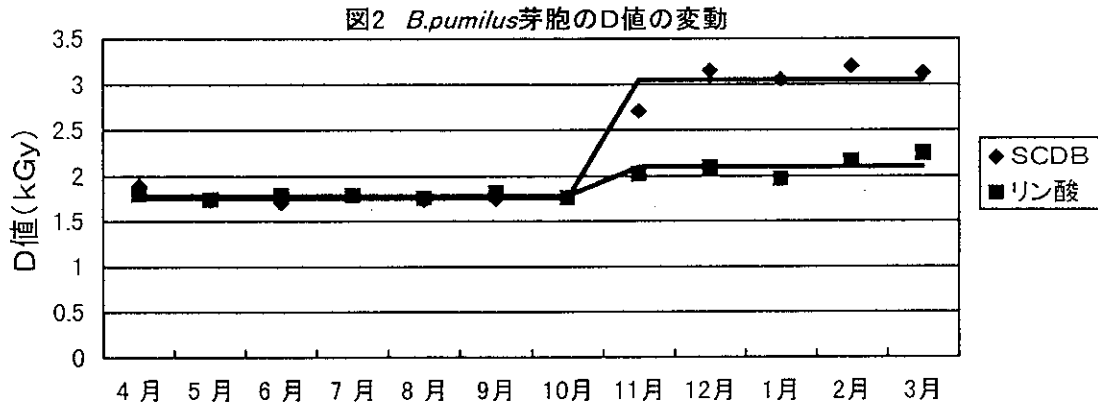
リン酸緩衝液懸濁系(乾燥状態)では、4月から10月までのD値はほぼ同じ値(平均D値は1.78 kGy)であったが、11月から3月までのD値は僅かに上昇し、ほぼ一

定した値を示した(平均D値は 2.10 kGy)。  
 両懸濁系の4月から10月までのD値は、  
 ほぼ同じであったが、11月から3月まで

のD値は SCDB 培地懸濁系では 1.73 倍、  
 リン酸緩衝液系では 1.18 倍高い値を示し  
 た。

表2 *B.pumilus* 芽胞のD値の変動

測定した月	放射線抵抗性値(D値)		測定した月	放射線抵抗性値(D値)	
	SCDB (kGy)	リン酸緩衝液 (kGy)		SCDB (kGy)	リン酸緩衝液 (kGy)
4月	1.89±0.16	1.80±0.11	10月	1.77±0.12	1.76±0.07
5月	1.73±0.11	1.74±0.07	11月	2.71±0.20	2.02±0.10
6月	1.70±0.09	1.79±0.14	12月	3.15±0.05	2.09±0.06
7月	1.79±0.12	1.79±0.09	1月	3.05±0.02	1.97±0.14
8月	1.73±0.10	1.76±0.04	2月	3.20±0.06	2.16±0.02
9月	1.74±0.09	1.82±0.14	3月	3.13±0.02	2.25±0.06



③ *B.cereus* 芽胞のD値の変動

*B.cereus* 芽胞のD値を1ヶ月毎に1年間測定した結果を表3及び図3に示した。SCDB 培地懸濁系(乾燥状態)では、4月から10月までのD値はほぼ同じ値(平均D値は 1.70 kGy)であったが、11月から3月までのD値は上昇し、ほぼ一定した値を示した(平均D値は 2.97 kGy)。

リン酸緩衝液懸濁系(乾燥状態)では、4

月から10月までのD値はほぼ同じ値(平均D値は 1.74 kGy)であったが、11月から3月までのD値は僅かに上昇し、ほぼ一定した値を示した(平均D値は 2.06 kGy)。

両懸濁系の4月から10月までのD値は、ほぼ同じであったが、11月から3月までのD値は SCDB 培地懸濁系では 1.71 倍、リン酸緩衝液系では 1.18 倍高い値を示した。